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# MFDS Report

## 2013



## Minister's Message on Publication

Public concerns for food safety are increasing rapidly with regard to development in the food industry, growth in imported food, expansion of the foodservice industry and changes in dietary lifestyle. Furthermore, the demand for safety control over drugs, cosmetics and medical devices is increasing to meet the social requirements for a healthy and happy life.



To accommodate such public demands, the Ministry of Food and Drug Safety has been launched in this March and takes a full responsibility for the public safety upon food and drugs in order to prevent risk factors threatening the safety of food and drugs in advance as well as to manage them efficiently.

With a vision, 'Safe Food and Drug, Healthy People, Well-being Society', in mind, the MFDS currently invests utmost efforts to accomplish 5 key strategies including 'eradication of adulterated foods', 'coherent safety management from farm to table', 'promotion of consumer participation and increase in consumer awareness for food safety', 'creation of job opportunities' and 'rapid release of medical products'.

As a part of such invested efforts, the MFDS publishes and distributes annual 'MFDS Report' describing major policies upon food, drugs, cosmetics and medical devices along with their progress reports where the publication is also used for the public relation purpose for the Ministry of Food and Drug Safety.

Again, I would like to urge the public for continuing support and interests as I sincerely hope that this first publication of 'White Paper on Food and Drug Safety' since the promotion of the Ministry would further enhance the communication and cooperation with the public regarding safety policies upon food and drugs.

December, 2013

Chung Seung, Minister *Chung Seung*

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2013 MFDS Report Ministry of Food and Drug Safety



# Introduction

- 01. Vision · Mission · Policy Strategies
- 02 . Organization
- 03. Direction of System Reorganization
- 04. History

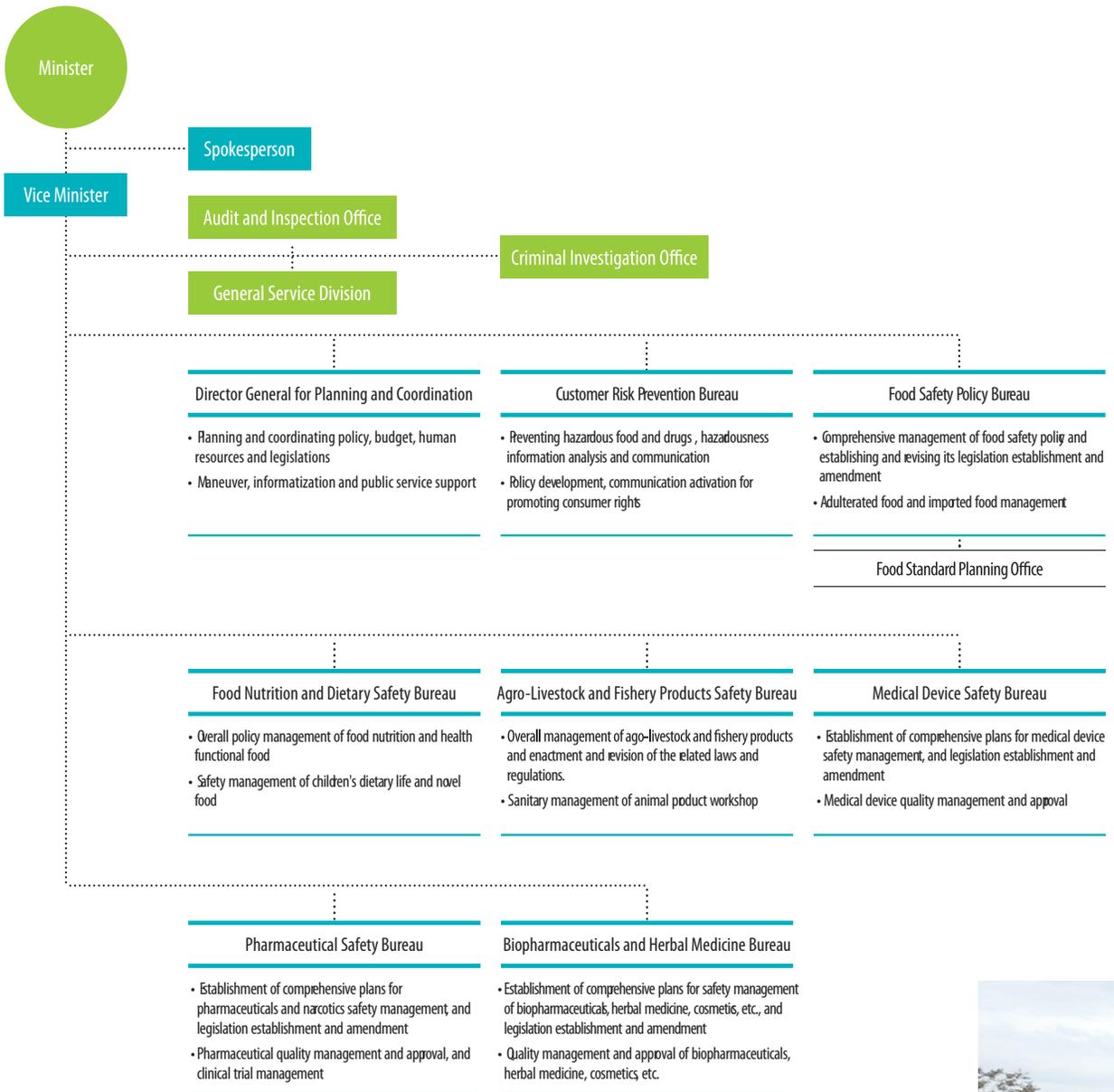




## | Vision · Mission · Policy Strategies



## Organization



### [MFDS Regulating Acts]

- **Food Area** : Food Safety Basic Act, Food Sanitation Act, Health Functional Food Act, The Special Act on the Safety Management of Children's Dietary Life, Livestock Product Sanitary Management Act, Agricultural and Fishery Product Quality Management Act
- **Drug Area** : Pharmaceutical Affairs Act, Act on Human Tissue Safety and Management, Act on Narcotics Management, Cosmetics Act, Medical Device Act, Act on Laboratory Animals



Ministry of Food and Drug Safety

National Institute of Food and Drug Safety Evaluation

Research Planning & Management Division

General Services Division

National Center for Lot Release

Blood Products Team

Food Safety Evaluation Department

Drug Evaluation Department

Biopharmaceuticals and Herbal Medicine Evaluation Department

Medical Device Evaluation Department

Pharmaceutical and Medical Device Research Department

Toxicological Evaluation and Research Department

Regional Food and Drug Administration

Seoul Regional FDA

Busan Regional FDA

Gyeongin Regional FDA

Daegu Regional FDA

Gwangju Regional FDA

Daejeon Regional FDA

Imported Food Inspection Center  
• Gangneung

Imported Food Inspection Center  
• Jaseongdae, Shinseongdae, Yangsan, New port, Tongyeong

Imported Food Inspection Center  
• Uwang, Gwangju, Incheon International Airport, Pyeongtaek

Imported Food Inspection Center  
• Yeosu, Mokpo, Gunsan



## Direction of System Reorganization

### Reorganization Overview

- In order to unify the safety management tasks on food, Ministry of Food and Drug Administration that was outside of Ministry of Health and Welfare were re-organized and expanded into 'Ministry of Food and Drug Safety'.
- (Basic principle) Adjusted measures from Prime Minister's office in 2006 + Drug Safety Management

#### Adjusted Measures from Prime Minister's Office in 2006

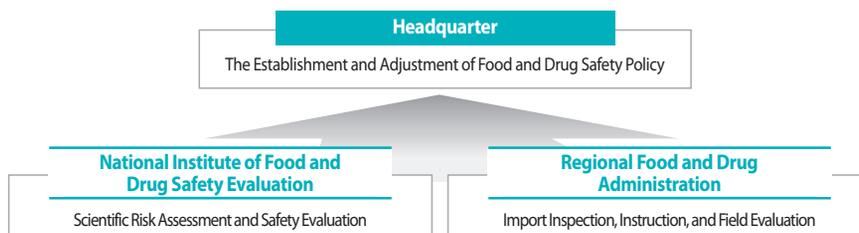
- ✓ Ministry of Food and Drug Safety is in charge of food and safety management from production to consumption(farm-to-table)
- ✓ The executive function for the production level is entrusted to Ministry of Agriculture and Forestry and Ministry of Maritime Affairs and Fisheries

- (Function) Ministry of Food and Drug Administration
  - + Food Safety Policy and Drug Safety Policy(Ministry of Health and Welfare)
  - + Sanitary safety of Agriculture, farming and fisheries(Ministry of Agriculture, Food and Rural Affairs)

\* Quality management and disease management is excluded for the transfer.

### Reorganization Details

The optimal safety management was established through role divisions



### The Size of Transferred Organization(Equipment/Personnel)

**Transferred equipment/manpower : 1 part 10 sections, a total of 270 people**

- Ministry for Food, Agriculture, Forestry and Fisheries
  - Livestock sector(including agriculture) : 1 part 8 sections and 172 people / Fisheries sector : 1 section and 88 people
- Ministry of Health and Welfare
  - Food sector(including common areas) : 1 part and 8 people / pharmaceutical sector : 2 people

## History

- 2013.03** The Ministry of Food and Drug Safety (MFDS) is restructured and expanded following the consolidation of food management system which now includes agricultural, livestock and fisheries products.  
Headquarter : 7 bureaus, 1 office(planning and coordination), 43 divisions, affiliated agency : 1 institute, 6 regional food and drug administrations (13 Imported Food Inspection Centers) 1,760 employees
- 2012.02** Established Biopharmaceutical Products and Medical Device Authorization and Evaluation Division
- 07** Established Gwangju Imported Food Inspection Center (Gyeongin RFDA)
- 2010.06** The National Tax Service transferred Liquor Safety Management responsibilities to the KFDA
- 11** The KFDA relocated to Osong Health Technology Administration Complex, Osong, Chungbuk
- 12** Established Pharmaceutical Safety Information Team(Headquarter)
- 2009.11** Established Blood Products Team under National Examination Center of National Institute of Food and Drug Safety Evaluation
- 2007.09** KFDA reinforced its staff and created 6 teams(including Headquarter)
- 2006.08** Established 10 teams including Customer Support Team
- 2005.12** Established New Port Imported Food Inspection Center(Busan RFDA) and Pyeongtaek Imported Food Inspection Center(Gyeongin RFDA)
- 2004.07** Established Medical Devices Management Division and Bio-product Technical Support Division
- 2003.07** Established Yangsan Imported Food Inspection Center (Busan RFDA)
- 2002.05** Established Surveillance Management Center  
The National Center of Toxicological Research was reorganized to National institute of Toxicological Research
- 2001.03** Established Incheon International Airport Imported Food Inspection Center(Gyeongin RFDA)
- 09** Established Adulterated Food Central Monitoring Team, Bio Medical Division(Food Safety Bureau, Medical Device Safety Bureau)
- 1998.02** The Korea Food and Drug Safety Headquarter was raised to the status of administration(Korea Food and Drug Administration)  
Established The National Center of Toxicological Research and 6 regional offices(Seoul, Busan, Gyeongin, Daegu, Gwangju and Daejeon)
- 1996.04** Established Korea Food and Drug Safety Headquarter and 6 Regional Offices Four departments of the National Institute of Health were reorganized to 6 Safety Evaluation departments





2013 MFDS Report Ministry of Food and Drug Safety



# 01

## Consumer Risk Prevention

- 01. Reinforce Responding Capacity to Protect Public Health
- 02. Encourage Communication to Improve Consumer Awareness on Food and Drug Safety
- 03. Collect and Analyse Food and Drug Safety Information
- 04. Strengthen International Competitiveness by Advancing Testing Laboratory



# 01

## Reinforce Responding Capacity to Protect Public Health

### 1. Competence Enhancement in Crisis Management to Prevent Safety Incidents

The Ministry of Food and Drug Safety develops and oversees the Manual for Crisis Response which defines responsive measures against various potential incidents in order to minimize public sufferings and to prevent crisis from spreading through prompt and pre-emptive responses upon a critical situation due to safety incidents with a variety of foods and drugs. In 2011, the Manual for Risk Management Against Medical Device Incidents was newly established and the Manual for Crisis Response against Food Incidents developed in 2009 was improved and amended through reclassification of the types of crises and refinement of criteria upon the level of severity based on early quick responses prior to the outbreak of a crisis and analysis upon food incidents. Each manual for foods, drugs and medical devices describes the details of the measures by dividing critical situations into the 4 levels of Concern(Blue), Caution(Yellow), Alert(Orange) and Serious(Red) and a feasible on-site responsive system was implemented after minimizing formalities and procedures. Based on this system, simulation training with actual situations applied is being conducted along with the Office of the Prime Minister, the Ministry of Health and Welfare and other local government agencies in order to further develop smooth operation of the responsive system, to enhance response capability when a critical situation outbreaks and to implement an organic cooperative system amongst relevant departments. At the same time, a specialized practical training program for crisis

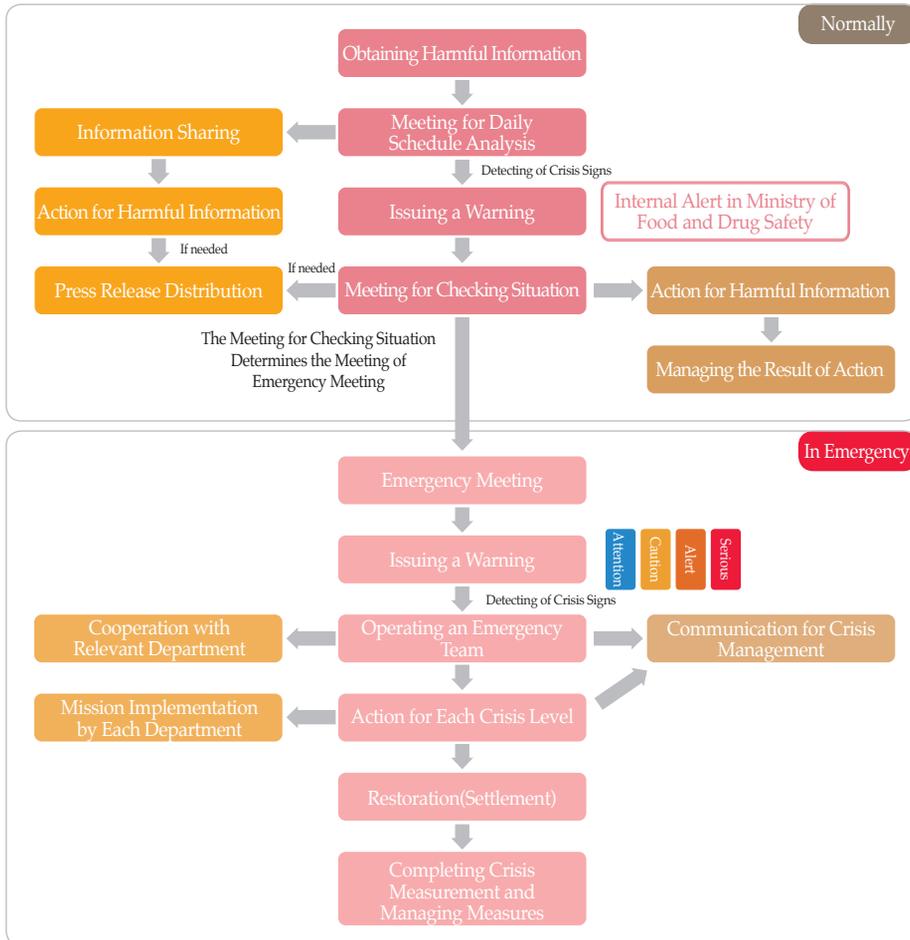
response is developed and implemented to enhance response capability for employees at the Food and Drug Administration and local governments. In addition, the competence to command and respond to crises have been highly enhanced by adopting conference calls where experts from both Korea and foreign countries can simultaneously participate in emergency meetings upon critical incidents related to food and drugs.



[ Figure 1-1-1 ] Simulation Training for Crisis Response(Food & Drug)

Moreover, risk information is to be analyzed and evaluated at all times by developing a system for risk information management including potential risk information and crisis response and emergency measures such as ban on sales and distribution, collecting inspection and safety letter remittance are to be executed when prompt response is required. When symptoms for risks are detected in the course of an analysis and evaluation upon risk information, emergency warning is to be immediately alerted followed by formation of the emergency response team.

In 2012, an integrated crisis management plan was established and simulation training was performed in order to efficiently respond to safety accidents which occur in connection with various fields including food, drug and cosmetics. A crisis response symposium was held by representatives from businesses, schools and government, which provided a foundation to empathize with the significance of risk management upon food and drug safety incidents as well as to seek out for new developmental directions. The Crisis Response Manual Upon Cosmetics Incidents as well as the Manual for Quick Response upon radiation leakage accidents was additionally prepared following the Fukushima Nuclear Plant disaster by the Ministry of Food and Drug Safety.



[ Figure 1-1-2 ] Crisis Response Strategy Map

## 2. Implementation of Food Management System through Advanced Prevention

### 1) Antecedent Study upon Hazardous Substances

To procure the safety of the food imported, distributed and manufactured in Korea, food risk information is to be collected through various channels including government agencies and public media both in Korea and overseas and the said information is to be analyzed and evaluated for its significance, urgency and necessities for responsive measures. Especially when an immediate response measure is required, a preventive measure is to be prearranged in order to avoid food safety accidents in advance by imposing ban on import, sales and distribution after examining management alternatives.

To accomplish the goal stated above, an antecedent study has been conducted since 2006 to shut down the inflow and distribution of at-risk food products in Korea based on the risk information collected and analyzed. The antecedent study is designed to collect and inspect distributed food products to examine and analyze them whether risk elements such as medicine ingredients are contained based on risk information from both Korea and overseas. Subsequent to the antecedent study, products that are nonconforming to standards and criteria are to be collected, discarded, administratively punished as well as further collected nationwide and inspected if highly hazardous substances are detected. Also, alternative measures for temporary safety management are under preparation, including new establishment of standards and inactivation upon products of which criteria and standards are yet to be established.

In 2012, an antecedent study was conducted on 39 items and 502 cases including eel(ofloxacin), where 5 items and 11 cases including soondae(bacterial count & colon bacillus group) were found to exceed the standard and subsequently sanctioned with administrative disposition, seizure and disposal, which led to successful outcomes of early prevention of potential crises.

In addition, antecedent studies are frequently being conducted upon potential harmful substances of which standards and criteria have not been established, such as harmful substances, animal medicines and residual pesticide, based on the information collected from both Korea and overseas.

The Ministry of Food and Drug Safety is determined to continuously prevent food safety incident by cracking down on risk elements affecting public health in advance. The ministry in 2013 enhanced its antecedent studies upon food products for risk potential by analyzing risk information from both Korea and overseas.

## 2) Inactivation of Harmful Substance Generated during the Course of Production, Cooking and Processing of the Food

Since 2001, the Ministry of Food and Drug Safety has developed the inactivation technology against harmful substances by each item through inactivation research projects upon harmful substances unintentionally generated in the course of production, processing and cooking.

And since 2006, a temporary task force was formed and operated to implement the

inactivation technology and for the case of Acrylamide which is generated during the production and processing of cookies using potato for its raw material, Acrylamide concentrations of under 1 ppm, which was the targeted goal, were detected from most products that inactivation technology was applied.

Since the massive volumes of Benzopyrene were detected from kastuobushi, raw material for ramen broth in 2012, a research project has been launched to develop technology to reduce Benzopyrene in the process of producing and processing of kastuobushi.

In addition to Benzopyrene, a total of 23 harmful substances were identified after investigating and reviewing harmful substances unintentionally generated during the course of producing, processing and cooking and comprehensive measures to reduce such substances are currently scheduled to be prepared and pursued.

### 3. Consumer Rights Promotion through Collaboration with Consumer Groups

The Ministry of Food and Drug Safety invests efforts in consumers' safety and protection of their rights by establishing a cooperative foundation with consumer groups regarding relevant safety policies upon food, drug, cosmetics and medical devices. The Ministry signed a MOU for the mutual cooperation with the Korea National Council of Consumer Organizations representing 10 consumer groups in 2007 and it subsequently formed an implementation committee where major current issues as well as cooperative agendas have been discussed.

Major cooperative agendas are focused on the field of research and study to improve the safety of food and drug, the field of public relations and education such as educational campaign and the field of major information sharing which directly affects public health. Also in 2009, the Ministry reached MOU with Korea Consumer Agency and has expanded its consumer-related network by sharing consumer-risking information.

By offering regular and irregular meetings with the representatives of consumer groups, the Ministry has been aggressively gathering inputs from consumer groups and discussing cooperative issues with them as well. Particularly in 2012, various thoughts and opinions were exchanged including preventive measures against the abuse of medicines, the imports of radioactive marine products caused by Japanese nuclear accident and simplification of examination procedure for functional cosmetic products.

# 02

## Encourage Communication to Improve Consumer Awareness on Food and Drug Safety

### 1. Vitalization of Communication with the Public

Because safe management of food and drugs shall be performed based on scientific studies and professional expertise, public communication upon food and drug safety just has to deal with a wide variety of reactions from the public depending on their age, environment, personal understanding and specialized knowledge. Thus, aiming to dissolve perceptible differences from the general public, to earn stronger public trust and to develop policies that the public can empathize with, the Ministry offers opportunities where the general public can personally participate in policy-making procedures by providing a place of interactive communication for the public.

#### 1) Operation of ‘Open Forum for Food and Drug Safety’ Where General Public Personally Participates

Recently, as the extent of accidents with food and drugs became massive, public expectation toward the governmental safety management performance is becoming ever so high. The Ministry of Food and Drug Safety delivers the ‘Open Forum for Food and Drug Safety’ where all interested parties from consumers, manufacturers, academic communities and the media can freely discuss relevant policies in order to develop practical government policies through

flawless communication.

The Open Forum for Food and Drug Safety was held a total of 48 times between 2006 and 2012 where 6,451 people attended and in 2012, the forum was held twice with themes such as 'Inspection and Management of Food with Illegal Additives' and 'Safe Management of Food Applied with Nano-technology'. Moreover, all the publications from the forum are made available on the official website of the Ministry for everyone to access and the collection of such publications is also being published every year.



[ Figure 1-2-1 ] Open Forum for Food and Drug Safety

## 2) Life-oriented Information for Consumers

The Ministry consistently provides useful information related to food and drug after systematically investigating and discovering life-oriented information. Prior to 2011, a total of 31 cases of information upon harmful substances related to food and drug was provided in the format of a booklet. Since 2011, however, information far closer to daily living of consumers including safe ways to ingest each food has been made available through the official website of the Ministry along with easy-to-understand terminologies. In 2001, a total of 12 cases of life-friendly information such as 'pork', 'tofu' and 'Ssam-vegetable' were provided and in 2013, such safe information on food and drug useful to consumers will continue to be offered.

## 3) Enhancement of Expertise in Risk Communication for Efficient Public Communication

In order to communicate efficiently with the general public on food and drug safety incidents

and policies, the Ministry prepared a plan to develop mid-to-long term communicators specialized in food and drug. Hence, the Ministry has developed training program for risk communication and implemented the 'Risk Communication On-the-job Training' (May 29~31, 2012) targeting on-site staffs from the Ministry and local governments. In addition, the Ministry also conducted the 'Risk Communication Jump-up Training' with the theme of 'Policy Promotion and Enhancement of Public Communication through SNS' and the 'Pleasant Communication and Sensitive Care' in order to enhance competency and understanding of the employees upon risk communication.

## 2. Establishment of Communication Network and Vitalization of the Operation

To recognize and respond to the information with potential to publicize prior to the outbreak of the food-and-drug-related incident, the Ministry built, launched and has been operating an advisory council for risk communication composed with specialists from public communication, risk managements, consumer groups and food/drug industry since September 2010. In 2012, the council discussed an integrated risk management plan on food and drug as well as a plan to establish an efficient risk communication strategy regarding the 'Analytical Study upon Harmful Substances of Electronic Cigarette'.

In 2013, the 'Risk Communication Advisory Council' changed its name to the 'Communication Advisory Council' to strengthen public communication and the council is scheduled to be expanded by reinforcing the talent pool of legal experts and PR specialists.

## 3. Operation of Tailored Communication Program for General Public

### 1) At-home Experience with Food and Drug

Since February 2011, the Ministry of Food and Drug Safety has been operating 'At-home Experience with Food and Drug', a visit-to-experience program to educate and communicate with college students, housewives and the general public upon how safety measures for food and drug are actually being implemented, every month.

Focused on actual experiences which participants acquire through personally witnessing and listening, At-home Experience with Food and Drug is developed with programs based on

current social issues as well as generation, gender and interested area of the participants.

In 2012, 344 people including college students and housewives visited the Ministry where they attended lectures and experiment practices with the themes of facts and myths on cosmetics, correct information on high-calorie/low-nutrient diet and food poisoning reduction policy.



[ Figure 1-2-2 ] At-home Experience



[ Figure 1-2-3 ] Participant at Experiment Lab with Food and Drug

## 2) ‘Young Leader of Food and Drug’, Youth Communication Specialists Appointed

To help the youth better understand proper lifestyle with food and drug, the Ministry oversees the ‘Young Leader of Food and Drug Program’, a promotional program led by teenagers to promote the safety information on food and drug. The teenagers who are appointed to Young Leaders of Food and Drug are to conduct autonomous promotional activities by their own yardsticks as honorary youth ambassador for food and drug where they share safety information with their peers and lead to promote changes in awareness amongst their neighbors.

24 teams of 90 students(10 teams of middle school students & 14 teams of high school students) were appointed to ‘Young Leaders of Food and Drug’ in 2012 with a theme, ‘Eat Less Sodium’. Selected students shared food and drug information with their peers, neighbors and numerous other people for 3 months via online as well as offline based on promotional proposals that each team previously submitted. Following their activities, 8 teams were awarded with the Food and Drug Safety Ministerial Award along with additional prizes after

their performances were evaluated. And these students are promised to continue receiving news and information from the Ministry in order to keep working as honorary ambassadors at their own discretion even after their official schedule is completed.



[ Figure 1-2-4 ] One-day Camp for Young Leaders



[ Figure 1-2-5 ] Taste Test

### 3) Experience Classroom for Future Talents

On every last Saturday of the month since April, 2012, the Ministry of Food and Drug Safety has been operating the 'Experience Classroom for Future Talents' which offers elementary and middle school students an introduction of the Ministry and opportunity to experience food and drug science at the Headquarter as well as its 6 local administration offices.

This Experience Classroom is being operated by the Ministry using its reserved resources on Saturday, where the program not only serves children caring function to make social contribution but also contributes to improving safety consciousness for food and drug. Participants are given an opportunity to experience lively on-site activities while they listen to the lectures as well as practice experiments.

From 9 classrooms regularly held once a month between April and December of 2012, a total of 1,577 students visited the Ministry to go through the experience classes of hand-washing, TLC pigment separation and prompt examination vehicle for food poisoning.

In 2013, the Ministry plans to diversify contents by selecting themes with cutting-edge experiments of gene recombination products and biomedicines while expanding hours of classrooms. Also, it also plans to provide theme-oriented training tailored for consumers based on their ages and backgrounds after involved agencies select their own contents.



[ Figure 1-2-6 ] Participants at the Experience Classrooms

#### 4) Safety Monitoring of Food and Drug

The Ministry of Food and Drug Safety performs preventive activities via both online and offline by operating safety monitoring group on food and drug composed with SNS operators selected from the general public. These individual monitors are to attend a workshop for the expansion of safety information on food and drug by using Facebook and Twitter for one year.

The ‘Safety Monitoring of Food and Drug’ is to form positive public opinions on food and drug safety activities by the Ministry through the expansion of safety information upon food and drug. Moreover, they are also to perform the role of honorary ambassadors leading the enhancement of awareness for the significance of food and drug safety.

So far, a total of 4 different monitoring groups have been operated between 2009 and 2012 and in 2013, the fifth monitoring group is to conduct preventive activities in various manners including the HACCP training, community services and social media activities.



[ Figure 1-2-7 ] 4th Monitoring Group Appointment Ceremony



[ Figure 1-2-8 ] Local Meeting in Seoul by the 4th Monitoring Group

# 03

## Collect and Analyse Food and Drug Safety Information

### 1. Direction of Information Collection on Food and Drug Safety

Due to many breakthroughs in information communication technology of internet and the SNS, the very food safety issues now transcend borders; and safety incidents related to food and drug which broke out in the foreign soil often affect many neighboring countries as well as the countries. Hence, the Ministry established a system which promptly collects and precisely analyzes the risk information in order to assist preventive measures and it also has enhanced the year-round interactive information-sharing system for the purpose of providing necessary information to the timely response measures prepared by relevant departments. Most of all, a variety of routes, i.e. overseas information monitoring reporters, were secured to collect all types of local information from foreign countries, reinforcing the cooperation with international agencies.

### 2. System for Prompt Collection and In-depth Analysis of Risk Information

#### 1) Collection of Risk Information on Food and Drug

Prompt collection and wide-spread of risk information related to food and drug which occur in foreign soil is not only critical to ensure the public safety on food but fundamental for

the Ministry to establish safety policies. Collection of all risk information is being conducted through online and offline simultaneously. For online risk information arising from food, food additives, health functional food and containers, it is collected through the National Food Safety Information Service on a real-time basis for 365 days a year. Consequently, the number of online information collected in 2012 was increased by 15 times comparing to the year of 2004, while the number was also increased by 45% from 13,500 cases in 2011 to 19,800 cases in 2012. Examining the performances taking necessary measures for major information out of collected information in 2012, which was shared with relevant departments, a total of 178 measures were implemented including 72 measures to ban imports, 25 measures to collect and inspect, 47 media releases and 28 other measures such as fact-finding study and it is deemed that information necessary for relevant departments to take actions was timely discovered and promptly shared.

In 2012, a total of 8,244 risk information on food and drug were collected, where 4,931 of them were on drug while 2,900 cases and 413 cases were on medical devices and cosmetics respectively and it showed that more than half of them were related to drug. By providing collected information to relevant department, it was possible for the Ministry to take aggressive, preventive and risk responsive measures such as distribution of safety notice, collection & inspection and ban on sales via internet.

## 2) Analysis and Sharing of Risk Information on Food and Drug

After reviewing the credibility of the information source and objectivity of its contents, it is to analyze the information based on the severity of the situation and damages, the feasibility for immediate management and the possibility for distribution. Furthermore, in order to collect more reliable local information to make policy-decision in foreign countries, it is to collect additional information by using various network channels of overseas posting officers from the Ministry and overseas information monitoring reporters; subsequently, it is to organize and provide key issues requiring the relevant department to make policy-decision.

### 3) Optimization of Collecting Capability of Local Information

#### (1) Enhancement of Local Information Gathering through Expansion of Overseas Information Monitoring Reporters

To gather risk information, the Ministry currently monitors 265 websites on food in 265 countries and 120 websites on drug in 18 countries; however, the Ministry operates a project of overseas information monitoring reporters composed with local Korean residents and Korea international students in order to collect local information that is hardly available through internet. In 2012 alone, a total of 835 cases of local information including 710 cases of spot-information and 125 cases of in-depth information were collected through overseas information monitoring reporters. Amongst major accomplishments made by these reporters, the Ministry was able to provide timely support to the relevant department with the information promptly provided by reporters from China, Vietnam and America when collecting trend information on the measures taken by foreign countries regarding the detection of Benzopyrene from Nongsim Ramen.

#### (2) Enhancement of Network with Neighboring Countries for Global Information Exchange

##### A. Construction of Asia INFOSAN and Leading Its Operation

When required cooperation in food risk information exchange amongst Asian countries, the Ministry proposed to build international food safety information exchange network among Asian countries, called 'INFOSAN in Asia', under the supports from the Headquarter of WHO/FAO INFOSAN. And in 2012, the Ministry along with WHO/WPRO co-hosted '2012 Food Safety Strategic Meeting for Asia INFOSAN & WHO Asian Region' in order to discuss how to promote the exchange of food safety information and how to enhance cooperation among Asian countries through Asia INFOSAN. Government officials in charge of food safety in 13 countries as well as officials from international agencies including WHO/FAO INFOSAN H.Q. and WPRO attended the meeting, where '(tentative) Strategy to vitalize the exchange of food safety information amongst Asian nations' was developed for the purpose of enhancing food safety management within Asian regions as well as the efficient emergency response in food incidents. At the same time, the details of 2012 Asia INFOSAN Meeting were publicized through official websites of WHO and FAO and the news was highly regarded by major news

outlets both in Korea and overseas.

#### B. Enhancement of Information Collaboration through Web-community of Asia INFOSAN

With a joint-effort from WPRO, the Ministry opened an 'Asia INFOSAN' community at the home -page of INFOSAN in order to expedite the food safety information exchange amongst Asian countries more promptly and efficiently. Through this web community, the Ministry proposed web-debates upon major issues regarding food safety to member countries and reference data on food safety from member countries as well as reports on 'Asia INFOSAN' international meetings are currently being shared.

### 3. Prompt Measures on Information through Systematic Information Analysis System

#### 1) Provision of Intensive Analysis on Food-related Key Information

##### (1) Assistance to Measures upon Detection of Benzopyrene from Ramen

Regarding the incident where carcinogenic substance, Benzopyrene was detected from the soup powder of Korean Ramen manufacturer, the Ministry made various attempts to protect Korean exporting companies by immediately sharing information with relevant departments and businesses through daily status reports after fully comprehending the actions taken by foreign governments including recall, inspection and counter measures. Especially with telephone calls and e-mails through various channels such as posting officers of the Ministry, overseas information monitoring reporters and relevant agencies in foreign countries, the Ministry focused its resources on collecting all lively local information including current status of administrative actions taken by local authorities and follow-up measures.

##### (2) Assistance to Measures against Food Contamination with Radioactive Substances due to Fukushima Nuclear Plant Disaster

In March 11, 2011, radioactive substances were released to natural environment from the Fukushima Daiichi nuclear facility due to earthquake and tsunami. Because of this disaster, agriculture, stock farm and fishery products were exposed to radiation; subsequently, the

entire world including Korea strengthened their restriction on Japanese import products. Risk Information Division of the Ministry immediately collected, via both online and offline, over 1,000 cases of information upon counter-actions taken by foreign countries as well as inspection reports on radioactive substances within products and shipment restriction measures made by Japanese Ministry of Health, Labor and Welfare and the division promptly analyzed the information while confirming its accuracy through wire-wireless communication if deemed necessary. Especially upon the items restricted for the shipment by Japanese government due to the excessive presence of radioactive substances, the Ministry assisted relevant measures, i.e. temporary import suspension, to be timely implemented by readily sharing the information with the relevant department of the Ministry as well as Ministry for Food, Agriculture, Forestry and Fisheries.

## 2) Provision of Intensive Analysis on Drug-related Key Information

### (1) Prompt Assistance to Measures against Information on ‘White Particles in Flu Vaccine Discovered’

Information was obtained on October 25, 2012 that Swissmedic declared a temporary ban on the distribution of Agrippal and Fluad in the wake of the announcement on October 24, 2012 issued by Italian health authorities stating that white particles were discovered from flu vaccines manufactured by Novartis. Upon receipt of the information, the Ministry immediately analyzed domestic authorizations and import volumes of such products, and the Ministry ordered temporary suspension on additional import and distribution of that products to Korean import companies for preventive purposes until final inspection report would be made available.

Although there had not been an incident report regarding this matter, none of the products with the production number confirmed for the presence of white particle were imported to Korea. At the same time, the ‘Safety News Alert’ was distributed to medical personnel informing a temporary ban on the products in question and urging to be extra cautious when prescribing(October 26, 2012).

### (2) Information on Detection of Chromium from Chinese Empty Gelatin Capsule

In April of 2012, China’s Food and Drug Administration(then known as the SFDA) released

a list of the companies related to empty gelatin capsules(including 13 products from 9 businesses) with excessive level of the toxic metal of chromium. After thoroughly reviewing the information announced by SFDA and news from Chinese media, the Ministry was able to confirm that the incident was caused when the empty gelatin capsules with excessive level of chromium were made of waste leather which was not allowed for medical use. Subsequently, the Ministry investigated risk potential in Korea after expanding a review parameter of the information to all gelatin-related products imported from China in addition to the 9 companies named by SFDA. Based on the review, the Ministry was able to confirm that the information carried minimal impacts on Korean market. Nonetheless, the Ministry continued to monitor all possible risk factors by constantly collecting and analyzing the information until Chinese authority declared otherwise.

#### **4. Protection of Korean Export Companies through Prompt Provision of Risk Information**

While dependency on imported products continues to increase with imported raw materials in addition to expanding Korean exports of processed products due to global free trade movements, Korean exported products are also frequently facing incidents where they are returned or discarded after found inappropriate. Such incidents not only cause a downfall of global image but also increase burdens on businesses. Thus, for the purpose of minimizing the rate of inadequacy on export goods, the Ministry conducts an in-depth analysis on the information and provides such information to businesses on regular basis in order to take preventive measures in advance by self-regulating risk factors as well as banning the imports. Building and operating the network to exchange information with businesses, the Ministry also provides weekly information on criteria and standards, enactment and amendment of laws and regulations and policy directions of the countries to export, which may not be readily available to businesses, in the format of PIMS.

#### **5. Future Plans and Prospects**

Currently, food-related risk information is scattered all over the departments and responses to the information also take up substantial time by each relevant department. Therefore, the

Ministry integrates food-related administrative network throughout the Ministry for Food, Agriculture, Forestry and Fisheries as well as local governments, and it also plans to pursue a project to build 'Integrated Food Safety Information Network' including a network of cohesive information utilization capable of easily accessing food-related information generated by 12 agencies including the Korea Custom Services. Through construction and operation of the 'Integrated Food Safety Information Network', all departments will be able to communicate more efficiently and it is also expected to consolidate a mutual-assistance system upon crises. Moreover, the soon-to-be-available portal site of food safety information is to deliver accurate and reliable food safety information from the government to the general public, businesses and group of institutions. And criteria and policies of foreign countries required for internal relevant department to develop long-term preventive projects will also be customized and provided.

Lastly, based on a precise analysis of food safety information collected from foreign countries, the Ministry is determined to further focus on preventive measures which all people, businesses and government can rely on.

# 04

## Strengthen International Competitiveness by Advancing Testing Laboratory

### 1. Overview of Test/Inspection Agency System

To ensure the safe management of food and drug, the Ministry regulates manufacturers to voluntarily comply with the self-quality inspection system on the products manufactured by them and it also tests and inspects the products after collecting them in the process of import and distribution. Although many companies have their own test facilities, those companies are unable to run self-quality inspections without such facilities are allowed to consign the inspection process to test/inspection agencies sanctioned by the government. Upon medical devices, the businesses may work with test/inspection agencies sanctioned by the government in order to obtain test reports for review purpose required for permits or certificates.

### 2. Appointment of Test/Inspection Agencies and Follow-up Management

The Ministry appoints test/inspection agencies in the fields of food and drug for the purpose of the safe management of food and drug. For those who wish to become a test/inspection agency shall apply to the Ministry after fulfilling specific requirements(i.e. inspection facility and personnel qualification), the Ministry is to review the requirements and inspect the site and the Ministry eventually appoint the applicant to be the test/inspection agency if found appropriate. Moreover, the Ministry is to instruct, inspect and evaluate the competency of

the agency on a regular basis at least once a year in order to assure the propriety of the test/inspection agencies.

### 3. Improvement on Reliability of Test/Inspection Agencies and Advancement of Operating System

As the test/inspection agencies are the safeguards to all foods and drugs imported into and distributed in Korea, it is critical to secure the reliability and fairness of the test results more than anything else. The Ministry makes extensive efforts to improve and advance the reliability of the test/inspection agencies by adopting world-class superb operating system for test/inspection agencies.

#### 1) Reasonable Modification of Regulations and System including Reinforcement of Eligibility Requirements for Test Agencies

Through the amendments of Food Sanitation Act(2009) and Pharmaceutical Affairs Act(2011), the Ministry introduced Designated Sunset Law where test agencies are required to go through re-appointment review process even if such agencies were previously sanctioned by the government. This is because the effectiveness of the appointment expires after a specified duration(3 years) passes and as the Ministry also adopted on-site evaluation system, test agencies with inadequate expertise are fundamentally prohibited from being sanctioned. And entire system of test fees for test/inspection agencies were also improved while mandatory training program was implemented to improve the expertise of the agencies. At the same time, the Ministry plans to integrate the relevant regulations for test/inspection agencies which are scattered throughout 6 laws including 'Food Sanitation Act', 'Pharmaceutical Affairs Act', 'Cosmetics Act' and 'Medical Appliances Act' in order to more systematically and efficiently manage, support and promote the test/inspection agencies in the field of food and drug. The Ministry also aggressively pursue to establish the 'Food/Drug Examination and Inspection Act' in order to accommodate international standards and to procure a foundation for industrial support and developments.

## 2) Reinforcement of Regular Guidance and Monitoring of Test/Inspection Agencies

As consumers become highly concerned over the safety of food and drug due to an illegal practice by test/inspection agencies such as issuance of falsified test reports, the Ministry has swept all the inadequate test agencies by conducting special guidance and inspection procedure against inspection agencies of food and drug as well as medicinal herbs. Test/inspection is a core procedure for the preventive safety management of food and drug; thus, when management of the test/inspection procedure is inadequate or improper, the general public is destined to become more weary and anxious. Therefore, the Ministry in 2013 is determined to develop an inspection plan upon inspection agencies for the farm stock products which are to be newly included while simultaneously focusing on regular inspection and intensive inspection followed by thorough management.

## 3) Support and Promotion of World-class Advanced Test/Inspection Agencies

As the guarantee for the reliability of test/inspection reports became required by test/inspection agencies, it also demanded the introduction of advanced operating system for test/inspection agencies. Based on international standard for test/inspection, the Ministry has developed and continuously distributed 'Osong Laboratory Quality Assurance System(Osong LaQAS)' since 2009.

Medicine and Medical Supplies	Medical Herbs	Cosmetics
The operation guideline for laboratory quality assurance scheme on drug testing	The operation guideline for laboratory quality assurance scheme on drug testing	The operation guideline for laboratory quality assurance scheme on drug testing
 <p data-bbox="294 1422 525 1446">Ministry of Food and Drug Safety</p>	 <p data-bbox="594 1422 825 1446">Ministry of Food and Drug Safety</p>	 <p data-bbox="893 1422 1125 1446">Ministry of Food and Drug Safety</p>

[ Figure 1-4-1 ] Osong LaQAS Guideline & Standard Model

To advance the storage and usage of test/inspection data, The Laboratory Information Management System(LIMS) has been developed and built since 2009. The system was first applied to health/environment researchers at city and province offices and it was further implemented upon private food sanitation inspection institutes and in 2010, the LIMS was

also supplied to test/inspection agencies in the medicine field. In 2013, the Ministry plans to develop and distribute the 'Management & Operation Guideline for the LIMS of the Ministry of Food and Drug Safety'.

#### 4) Competency Enhancement for Test/Inspection Agencies both in Korea and Overseas

Proficiency Assessment Scheme, which had been limited to food sanitation inspection agencies, has been expanded to the inspection agencies for pharmaceutical, medicinal herbs and cosmetics since 2010 in order to strengthen the competency of test/inspection agencies. In 2012, the international proficiency assessment was performed on foreign inspection agencies(13 agencies from 5 countries) and 14 agencies from 6 countries are scheduled to participate in the same assessment in 2013.

The Ministry also adopted and currently operates the assessment system upon inspection system in order to evaluate propriety of overall operating system for inspection performance by test/inspection agencies. The assessment on inspection system is designed to evaluate the standardization of inspection-related documents and reagent management, utilization of tried and tested analysis equipments and competency of inspectors; thus, it is an advanced assessment system capable of preventing errors prone to occur during the process of test/inspection and it is also expected to help inspection agencies to improve.

#### 5) Enhancement of Communication with Test/Inspection Agencies and Cooperative Job Performances

Ministry of Food and Drug Safety hosts regular meetings with test/inspection agencies in order to strengthen cooperative system with them. As Korea Food Testing Laboratory Association was founded for the purpose of healthy advancement and competition amongst test/inspection agencies in 2012, it is expected to strengthen communication and cooperation among test/inspection agencies. The Ministry also provides a variety of information by developing English website for foreign inspection institutes for the purpose of vitalizing foreign test/inspection agencies. In addition, it enhances the knowledge/information sharing system for inspection agencies by biannually publishing e-Newsletter in order to share information with foreign inspection agencies.



2013 MFDS Report Ministry of Food and Drug Safety



# 02

## Food

01. Strengthened Safety Control from Manufacture to Consumption
02. International Harmonization of Standards for Food and Scientific Risk Assessment
03. Establishment and Execution of the Pan-governmental Measures to Eliminate Unsanitary Food



## 01

**Strengthened  
Safety Control from  
Manufacture to  
Consumption****1. Safety Control for Foods in Distribution****1) Overview**

With an aim to ensure preemptive control and management of food-related companies for maximization of effective guidance and control, arrangement of safe food supply, prevention of food poisoning and social food issues by periodic and seasonal characteristics, the nation-wide joint control activities were in place five times in 2012 and 754 companies did not come up to hygienic standards among 24,038 companies pertaining to popular foods during traditional holidays such as Chusok, Lunar New Year Holiday, Summer season, kimchi-making season as well as companies supplying food to schools and groups. The 754 companies found in violation, taking up 3.1%, were subject to corrective measures and improvement.

「The Regulation on the Range, Survey and Procedure Pertaining to Foreign Materials Subject to Reporting」 was established on January 4, 2010, requiring businesses to report any complaints from consumers to administrative agencies. This leads to conduct surveys and analyses of causes of all foreign materials reported and improvement of the manufacturing environment.

Also, surveys involving collection from hygienically vulnerable areas were expanded for the efficient collection of foods in distribution. 174,080 samples were collected from 42 food groups

including agricultural, livestock and marine products and processed foods including (health functional foods) and 320 items. 1,241 samples were non-conforming (0.7%) and subject to the Emergency Notification System for Nonconforming Foods based on real-time information, prompt suspension of sales and recall, seizure and disposal for the betterment.

The Automatic Hazardous Product (Food) Sale Block System was developed and distributed for collaboration between private (sellers and distributors) and public sectors (the Ministry of Trade, Industry and Energy, the Ministry of Food and Drug Safety, etc.) crack down on non-conforming products in the final stage of consumer purchase at counters by using product bar codes. In 2012, 34,762 businesses including 28 large and small and medium-sized distributors, Nadle shops and military welfare shops engaged in voluntarily to provide a safe consumption environment to 15,310,000 consumers on a daily average, contributing to prevention of damage and further distribution through the instant deterrent of sale and timely recalls.

At the same time, for rapid control of distribution and sale, there has been a shift of policies for proactive measures to hold back sale and distribution temporarily, to execute risk assessment and inform the nation of the results from previous follow-up policies involving presentation of survey results.

## 2) National Joint Control

The Ministry of Food and Drug Safety is responsible for joint control with related institutions of local governments and educational offices to maximize efficiency in guidance and control and share data about food safety from each institution. The inspection takes place regularly every year in relation to business types and items such as manufacture, cooking, distribution and transportation nationwide to arrange the safe food supply infrastructure.

### (1) Regular Joint Control

Yearly joint control is under way in cooperation with local government according to the characteristics of each time period and season in order to prevent food-related accidents and secure food safety. This control covers the foods subject to social issues, higher chances of non-conformity and deliberate violations.

Also, prior to joint control, advance notices are given through media release so that businesses have chances to improve hygiene voluntarily. The results of control are made available

to realize consumers' rights to know. The nation-wide joint control activities were in place five times in 2012 and 754 companies did not meet to hygienic standards among 24,038 companies pertaining to popular foods during traditional holidays such as Chusok and Lunar New Year Holiday, Summer season, kimchi-making season as well as companies supplying food to schools and groups. The 754 offenders, taking up 3.1%, were subject to corrective measures and improvement.

### 3) Performance of Collection and Inspection

#### (1) Collection and Inspection System

With aims to secure food safety in distribution and improve efficiency of collection and inspection, roles are divided among local authorities and provincial and municipal(cities, counties and districts) governments. Items occupying larger pies in the market or of higher non-conformity rates are selected and subject to special control and intensive collection and inspection.

174,080 samples were collected from 320 items under 42 food categories were intensively collected and inspected, resulting in 1,241 products found non-conforming(0.7%) and subject to collection, seizure and disposal. Comparing the results of collection and inspection over the last five years, non-conformity is continuously decreasing.

[ Table 2-1-1 ] Annual Collection and Inspection

Year	Collected	Non-conforming	Non-conforming
2008	198,699	1,928	1.0
2009	218,805	2,010	0.9
2010	219,910	1,645	0.7
2011	181,391	1,254	0.7
2012	174,080	1,241	0.7

### 4) Private and Public Joint Monitoring System

#### (1) Expansion of Consumer Food Hygiene Inspectorate

The Food hygiene monitoring was straightened out in terms of fairness, reliability and transparency with the Consumer Food Hygiene Inspectorate by engaging specialists such as consumer groups and inducing proactive food hygiene monitoring for consumers.

As of 2012, 94,146 Consumer Food Hygiene Inspectors are responsible for food hygiene monitoring along with Food Hygiene Inspectors every year. One inspector took part in the activities for 8 days on an yearly mean, inspected 556,767 sites handling food and looked out for 9,760 offense sites(1.8%) against the Food Sanitation Act and they were subject to administrative measures.

## (2) Reward System for Reporting Adulterated or Unsanitary Foods

With an aim to raise a national awareness to report adulterated or unsanitary foods, there are the standards to give a reward ranging from 10,000 to 10 million won to countermeasure violations of the food hygiene laws involving manufacture, processing, transportation and nonconforming food sale. In 2012, 5,712 reports were accepted from all civil complaints and subject to status assessment and administrative measures. In total, 1,216 reports resulted in rewards amounting to 117,330,000 won.

Additionally, with an aim to induce proactive participation of the nation, the consistent promotion in relation to reporting of adulterated or unsanitary foods was settled on the internet, newspapers, professional journals, news from neighborhood meetings, radio broadcasting, electronic displays and subways.

## 5) False or Exaggerative Advertisement Monitoring

False or exaggerative advertisements of foods are a task to be controlled to safeguard consumer health and economic loss. In order to control false or exaggerative advertisement through excessive media such as internet, TV, newspapers and magazines, the Ministry of Food and Drug Safety and local governments designate and manage advertisement media.

[ Table 2-1-2 ] Monitoring of Advertisement Media by MFDS and Local Governments

Responsible for Monitoring and Crackdown	Advertisement Media	Note
The Headquarters, Local MFDS(advertisers within the jurisdiction)	<ul style="list-style-type: none"> <li>• Major daily, home shopping broadcasting and local cable broadcasting companies</li> <li>• Internet sites</li> </ul>	Responsible person to be arranged for each medium monitoring
Municipal and Provincial Governments, City, County and District	<ul style="list-style-type: none"> <li>• Newspapers(local newspapers), professional magazines and general magazines</li> <li>• Local TV broadcasting companies(relay operators, overall cable broadcasting, multichannel users and local cable)</li> <li>• Local small papers, printed materials and other ads</li> </ul>	

Also, professional monitors and agents are recruited for full-time monitoring of false or exaggerated advertisement. As a result, 2,217 cases were monitored and some of them were subject to administrative measures by imposing them public charges. Also illegal overseas website were subject to access prohibition by the Korea Communication Standards Commission. On top of that, the 'False or Exaggerative Food Advertisement Disclosure System' was arranged on the website of the Ministry of Food and Drug Safety and Food Nara to inform the nation of the wide range of exaggerated advertisements.

[ Table 2-1-3 ] Status of Monitoring of False or Exaggerated Advertisement of Food  
(Unit : number)

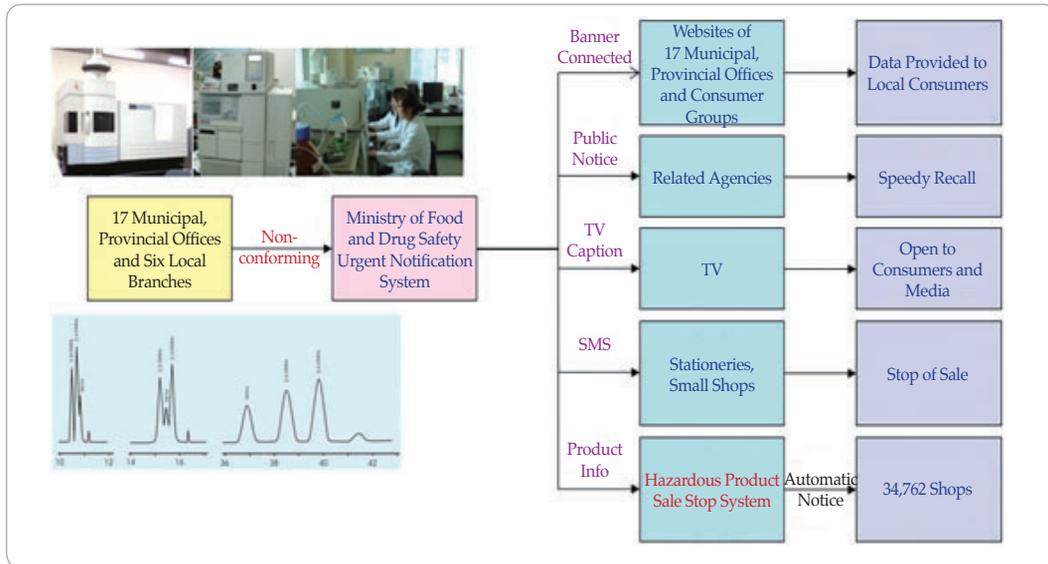
Year	Number Monitored	Media Released Exaggerated Advertisement					
		Newspaper	Magazine	Internet	Printed Materials	TV	Others
2008	929	34	2	840	32	2	19
2009	1,190	22	2	1,122	13	1	30
2010	2,420	83	2	2,305	8	4	18
2011	2,815	91	8	2,662	18	3	33
2012	2,217	101	0	2,083	12	4	17

## 6) Hazardous Food Recall System and Data Disclosure to Consumers

### (1) Hazardous Food Recall

Data as to non-conforming foods(hazardous food) are shared and used among related institutions, distributors and consumers on a real-time basis to prevent possible damages and to forewarn consumers of food safety problems arising from nonconforming food. Including the disclosure on the website, various methods are applied by setting up expeditious recalls and earlier suspension of distribution and sales.

For the purpose of expediting and systemic recall and control of hazardous foods, 「The Guideline for Collection of Hazardous Food」 and the Emergency Notification System for Nonconforming Foods were arranged in April 2008. SMS Notification services are provided to businesses handling foods subject to recalls. Sales are quickly and automatically cracked down at the counter, in the final stage of consumption through a private and public collaborative system called The Automatic Hazardous Product(Food) Sale Block System.



[ Figure 2-1-1 ] Hazardous Food Data-sharing System

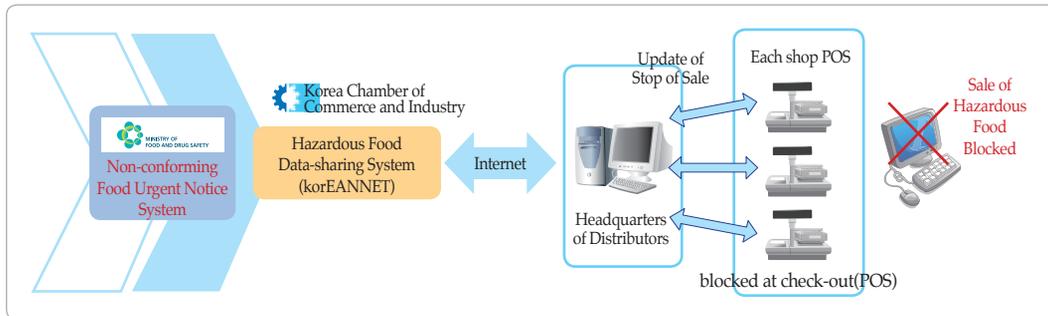
## (2) The Sale Block System of the Automatic Hazardous Products

The Sale Block System of the Automatic Hazardous Products is a collaborative system among public and private institutions (The Ministry of Trade, Industry and Energy, the Ministry of Food and Drug Safety, the Korea Chamber of Commerce and Industry and distributors). This system is arranged for prompt deterrent of sales and recalls based on real-time notifications to private distributors through the KORANNET of the Korea Chamber of Commerce and Industry affiliated with the Emergency Notification System for Nonconforming Foods under the Ministry of Food and Drug Safety in the event of any non-conformity found as a result of collection and inspection of foods in distribution.

Meanwhile, as an increasing dependence on overseas food consumable, risk factors of consumers' safety increase as well. At the same time, while the prearranged food safety control is enhanced, the follow-up measures of suspension of sales and recalls become skimpy, resulting in the introduction of this system for effective suspension of nonconforming foods sale.

Starting from the large distributor of Lotte Mart, in 2009, it was expanded to cover 34,762 shops including 28 large to small distributors, Nadle Stores and military welfare shops in 2012, providing a safe consumption environment at about 15,310,000 on a daily average. This will

continuously expand to cover middle and small distributors to ensure the larger safety nets and to push forward the distribution based on the timely suspension of sale and distribution as well as recalls of hazardous food.



[ Figure 2-1-2 ] Flow of Hazardous Product(Food) Sale Stop System

※ If it is non-conforming based on the nation-wide collection and inspection, the results shall be sent to the Ministry of Food and Drug Safety and then, to electronic networks of large (small and middle-sized) distributors as members of the Korea Chamber of Commerce and Industry KOREANNET. The data will be sent to each shop terminal and end users can avoid buying the products through the bar-code reading by the counter.

### (3) Establishment and Management of the Consumer Report Center for Food Safety

The 「Adulterated or Unsanitary Food Report Center」 used to receive and handle consumers' complaints through 1339 calls, mails and visits. But it was upgraded to have banners of the 「Consumer Report Center for Food Safety」 for consumers so that they can conveniently report and register their complaints through the internet and websites to the Ministry of Food and Drug Safety, local Food and Drug Safety Administrations and municipal and provincial (city, county and district) websites in March 2008.

The system functions were fortified to handle overflowing consumers' complaints. As a result, the data are shared with other related agencies, which enable the survey results to be transferred to relevant administrative agencies immediately.

## 7) Status of Foreign Material Notification and Report

The Food Sanitation Act was revised on February 6, 2009 to handle consumers' complaints about foreign food materials, to take corrective measures against recurrences and to resolve

conflicts and distrust among food companies and consumers. Under the revision, as a business receives a report from a consumer about any foreign material, it shall immediately make it public to the relevant city, county, or district government.

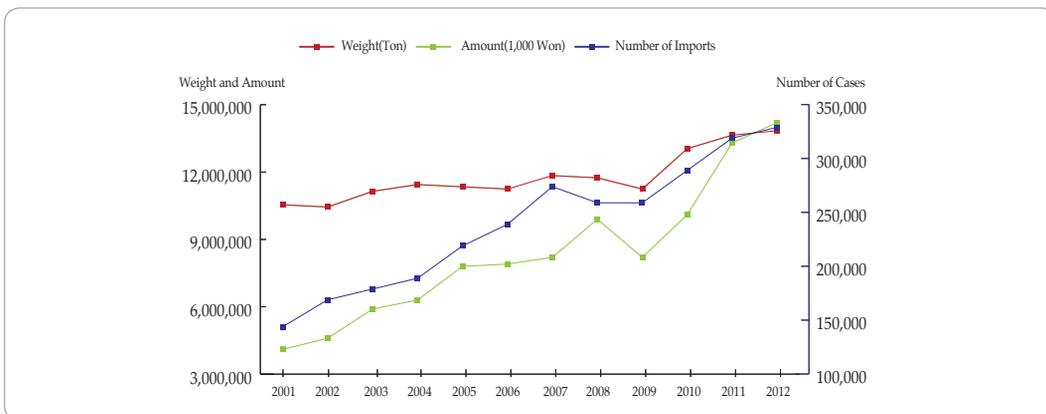
The causes of mixture with foreign food materials will be divided into the stages of consumption, distribution and manufacture. Based on the scientific surveys, exact causes will be analyzed for improvements. In order to enable this survey of scientific arrangement the detailed methods and procedures will be arranged in each stage. Standardized techniques and guidelines for surveys will be shared with related agencies to resolve national anxiety over food safety and to prevent similar recurrences and proactively lead facility improvement, by establishing foundation of manufacture, distribution and safe food sale.

## 2. Establishment of Safety Control System for Imported Food

### 1) Trends in Imported Food

The FTAs have continuously increased the number and quantity of imports by 96.3%(166,026 → 325,936 cases) and 31.4%(10.5 → 13.8 million tons), respectively in comparison with the statistics in 2002.

The yearly import numbers(7.0% on average), quantities(2.8% on average) and items(5,167 → 6,455) are also increasing. Imported food takes up 65% in calorie intake and 34.1% in the amount of distribution.



[ Figure 2-1-3 ] Trends in Yearly Increase of Imported Food(2001~2012)

As regarding Korea's food safety, the safety control of imported food is gradually increasing. There have been transnational accidents such as melanin in Chinese dairy products(2008) and Japanese radioactive contamination(2011) and there is a concern for wide spreads of such materials. Accordingly, the Ministry plans to establish the 'Preliminary Import Predictive System' to conduct local due diligence at manufacturers exporting in large quantities or producing non-conforming products, by classifying the grades of imported food through analysis of previous history and results of inspection. Also, the Ministry plans to establish the 「Special Act for Safety Control of Imported Food」 which will arrange the heavier duties of importers and carry out history-based intensive inspection by strengthening importer's duties and increasing penalties and disadvantages against deliberate or frequent violators, which will fundamentally crack down on the import of unsanitary food.

## 2) Imported Food Inspection

The imported food inspection is conducted by six local Food and Drug Safety Administrations and all imported foods will be subject to appropriate reporting review to cover availability of raw materials, compliance with the standards for food additives and standards for labeling and GMOs(Genetically Modified Organism) based on the import reports.

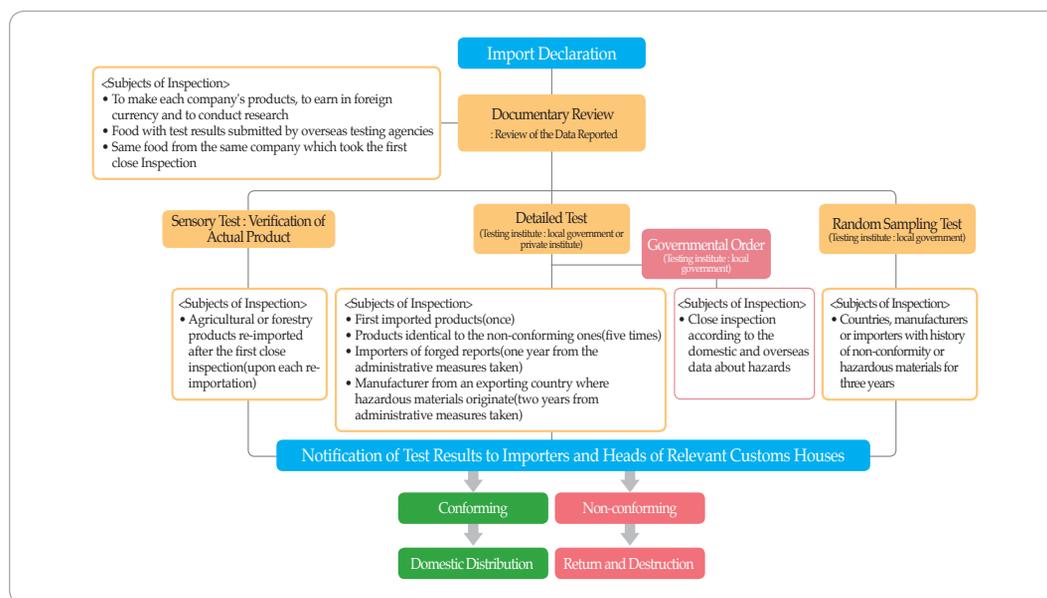
Potentially hazardous food including food imported for the first time, food with history of a non-conformity decision and food imported with history of false reports and administrative measures will be subject to close examination including physical, chemical or microbiological inspection, based on the Food Sanitation Laws and Regulations. Later imported food will be subject to random sampling and inspection in consideration of hazard-related data and frequency of non-conformity decisions, ensuring thorough imported food inspection from the import and customs clearance stages.

[ Table 2-1-4 ] Types, Subjects and Methods of Imported Food Inspection

Type of Test	Subject Food	Testing Method
Document Review	<ul style="list-style-type: none"> <li>• Earning in foreign currency(excluding tourism purposes)</li> <li>• Raw materials to produce each company's products</li> <li>• Research and survey</li> <li>• Food imported by the governments or local agencies</li> <li>• Wooden materials, stones or glass without colors</li> <li>• Food re-imported after the first close inspection(conforming)</li> <li>• Food for exhibitions and expositions, patients of generic metabolic problems and subject to refining or processing</li> </ul>	Test to decide conformity based on a review of the documents submitted

Type of Test	Subject Food	Testing Method
Sensory Test	<ul style="list-style-type: none"> <li>Food without the standards among agricultural or forestry products</li> <li>Same food among the agricultural and forest products re-imported after the first detailed test(conforming)</li> <li>Other food types decided by the Ministry of Food and Drug Safety to necessitate a sensory test</li> </ul>	Test to decide conformity by summing up the product properties, tastes, conditions, smell, colors, labels, packaging status and history of close inspection
Detailed Test	<ul style="list-style-type: none"> <li>Food imported for the first time</li> <li>Food with problems in the country or overseas</li> <li>Imported food with non-conformity history</li> </ul>	Test conducted according to physical, chemical and microbiological methods
Random Test	<ul style="list-style-type: none"> <li>Food selected based on the random sampling plan among the food types subject to document review and sensory test</li> </ul>	Test conducted according to physical, chemical and microbiological methods

The imported food reporting and inspection procedure is as follows.



[ Figure 2-1-4 ] Import Declaration Procedure for Food, etc.

### 3) Status of Imported Food

In 2012, Korea imported 325,936 (13,750,000 tons worth of 14.3 billion dollars) items from 121 countries including China, USA and Japan, an increase by 27.9% (weight by 17% and amount of money by 45.7%) from the records of import in 2008.

[ Table 2-1-5 ] Inspection of Imported Food for the Recent Five Years

(Unit : number, 1,000 tons, 1 million dollars, %)

Division	2008	2009	2010	2011	2012
Number of Inspection(Case)	254,809	255,341	293,988	312,723	325,936
Weight(1,000 tons)	11,731	11,301	12,905	13,471	13,756
Amount(One Million Dollars)	9,860	8,434	10,335	13,195	14,369
Non-conformity Cases Number)	1,020(0.40)	1,229(0.48)	1,143(0.39)	1,014(0.32)	783(0.24)

Note : Non-conformity rates within the parentheses(%)

Inspection types include document review(215,182 cases, 66%), sensory test(30,256 cases, 9.3%), close examination(62,616 cases, 19.2%) and random sampling test(17,882 cases, 5.5%). There were 80,498(24.7%) close examination(including random sampling) on hazardous food which threatens Korea's food safety such as first-time imported or non-conforming food.

[ Table 2-1-6 ] Status of Inspection of Imported Food by Item for the Recent Five Years

(Unit : number, %)

Division	2008	2009	2010	2011	2012
Agricultural and Forestry Products	35,026	33,118	39,413	42,416	46,773
Processed Food	155,536	139,782	157,570	167,084	174,120
Health Functional Food	6,533	7,062	6,555	8,017	7,423
Food Additives	31,423	31,111	33,503	32,155	31,365
Devices, Containers or Packages	26,291	44,268	56,947	63,051	66,255
Total	254,809	255,341	293,988	312,723	325,936

Korea imported products from 121 countries in 2012 and the top five countries of the number of imports were China, USA, Japan, France and Italy and these countries occupy 61.4% of the total import.

[ Table 2-1-7 ] Status of Import of Food among the Top Five Countries in 2012

(Unit : number, %)

Rank	Country	Number	Rate	Country	Weight	Rate	Country	Amount	Rate
1	China	89,116	27.3	USA	2,546	18.5	USA	2,741	19.0
2	USA	51,658	15.8	Australia	2,490	18.1	China	2,595	18.0
3	Japan	32,884	10.1	China	2,283	16.6	Australia	1,075	7.5
4	France	13,346	4.2	Brazil	974	7.1	Thailand	784	5.5
5	Italy	13,111	4.0	Serbia	618	4.5	Brazil	779	5.4
	Sub-total, Five Countries	200,115	61.4	Sub-total, Five Countries	8,911	64.8	Sub-total, Five Countries	7,974	55.5
	Total	325,936	100	Total	13,756	100	Total	14,369	100

#### 4) Major Good Results

Based on local due diligence of 25 dried filefish fillets registered with the Vietnamese government(NAFIQAD), 14 unsanitary manufacturers were subject to the suspension of import. In cooperation with Chinese governmental inspectors, the Ministry conducted local due diligence of manufacturers producing kids favorite food and held explanation sessions to lead safe food export.

Also, in the event of local due diligence of manufacturers in exporting countries, excellent importers with good processing or hygiene were invited to register them as excellent importers. The number increased from 17(2011) to 43(2012), setting up a system to help importers introduce good food and manage manufacturers. The Ministry provided training for exporters to improve the capacity for due diligence of manufacturers(30, July 11-13, 2012) and hosted explanatory sessions about local food safety system and Korean standards for four occasions, securing safety of imported food in advance. Additionally, continued MOUs(Memorandum Of Understanding) with other countries also helped to secure safety of imported food in advance.

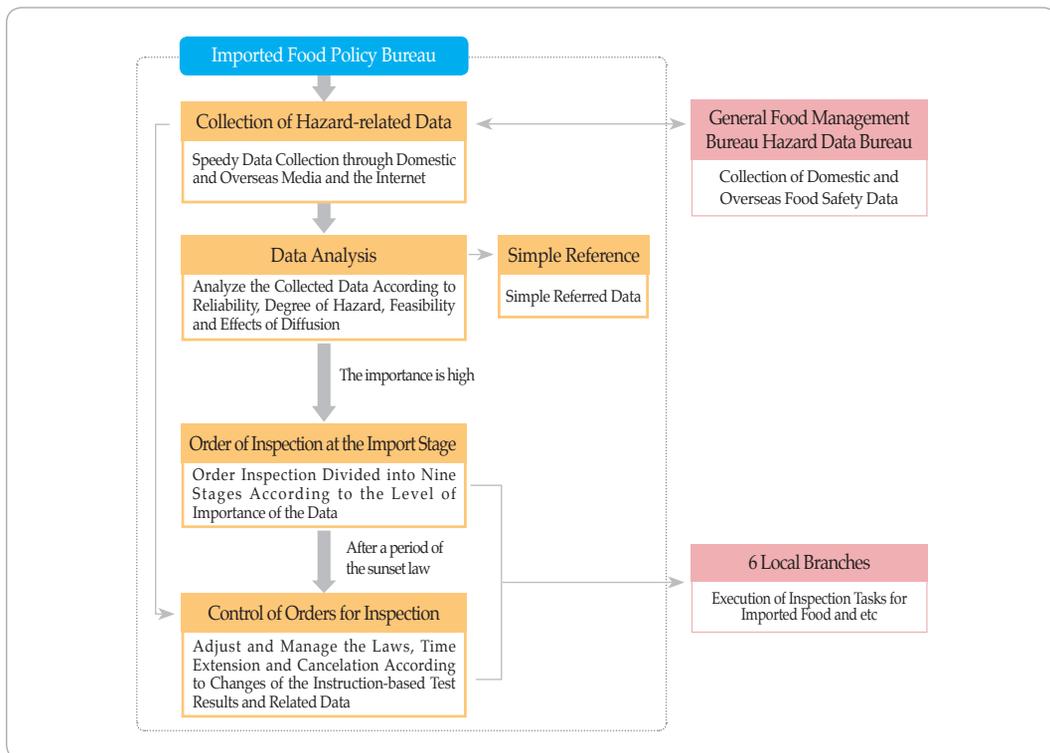
[ Table 2-1-8 ] MOUs Entered

Country	China	Chile	Vietnam	Germany	WHO	Australia· New Zealand	Indonesia
Organization	China Health Inspection Agency	Chile Health Ministry	Vietnam Health Ministry	Germany Federal Hazard Assessment Agency (DFR)	West Pacific Headquarters (WPRO)	Food Standards Australia New Zealand (FSANZ)	Indonesian Food and Drug Safety Ministry (NADFC)
Date Entered	Oct. 31, 2003	Jun. 20, 2006	May. 29, 2009	Jul. 30, 2010	Jul. 11, 2011	Jul. 14, 2011	Jul. 12, 2012
Date Revised	Nov. 26, 2007	-	-	-	-	-	-



[ Figure 2-1-5 ] MOUs with Other Countries(Indonesia's Food and Drug Administration, Jul. 12, 2012)

The Ministry conducted intensive imported food inspection considering the data of hazards and non-conformity rates and secured imported food safety through the orders for inspection. It strengthened the prearranged advance safety control with closer examination against radioactive materials in imported food related to the nuclear power plant accident in Japan.



[ Figure 2-1-6 ] Workflow of Order for Inspection According to Hazard-related Data



[ Figure 2-1-7 ] Media Promotion for Food Safety after a Nuclear Power Plant Accident in Fukushima

Especially, radioactive tests with each food item imported from Japan were conducted to protect national health from the nuclear power plant accident in Fukushima(March 2011). Even when result is below the reference value, if there is no verification

of safety in relation to other nuclides, the import ban was implemented. The Ministry took temporary measures to suspend import of the items subject to restriction of release by the

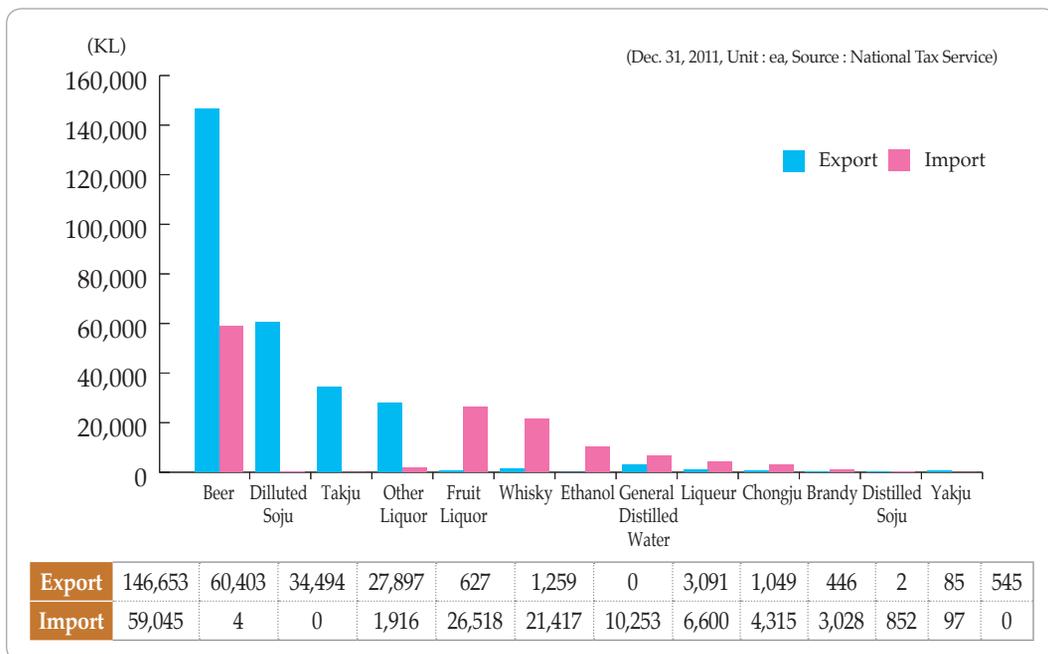
Japanese government(26 items from 13 prefectures) and show up at TV discussions to relieve the nation from increasing anxiety about Japanese food.

The Ministry designated education and training facilities under the order for imported food safety and provided two training courses for 69 participants, strengthening capacity for safety control of imported food so that import declaration agents can import safe and excellent food.

### 3. Strengthened Safety Control of Alcoholic Beverages

#### 1) Necessity for Strengthened Safety Control of Alcoholic Beverages

The alcoholic beverages industry has been managed under the governmental and institutional control and protection for taxation. However, as they are subject to each individual's favor and consumers require various types of alcohol, with following globalization trends, there has been an increase of import and rapid change of consumption behaviors, urging the additional safety control. Especially, the globalization of Korean traditional alcoholic beverages has led to more governmental interest and support. On the other hand, the industry fails to add the endeavors for sanitation and safety control to their traditional methods.



[ Figure 2-1-8 ] Trends in Import and Export of Alcoholic Beverages Export

Recently, dichlorobiz, an agricultural chemical or Phthalate, a plasticizer-contaminated white liquor was in distribution in China and detected by the Chinese Police, Also there were continued media reports that small Korean businesses making Takju(raw rice wine) needed to improve sanitation and safety control. There are constant needs for the safety control to reduce Ethyl carbamate, a noxious material without standards in the process of fruit-based alcoholic beverage making.

Additionally, the increased domestic consumption and export of Takju(raw rice wine) since 2009 began to fall rapidly in 2011, urging manufacturers of traditional alcoholic beverages such as Takju(raw rice wine) and Yakju medicine wine) to ensure the safety control, new product development and the homeogenous quality control. However, as most of the manufacturers are small scale businessmen and use old facilities, it is necessary to improve systemic quality control and awareness of employees to ensure the industrial competitiveness.

### (1) Safety Control of Alcoholic Beverages Manufacturers

There are 1,695 licenses to manufacture alcoholic beverages(as of December 31, 2012) and there are 1,307 licenses to make Takju(raw rice wine), Yakju(medicine wine) and fruit wine(77.1%). Manufacturers differ greatly in sanitation and the safety control. The Ministry divided the manufacturers into voluntary, general and intensive management subjects based on the results of the 2011 survey of the status considering the characteristics of the manufacturers and the limited governmental control, which is called the separate control system. The focus is laid on guidance and dissemination to strengthen the capacity and awareness.

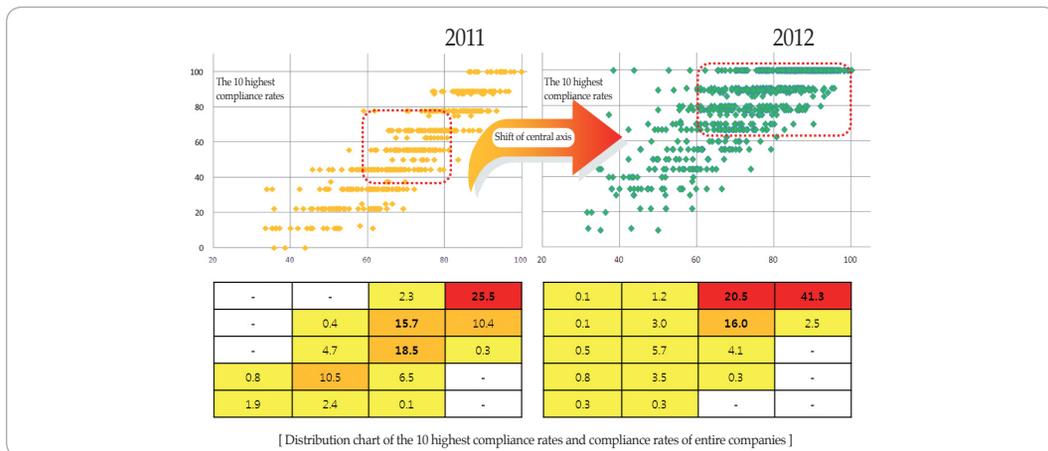
[ Table 2-1-9 ] Licensed Alcoholic Beverage Manufacturers

(Dec. 31, 2012, Unit: ea, Source : National Tax Service)

Total	Takju (raw rice wine)	Yakju (medi cine wine)	Fruit wine	Liquor	Beer	Small- scale beer manufac turer	General spirits	Distilled Soju	Diluted Soju	Whisky	Brandy	Ethyl alco hol	Cheong ju(Clear rice wine)	Other alcoholic bever ages
1,695	820	253	234	93	10	48	80	50	18	12	8	10	6	53

As a result, the overall control improved by 9.1%(2011, 74.9% →2012, 84.0%) from the previous year. Based on the intensive care of poor-quality and general manufacturers, the safety control levels increased by 23.3%(55.3% → 78.6%) and 8.5%, respectively. However,

excellent companies decreased in their assessment results by 0.9% under the different assessment method. By area, safety control improved in the areas of general hygiene, manufacturing processes, machine and apparatus control, product control, facility sanitation and raw and subsidiary materials by 14.7%(59.2% → 73.9%), 14.6%, 9.4%, 7.1%, 6.5% and 4.2%.



※ The x-axis is 'the total compliance rate' and the y-axis is 'the 10 highest compliance rates'. Higher numbers relate to higher safety control.

[ Figure 2-1-9 ] Change Transition of Yearly Observance

## (2) Technological Support for Manufacturers to Improve Safety Control

Support in analysis of hazardous materials and training was provided to companies demanding safety and quality control for alcoholic beverages. This reduced hazardous materials and improved the capacity for quality control. There were explanatory sessions to manufacturers of Takju(raw rice wine), Yakju(medicine wine) and fruit wine and 'visits excellent manufacturers in safety control', authorizing visitors to benchmark the companies.

The Ministry prepared and distributed various materials such as 'the First Step to Make Safe Takju(raw rice wine) and Yakju(medicine wine)', 'the Manual to Prevent Mixture of Foreign Materials in Alcoholic Beverages' and 'the Guideline to Wash Manufacture Facilities and Containers' as the companies need the methods to wash machines and apparatuses to manufacture safe beverages and control hazardous materials that may occur in the process of manufacture.

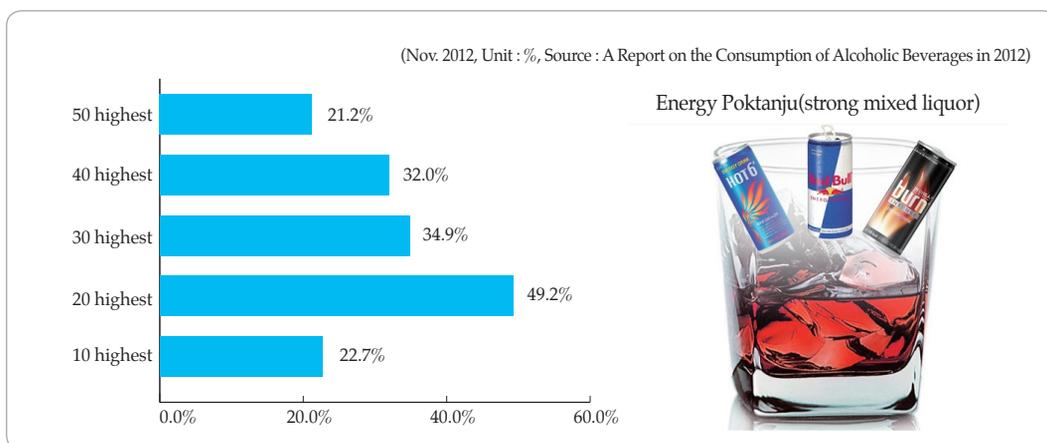


[ Figure 2-1-10 ] Sanitation Training and Visit Programs in 2012

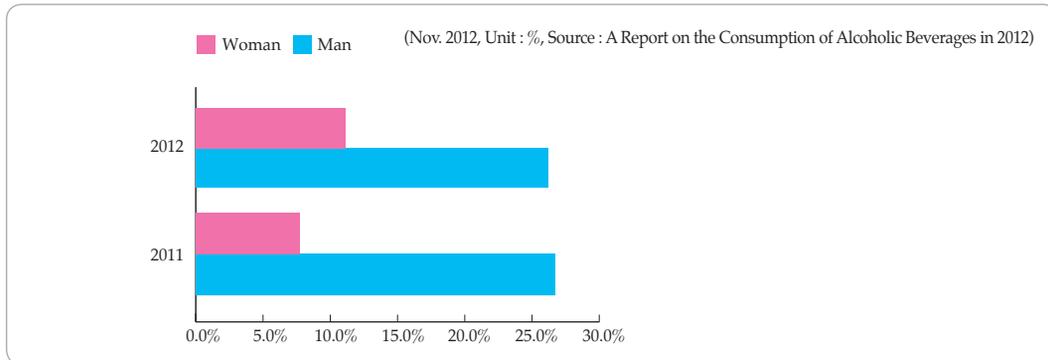
### (3) Survey on the Behaviors of Alcoholic Beverage Consumption

The Ministry surveyed the status of consumption and intake of alcoholic beverages of 2,066 participants, aged 15 or older to arrange the methods to control the safety of alcoholic beverages from 16 local areas of the country. There were two surveys in June and October. Surveyors visited and interviewed the informants. Major questions were about the amount of alcoholic beverage intake by type and age, status of high-risk group and behaviors and habits.

Based on the results of the year, the major characteristics of consumption and the intake of alcoholic beverages included that those in their 20s preferred Poktanju(strong mixed liquor) more, there was a new drinking trend called 'Energy Poktanju(strong mixed liquor)' to mix alcoholic beverages with other beverages containing much caffeine and there were more female high-risk informants.



[ Figure 2-1-11 ] Experience of Drinking Poktanju(Strong Mixed Liquor) for the Recent One Year(Age)



[ Figure 2-1-12 ] High-risk Drinking Rate, Twice or More a Week

## 4. Establishment and Management of the National Food Safety Information Service

### 1) Establishment of the National Food Safety Information Service

'The National Food Safety Information Service' was established on July 16, 2009 for collection, analysis and the provision of domestic and overseas food-related safety data, systemic and professional management of the food history as a tracking project for the prevention of distribution of hazardous food and improvement of national health.

At the time of the establishment, there were two teams, The Food Data Team and Tracking and The Management Team consisting of 17 members. Currently, there are four teams of Planning and Management, Food Data, Food History and Data Cooperation consisting of 25 people with strengthened expertise.

The major duties of the National Food Safety Information Service are the collection, analysis and speedy dissemination of domestic and overseas food safety data to the Ministry of Food and Drug Safety to prevent the introduction of hazardous food and ensure prevention and quick responses. It manages the infrastructure for the Food History Tracking Management System for the expeditious responses to any safety accidents, promoting and training companies.

Also, it manages the national portal site for the food safety called Food Nara to integrate the currently dispersed food safety data and to provide the level of consumer's awareness. This is to remove the anxiety related food. It has established and managed data cooperation systems with domestic and overseas relevant groups such as consumer's associations.

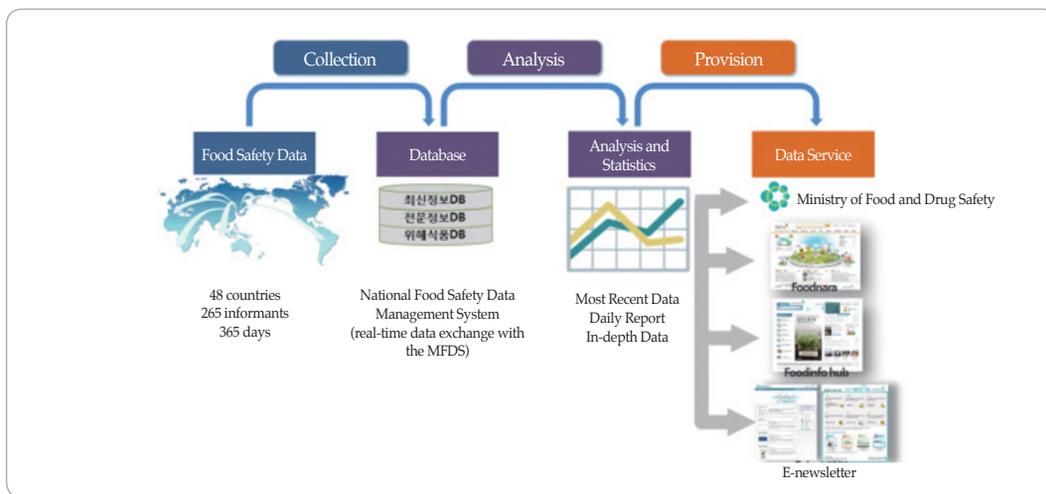
## 2) Status of the Management(Project) of the National Food Safety Information Service

### (1) Collection, Analysis and Provision of Food Safety Data

‘The National Food Safety Information Service’ collects and provides the domestic and overseas food data(risk and hazard) from 265 websites of 48 countries all throughout the year as well as food safety policies and strategies, standards and exported and imported food by subject and issue tailor-made to the Ministry of Food and Drug Safety.

The National Food Safety Information Service opened in July 2009 and collected and provided 67,898(20,495, 2012) food safety-related data and 337(63, 2012) professional data to contribute to the food safety control with prevention of distribution and the sale of hazardous food(recall, destruction and data publication). It runs an integrated the control system of food safety data called ‘Food Safety Database’, sharing the system and providing the systemic integrated data management.

Also, it established a crisis-responding data system through the ‘mobile provision of urgent data’ to use mobile MMS to speedily deliver overseas accidents and events to the Ministry of Food and Drug Safety.



[ Figure 2-1-13 ] Flow of Food Safety Data

### (2) Facilitation of the Food History Tracking Management

‘The National Food Safety Information Service’ established ‘the comprehensive data system

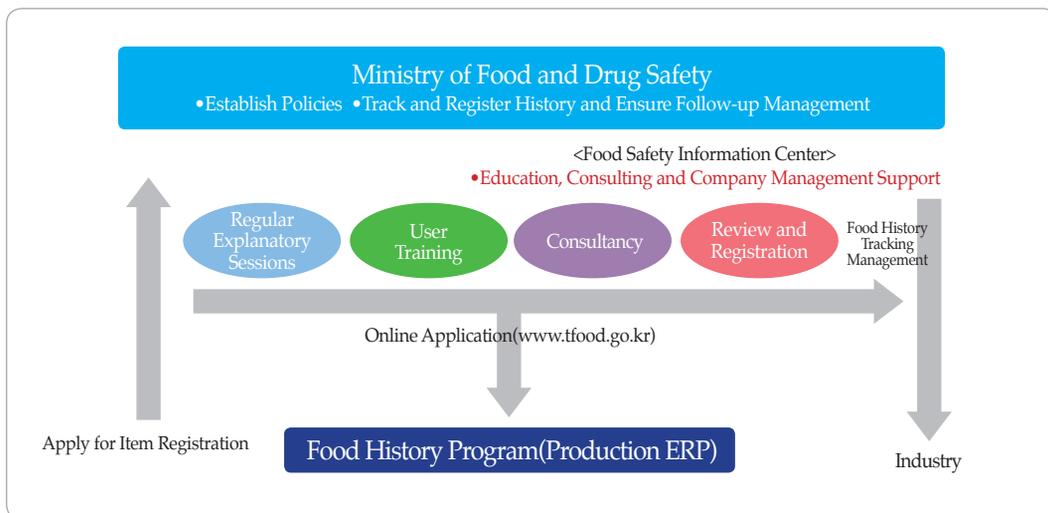
for food history tracking' and disseminated 'the food history management program' to support the food industry. It promotes the voluntary industrial participation through yearly explanatory sessions, training and consultancy with a focus on the settlement of the system.

From the establishment to December 2012, the Ministry provided 101 explanatory sessions about the system, 224 standard education programs and 347 on-site consulting services, supporting the registration of 411 items.

### (3) Promotion, Education and Management of the Food History Tracking Management System

'The National Food Safety Information Service' considered 'the tracking management system of food history' and companies' manufacture environment to develop 'tailor-made programs' to track food history. It holds 20~30 explanatory sessions every year to induce voluntary industrial participation. It has tried to establish and expand the system through on-site training(visit) and consultancy.

The Ministry held 101 explanatory sessions about the food history tracking system and standard programs, 223 standard program training sessions and 347 on-site consulting services as well support in registration of 411 items until December 2012.



[ Figure 2-1-14 ] Promotion, Distribution and Operation System for Food History Tracking Management

'The National Food Safety Information Service' manages 「the National Food Safety Portal Food Nara」 to provide the appropriate data to consumers and industrial sources and to have

them realize a society where all people enjoy healthy life by promoting the use of Food Nara, improving the national awareness and reliability. It worked out in a way that the National Food Safety Information Service was established as a national integrated food safety data provider. Especially, its consumer-friendly website remodeling and contents developments(new 4,523 contents and 404 SNS) increased the number of yearly users by 65%(3.71 million in 2010 → 5.68 million in 2012) in one decade.



[ Figure 2-1-15 ] New Main Screen and Contents of Food Nara

‘The National Food Safety Information Service’ entered into two agreements with domestic agencies, took part in 12 domestic cooperation projects, 11 exchanges with overseas agencies, one food safety data exchange event and two consumer hotline discussions, fulfilling the lead role to establish the global food safety data cooperation system.

Especially, in September 2012, the Ministry was designated by the WHO as an official partner of the International Food Safety Authorities Network(INFOSAN). In the second INFOSAN IN ASIA MEETING(2012.11), the Ministry conducted two discussions as to the data collection and management system of the National Food Safety Information Service and the cooperation methods to share database, improving its international position related to food safety data.

### 3) Future Plan

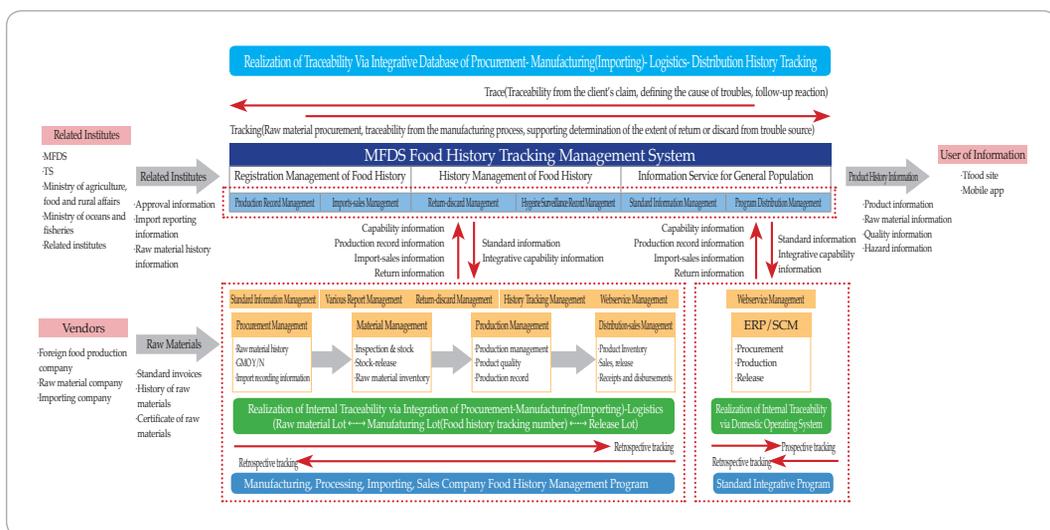
#### (1) Collection, Analysis and Provision of Food Safety Data

The National Food Safety Information Service plans to expand the scope of data collection such as agricultural, livestock and marine products as well as drinking water and school meals, to ensure the uninterrupted sharing of the data and to arrange the response and support

system by situation by developing ‘the Standard Operation Procedure for Food Safety Data Collection Network’, securing the efficient support for safety functions. Also, it will develop analytic tools for the collected data and support reasonable policy-making decisions through the statistical analysis. Consumer-oriented data services will be strengthened to provide proper data about hazardous food to the nation. There will be services related to consumer and consumption-oriented food safety data through the Food Safety Data Portal(Food Nara). Additionally, the national verification system will be established as the Ministry was designated as the one-stop agency to process data and reports about side effects of health functional food.

## (2) Promotion, Training and Operation Related to Food History Tracking Management System

The National Food Safety Information Service plans to develop a tracking management system of food history tailor-made to business type or level to expand the system and to strengthen the support for the industry through dual consultancy services on the site which link in easier and more accessible ways. Also, it will establish a tracking management system of the user-oriented food history through tailor-made program development and distribution with more conveniences in manufacture and processing, import and sale and distribution and sale, facilitating the distribution of this system.



[ Figure 2-1-16 ] Comprehensive Food History Tracking System

### (3) Establishment and Operation of the Cooperation Network

'The National Food Safety Information Service' plans to produce and provide the domestic and overseas food safety data and contents in a user-friendly design to prevent the inaccurate data and national anxiety by consistently providing food safety data through the 「the National Food Safety Portal Food Nara」. The data provided by national agencies responsible for food safety and national health such as the Ministry of Food and Drug Safety, the Ministry for Food, Agriculture, Forestry and Fisheries, the Ministry of Health and Welfare and local governments will be consistently and solidly summed up along with better web accessibility and standardization. This will provide universal web services to users including disabled or senior citizens based on the web accessibility which will reinforce the reliability of the website. Also, Food Nara apps such as 「Food Additives Smart Info App」 and the social media(Twitter and Facebook)-based promotion will be strengthened, helping consumers to solve their problems and questions.

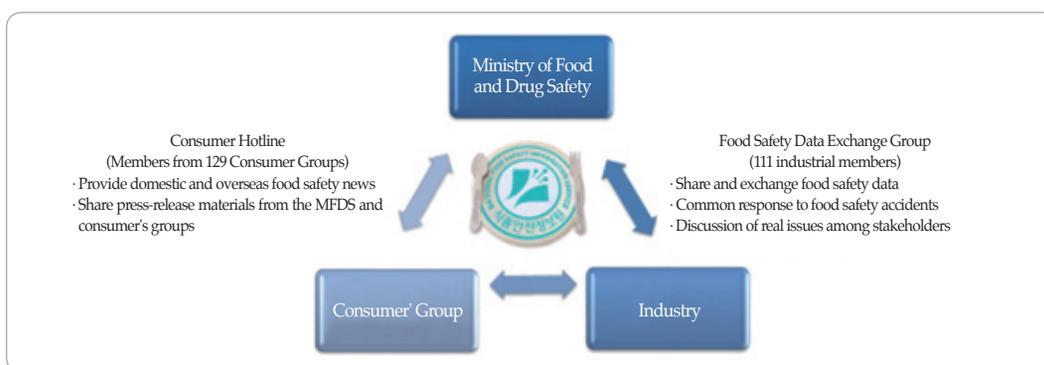
'The National Food Safety Information Service' will establish the response system by exchanging food data and cooperating with domestic stakeholders. Especially, it will strengthen the cooperation and expand network with 11 cooperative organizations which entered into MOUs with 'the National Food Safety Information Service', including better data collection, more active data exchange, joint projects (food data provision and promotion) and expanded network.

Additionally, there will be discussions with the representatives from 11 consumer hotline organizations, promoting real encounters and two-way data communication with consumers' groups through web communities such as the Food Safety Data Exchange Association. This will diversify and facilitate the means to share data with industrial sources. It will promote the exchange and cooperation with overseas agencies related to food data. This will develop pilot projects for data exchange(regulations, systems, etc.) and establish the network with major Asian trade partners to promote the exchange of food safety data, regulations and systems.

'The National Food Safety Information Service' will establish a response system by strengthening food data exchange and cooperation. Especially, it will ensure better cooperation and networking with the 11 affiliate organizations through the exchange of more active data and joint projects(food data provision services and promotion).

Additionally, there will be discussions with the representatives from 11 consumer hotline organizations, promoting real encounters and two-way data communication with consumers'

groups through web communities such as the Food Safety Data Exchange Association. This will diversify and facilitate the means to share data with industrial sources. It will promote the exchange and cooperation with overseas agencies related to food data. This will develop pilot projects for data exchange (regulations, systems, etc.) and establish the network with major Asian trade partners to promote the exchange of food safety data, regulations and systems.



[ Figure 2-1-17 ] Data Sharing and Communication among Food Safety Stakeholders

## 5. Improvement of Food Labeling to Realize Consumer's Sovereignty

### 1) Standards for Labeling of Food

The standards for labeling of food, etc. were noticed by the Minister of Food and Drug Safety to promote hygienic food handling, accurate data provision to consumers, and fair trade according to Article 10 of the 「Food Sanitation Act」 (the Ministry of Food and Drug Safety Notice No. 2013-132, April 9, 2013). The Standards aim to ensure accurate and appropriate data for consumers with names of products, raw materials, contents, dates of manufacture, circulation periods, ingredients, methods of keeping and conservation for sanitary handling and matters to be considered for handling appearing on the food containers or packages.

[ Table 2-1-10 ] Major Contents of the Labeling Standards for Food, etc.

Labeling Standards for Food, etc.	Detailed Labeling Standards for Food, etc.
Article 1(Purpose)	・ 「Annexed Form 1」 Detailed Labeling Standards for Food, etc. 1. General Standards for Food, etc. - Food·Food Additives, Devices, Containers or Packages 2. Labeling Standards for Long-term Preserved Food - Bottled, canned food, retort food, or frozen food
Article 2(Definition of Terms)	
Article 3(Subject)	
Article 4(Description)	
Article 5(Method)	

Labeling Standards for Food, etc.	Detailed Labeling Standards for Food, etc.
Article 6(Labeling Cautions for Consumer's Safety) Article 7(Labeling Misunderstood or Confused by Consumers) Article 8(Special Cases of Application of Labeling) Article 9(Detailed Labeling Standards for Food, etc.) Article 10(Allowable Errors of Weight, etc.)	3. Individual Standards for Each Food : 1) ~ 29) · 「Annexed Form 2」 Allowable Error(Range) between the Labeled and Actual Amounts · 「Annexed Form 3」 Standard Doses · 「Annexed Form 4」 Detailed Labeling Standards for Irradiated Food · 「Annexed Form 5」 Detailed Labeling Standards for Organic, Processed Food · [Diagram 2] Diagram for Forms Displaying Nutrients · [Table 1] Basic Draft for Origin of Ginseng · [Table 1-2] Standards for Korean Nutrition Intake · [Table 2] Table of Reference Values for Nutrients · [Table 3] Materials Applicable for Production and Handling of Organic, Processed Food · [Table 4] Food Additives Whose Names or Major Purposes of Use Must be Labeled · [Table 5] Food Additives Whose Names or Simple Names Must be Labeled · [Table 6] Food Additives Whose Names, Simple Names, or Major Purposes of Use Must be Labeled

## 2) Necessity for Improvement

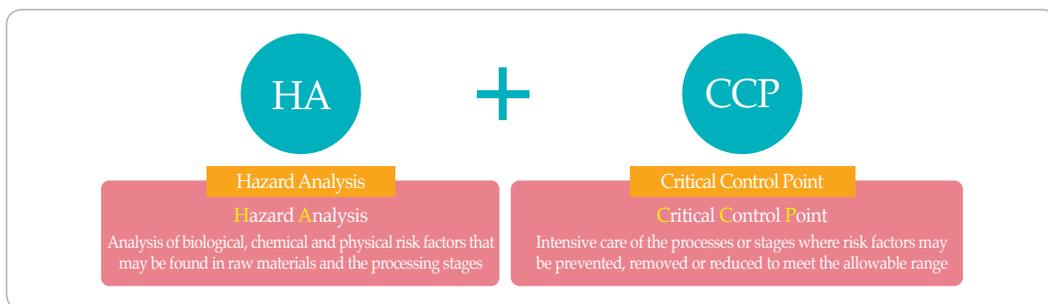
The Ministry reviews the issues to be revised every year for accurate data provision and sanitary management of food on sale reflecting the results in the food labeling standards. On the other hand, frequent revisions of the labeling may induce costs on the part of companies as they have to dispose of the obsolete packaging materials, which may lead to waste of resources. To resolve these problems, the Ministry enforces the 'Integration of the Date to Execute the Food Labeling Standards'. Therefore, regardless of the frequency or time for revision of food-labeling standards, they will be integrated on the same day once a year(for example, January 1st). This will change food data once a year, early every year on the food-packaging materials. This will reduce the burdens of companies arising from the frequent changes of the packaging materials and consumers will find it more helpful to select food with more verifiable dates.

Additionally, the Ministry ensures the improved readability to satisfy the requirements from companies and consumers, the extended display of allergens and division of food containers and tools, which will secure the accurate data to consumers and eventually will develop the food industry.

## 6. Facilitation of Food Safety Control Certification(HACCP)

### 1) Concept of the HACCP System

The HACCP(Hazard Analysis Critical Control Point) is pronounced as 'haessup' and stands for 'the Hazard Analysis & Critical Control Point'. It is a scientific and preventive food safety control technique developed by the US NASA(National Aeronautics and Space Administration) to provide completely safe food to astronauts. It has not developed into a food safety management system under which all risk factors that may arise in each process are checked and analyzed to prevent any mixture or contamination in all processes from raw materials, manufacture, processing, cooking, distribution and consumption of the final users, ensuring the intensive control.



Recently, there have been more accidents such as enterohemorrhagic coliform bacillus food poisoning in Europe and melon-led food poisoning in the USA and foreign materials found in food, which increased the national anxiety and interest. Under these circumstances, it is more than urgent to expand the scientific and preventive HACCP to supply safe food to consumers, to improve the overall safety control of the food industry and secure international competitiveness of the food industry.

### 2) Effects of the HACCP Application

Based on the analysis of comparative effects before and after the HACCP designation for the relevant companies, as the HACCP is applied, a company's production, sale and short-term net income increase while the number of consumer's claims fall. In conclusion, the HACCP application benefited a company's sale. Also, as the HACCP is applied, consumer's awareness,

corporate image and reliability improve, reducing costs arising from product recall or disposal and improving domestic and overseas competitiveness.

[ Table 2-1-11 ] Comparison of Effects before and after the HACCP Designation

Item	Before Designation	After Designation	Amount of Increase or Decrease(Mean)	Increase or Decrease Rate(%)
Short-term Net Income (one million Won)	891.1	1,110.3	219.2	24.6 ↑
Sale(one million Won)	8,333.9	11,407.6	3,073.7	36.9 ↑
Amount of Production(ton)	5,295.2	5,931.6	636.5	12.0 ↑
Delivered to(number)	224.2	311.2	87.0	38.8 ↑
Delivered to(number)	15.5	10.9	4.6	29.7 ↓

※ 2012, HACCP Support Team

On the part of consumers, too, as the HACCP application becomes wider, there will be a wider selection for food, reducing safety problems such as foreign materials and food poisoning and increasing assurance for overall food distribution.

### 3) Introduction of the HACCP

The Hazard Analysis & Critical Control Point(HACCP) was established in 1995 in Korea under the 「Food Sanitation Act」 as the Codex Alimentarius Commission(CODEX) suggested 'the Guideline for the HACCP Application' in 1993 and recommended all member states to introduce the HACCP to reinforce food safety. In 1996, the country established 「the Hazard Analysis & Critical Control Point(The Ministry of Food and Drug safety Notice)」, a turning point to proactively introduce the system.

Later, mandatory HACCP application was in place, covering the types of food highly likely to be dangerous or much consumed by the nation with aims to secure the food safety in advance and protect national health.

The mandatory HACCP introduction was based on the 2002 Food Sanitation Act under which six items including fish sausage were designated as mandatory subjects<sup>1)</sup> in August 2003(Korean cabbage Kimchi added in December 2006). In October 2005, 「the Hazard Analysis & Critical Control Point(the MFDS Notice)」 was revised and executed from 2006 stage by stage until 2012 based on annual sales of the items subject to mandatory application and number of employees (Korean cabbage Kimchin from 2008 to 2014).

[ Table 2-1-12 ] By-stage HACCP Mandatory Application

Stage	Subject	Time for Six Items	Time for Cabbage Kimchi
1	Annual sale of more than 2 billion Won and more than 51 employees	Dec. 1, 2006	Dec. 1, 2008
2	Annual sale of more than 0.5 billion Won and more than 21 employees	Dec. 1, 2008	Dec. 1, 2010
3	Annual sale of more than 0.1 billion Won and more than 6 employees	Dec. 1, 2010	Dec. 1, 2012
4	Annual sale of less than 0.1 billion Won and less than 5 employees	Dec. 1, 2012	Dec. 1, 2014

#### 4) HACCP Designation and Expansion

In 2008 when the new administration launched, the ‘expanded HACCP designation’ was a national task(2,500 HACCP-designated sites until 2012), which is still in application. In July 2008, all ministries worked together and announced 「the Overall Food Safety Measures and the 2011-July Second 「Comprehensive Food Safety Measures」 selected the ‘HACCP designation and expansion’ as the main task, under which 4,400 companies are aimed at the designation by 2014.

[ Table 2-1-13 ] Plan to Expand the HACCP Designation

Division	2012	2013	2014
Designated(Number)	800	900	1,000
Total(Number)	2,500	3,400	4,400
Rate(%)	11.4	15.4	20

※ The Second Comprehensive Food Safety Measures(2012~2014)

However, 90% or more of Korean food manufacturers and processors are small in scale with less than ten employees. These companies do not want to put their money into the facility improvement for the HACCP application, making it difficult to expand the application.

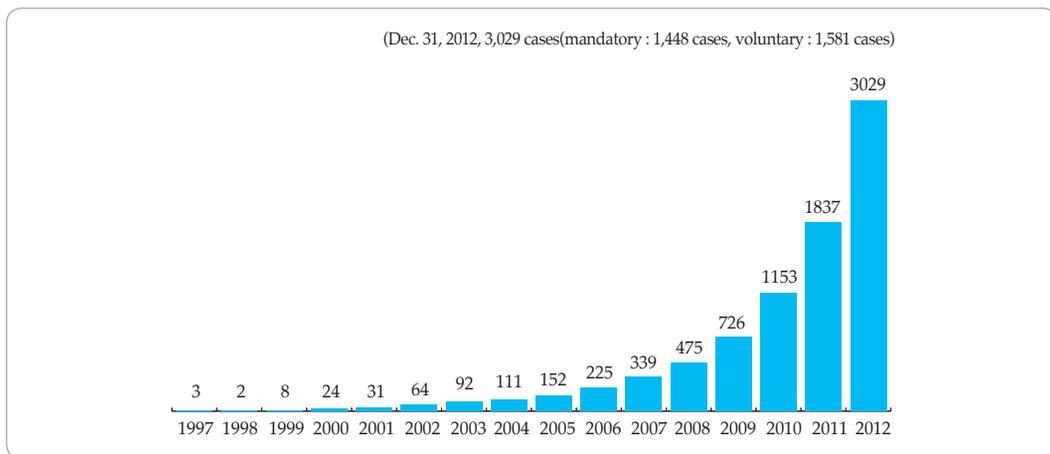
In 2012, the participation of small companies in HACCP was expanded and the civil request processing term was reduced from 60 to 40 days so that small scale enterprises subject to Stage 4 or above of the mandatory application<sup>1)</sup> may find it easy to apply the HACCP. Also, the number of documents for application was reduced(Letter of the Hazard Analysis & Critical

1) Annual sale less than 0.5 billion Won or less than 21 employees

Control Point for each food and one month or more operation performance→HACCP Plan) and the fee of 200,000 Won was temporarily removed. Hygiene inspection will be exempted as a HACCP-designated company is invited for manufacture and processing.

The separate management system was applied to the HACCP-designated companies. Excellent companies benefited from exemption of regular assessment while poor companies were subject to mandatory follow-up management support(May 17, 2012). Among the designated companies, those in the violation of the Food Sanitation Act were subject to frequent survey and assessment to back up the follow-up management against the poor management and for improved capacity.

Based on the results, there has been a continued increase of the HACCP-designated companies from 726 in 2009 to 3,029 in 2012 but the overall rate of all food manufacturers is still low.



[ Figure 2-1-18 ] Yearly HACCP Designation

[ Table 2-1-14 ] HACCP Operation by Item

(Dec. 31, 2012, Unit : number)

Total	Food Manufacture and Processing										Group meals	Food Sold for Group Meals	Food and Hospitality	Food Subdi Vision	
	Sub-total	Mandatory HACCP Application													Gene ral
		Sub-total	Unheated	Ice	Frozeon Marine	Frozen	Fish Sausage	Retort	Korean Cabbage Kimchi						
3,029	2,966	1,448	14	42	756	203	99	53	281	1,518	18	8	33	4	

### 5) Support for More HACCP Designations

The Ministry of Food and Drug Safety established the 「HACCP Support Team」 under the

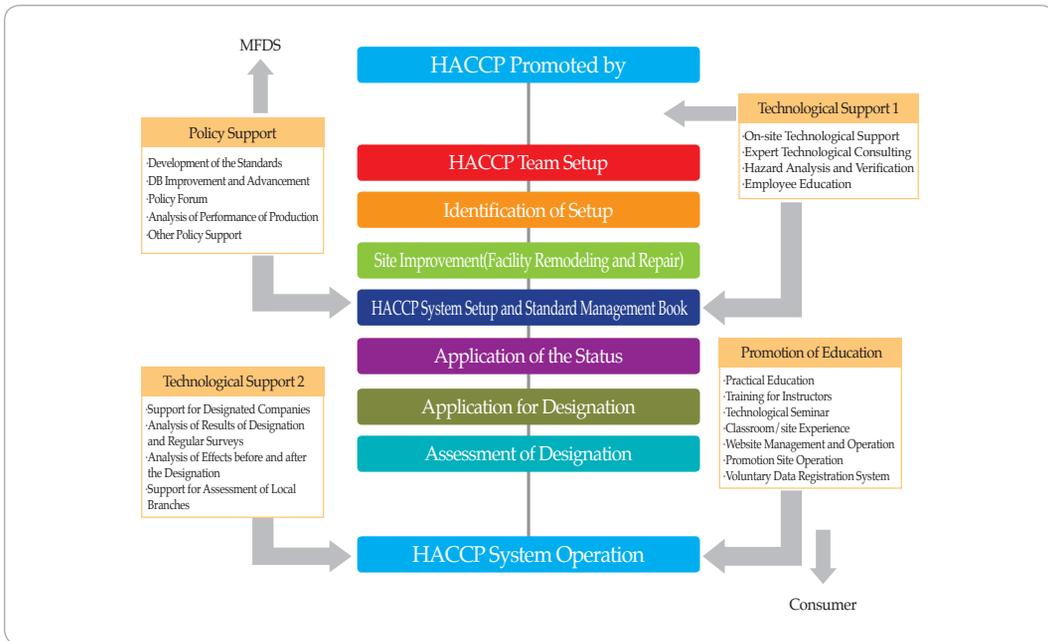
Korea Health Industry Development Institute in 2007, providing various support projects to companies applying for HACCP designation or HACCP-designated companies.



[ Figure 2-1-19 ] HACCP Support Team Website(www.hacphub.or.kr)

In 2012, the HACCP support business was expanded, enabling more SMEs to benefit and the Ministry arranged the responsible teams for companies to induce the continued management and maximization of support until the HACCP designation.

Also, medium and small-sized HACCP-required companies with poor expertise or technology are provided with the managerial knowhow such as efficient follow-up methods,



[ Figure 2-1-20 ] 2012 HACCP Support Program Diagram

establishing the proper HACCP application.

Also, with an aim to remove the burden for HACCP application on financially vulnerable required companies, the government provided a certain amount of money for the facility repair and remodeling(50% of the investment, within 10 million won) for free(2011, 1.5 billion, 150 sites → 2012, 3.5 billion, 350 sites).

[ Table 2-1-15 ] Results of Consumer's HACCP Awareness

Division	2008	2009	2010	2011	2012
Rate(%)	18.1	25.6	30	40.2	48.25

However, five out of ten people in the country do not understand the HACCP, necessitating continued and more promotion for the successful formation of the system.

### 6) The 2013 Plan for the HACCP Facilitation

In 2013, according to the current administration's policy tasks, the Ministry aims to designate 4,000 cases and carry out the mandatory application to six items(2012.12) and Korean cabbage Kimchi(2014.12) based on the continued financial and technological support for expanded HACCP application.

Also, the Ministry will arrange the local government staff and the HACCP Support Team members for the companies subject to mandatory application without the HACCP designation to ensure intensive control until the HACCP designation. It will proactively extend the application to large companies, OEM food manufacturers, restaurants and distributors. Also, for the purpose of the improved consumer awareness, there will be more TV ads, consumer visits and exclusive shops.



[ Figure 2-1-21 ] TV Ads for HACCP

# 02

## International Harmonization of Standards for Food and Scientific Risk Assessment

### 1. Food Standards Management

#### 1) Backgrounds

The rapidly changing food environment of supply and demand and development of food industry led to the discovery of new food raw materials and hazardous materials. Internationally, the standards for hazardous materials or the reduction measures are promoted. Some hazardous materials not subject to the country's standards were sometimes subject to those in other countries, resulting in returns. There is also a chance where there is no domestic standard while not appropriate based on the foreign standards. It is necessary to intensify the standards and to harmonize these materials. Accordingly, the standards for food in other countries are continuously examined. The Ministry arranged the international-quality standards for the materials requiring such ground based on the review of the necessity to arrange the standards for food and hazardous materials without domestic standards.

#### 2) Procedure of Standards Establishment and Revision and Major Contents

Based on the food monitoring results to arrange the scientific and reasonable standards, the Ministry reviewed the scientific grounds of exposure analysis risk assessment and collected

opinions from various areas to set up the standards. It announced administratively the revision of the standards, collected domestic opinions for 20 days and notified to the WTO within 69 days before the review by the Food Sanitation Review Committee consisting of six divisions. After the review, the standards subject to regulatory screening were subject to those of the Korea Food and Drug Administration and the Regulation Innovation Committee under the Office of the Prime Minister prior to the public announcement.

[ Table 2-2-1 ] Procedure to Establish and Revise the 「Food Standards」

Procedure	Description	Time Required
① Foundation	<ul style="list-style-type: none"> <li>• Found by the MFDS(personal and corporate opinions, results of monitoring), municipal and provincial opinions, opinions of other Ministries and consumer's groups. All the opinions to be summed up and discussed by the expert forum</li> </ul>	-
② Drafting	<ul style="list-style-type: none"> <li>• Drafting the standards based on the results of risk assessment considering monitoring and amount of intake</li> </ul>	-
③ Ministerial Discussion	<ul style="list-style-type: none"> <li>• Related ministries(the Ministry for Food, Agriculture, Forestry and Fisheries, etc.) to discuss in advance and the MFDS's preliminary check</li> </ul>	-
④ Assessment of the Subjects of Regulation and Impact of Corruption	<ul style="list-style-type: none"> <li>• Ask about the subject within a notice and assess impact of corruption</li> </ul>	-
⑤ Administrative Announcement, WTO Notified for Collection of Opinions	<ul style="list-style-type: none"> <li>• Domestic : the Administrative Procedure Act</li> <li>• WTO : SPS/TBT regulations</li> </ul>	<ul style="list-style-type: none"> <li>• Domestic : 20 days or longer</li> <li>• WTO : 60 days or longer</li> </ul>
⑥ Review by the Food Sanitation Review Committee	<ul style="list-style-type: none"> <li>• The submitted opinions to be reviewed by related Ministries. The established(revised) plan to be reviewed by the Food Sanitation Review Committee</li> <li>• General citizens taking part in the review committee according to the national observation system</li> </ul>	<ul style="list-style-type: none"> <li>• Generally, 10 days</li> </ul>
⑦ Independent Regulation Check	<ul style="list-style-type: none"> <li>• Independent review of the established(revised) plan : Necessity, clarity, costs, etc.</li> </ul>	<ul style="list-style-type: none"> <li>• Generally, 30 days</li> </ul>
⑧ Regulatory Check by the Regulation Innovation Committee	<ul style="list-style-type: none"> <li>• Regulatory check by the Regulation Innovation Committee under the Office of the Prime Minister according to 「the Framework Act on Administrative Regulations」</li> </ul>	<ul style="list-style-type: none"> <li>• 45~60 days from 「the Framework Act on Administrative Regulations」</li> </ul>
⑨ Notice	<ul style="list-style-type: none"> <li>• Notice appears in the MFDS website</li> <li>• Effective date and progress to be decided in consideration of the preparation period</li> </ul>	<ul style="list-style-type: none"> <li>• 150 days from the Administrative announcement</li> </ul>

The recent revision of food standards promotes the standards for hazardous materials and alleviates the quality standards of new hazardous materials, new food development and

environmentally noxious materials out of industrial development.

In 2012, the levels for noxious materials in heavy metal, fungal toxins, agricultural chemicals, microorganisms and new hazardous materials increased to those of the Codex Alimentarius Commission(Codex Alimentarius, CODEX), European Union(European Union, EU), USA and Japan. The unreasonable standards which do not reflect the reality were readjusted to arrange the foundation to develop various types of food.

[ Table 2-2-2 ] Establishment and Revision of 「Food Standards」

Division	Establishment and Revision of the Standards	Date
Notice	<ul style="list-style-type: none"> <li>• Addition and re-classification of some items including corn in the table of raw materials for food</li> <li>• Establishment and revision of the standards for residual amount of 112 agricultural chemicals such as Iminoctadine</li> <li>• Revision of the Animal Medicine Testing methods for three items such as moxidectin</li> <li>• Revision of colon bacillus group testing methods among meat or egg-processed foods</li> </ul>	Jan. 20, 2012
Notice	<ul style="list-style-type: none"> <li>• Establishment of the standards for residual amounts permitted for agricultural chemicals and animal medicine in food</li> <li>• Revision of residual amounts permitted for 17 agricultural chemicals in agricultural products such as diazinon</li> <li>• Deletion of the standards for HEXACONAZOLE in banana and coffee beans</li> <li>• Revision of residual amounts permitted for 17 agricultural chemicals in agricultural products such as flunixin</li> <li>• Revision of the classification for animal medicine such as antibiotics and growth hormones</li> <li>• Establishment and revision of animal medicine testing methods for nine stuffs including Narasin and Lincomycin</li> </ul>	Apr. 23, 2012
Notice	<ul style="list-style-type: none"> <li>• Specification of the methods to melt frozen raw materials</li> <li>• Establishment of the standards for ochratoxin A in dried fruits</li> <li>• Revision of the terms of food subject to the standards of fungal toxins</li> <li>• Establishment of the methods to apply the standards for contaminants in processed food</li> <li>• Revision of the tin standards in food</li> <li>• Reclassification of flax as a raw material for limited use</li> <li>• Establishment and revision of the methods of testing of heavy metal, irradiated food, impotence treatment materials and similars and benzopyrene</li> </ul>	May. 10, 2012
Notice	<ul style="list-style-type: none"> <li>• Revision of the irradiation terms and standards</li> <li>• Revision of food subject to standards for aflatoxin</li> <li>• Revision of sorbic acids standards in salted food or tar color standards in salted preserved food</li> <li>• Revision of the standards for vibrio parahaemolyticus in immediate intake food, convenience store food, marine products and cooked food from hospitality industry</li> <li>• Specification and clarification of the terms for hemp in raw materials</li> <li>• Revision of the testing methods such as glucide, dietary fibers, microorganism, fungal toxins and irradiated food</li> </ul>	Jul. 30, 2012

Division	Establishment and Revision of the Standards	Date
Notice	<ul style="list-style-type: none"> <li>• Establishment of the standards to decide 'No Detection' as to the methods of testing for agricultural chemicals and animal medicines among food</li> <li>• Revision of the testing methods for 102 agricultural chemicals including Iminoctadine</li> <li>• Establishment of the permitted amounts for 6 animal medicines including mebendazole</li> <li>• Establishment and revision of the testing methods for 28 agricultural chemicals such as various types of agricultural chemicals containing many different ingredients</li> <li>• Revision of the testing methods for 13 animal medicines including novobiocin</li> </ul>	Sep. 5, 2012
Notice	<ul style="list-style-type: none"> <li>• Establishment and revision of the testing methods for 15 agricultural chemicals including Metazosulfuron</li> <li>• Establishment and revision of the testing methods for six residual animal medicines such as mebendazole</li> <li>• Establishment and revision of the permitted residual amounts for 46 agricultural chemicals such as Saflufenacil</li> <li>• Establishment of the principles to select radioactive nuclide</li> <li>• Establishment of the principles to set up the standards for hazardous contaminants</li> <li>• Introduction of definition of terms related to the methods of sampling with the statistical techniques</li> <li>• Revision of the requirements for raw materials</li> <li>• Expanded use of food raw materials for extracts of fermented sap of lacquer trees</li> <li>• Establishment of the heavy metal standards for marine plants(sea weed), sweeteners and marine products(blue crab and small octopus)</li> <li>• Revision of the heavy metal standards in dried agricultural, forest and marine products</li> <li>• Revision of the effective digit for fungal toxins in food</li> <li>• Establishment of the standards for benzopyrene in black ginseng and concentrated liquids of black ginseng</li> <li>• Revision of definition for cold noodles and pastas</li> <li>• Revision of the microorganism standards and introduction of statistical concepts for baby food</li> <li>• Establishment of the standards for coliform bacillus in Korean rice cake(Ddeok)</li> <li>• Additional establishment of the general principles for collection of specimen along with the introduction statistical concepts for microorganism</li> <li>• Revision of the testing methods for flour powder, acid value and preservatives and Enterobacter sakazakii</li> <li>• Deletion of the poppy among the 'raw materials not applicable to food'</li> </ul>	Dec. 27, 2012
Administrative Announcement	<ul style="list-style-type: none"> <li>• Establishment and revision of the testing methods for 12 agricultural chemicals such as Metazosulfuron</li> <li>• Establishment and revision of the testing methods for six animal medicines such as mebendazole</li> <li>• Establishment and revision of the standards for permitted amounts of 43 agricultural chemicals such as Iminoctadine</li> </ul>	Aug. 8, 2012
Administrative Announcement	<ul style="list-style-type: none"> <li>• Expanded use of raw materials for extracts of fermented sap of lacquer trees</li> <li>• Revision of the definitions and terms of food types</li> <li>• Revision of the benzopyrene standards in fumigated and dried fish</li> <li>• Deletion of the poppy among the raw materials not applicable to food</li> <li>• Revision of the testing methods for flour powders, acid values, preservatives and deoxynivalenol</li> </ul>	Sep. 25, 2012
Administrative Announcement	<ul style="list-style-type: none"> <li>• Establishment and revision of the permitted amount for three agricultural chemicals such as Saflufenacil</li> </ul>	Sep. 28, 2012

Division	Establishment and Revision of the Standards	Date
Administrative Announcement	<ul style="list-style-type: none"> <li>• Expanded application of the standards for enterohemorrhagic coliform bacillus in food poisoning germs</li> <li>• Establishment of the standards for heavy metal in mushrooms</li> <li>• Establishment of the standards for aflatoxin M1 in baby food</li> <li>• Revision of the standards for permitted amount of agricultural chemicals such as sulfur dioxide in bean sprouts</li> <li>• Expanded application of benzopyrene standards in baby food</li> <li>• Establishment of the standards for histamine in marine products</li> <li>• Establishment of the standards for honey</li> <li>• Establishment of the standards for edible oysters</li> </ul>	Oct. 11, 2012
Administrative Announcement	<ul style="list-style-type: none"> <li>• Revision of the permitted amount for agricultural chemicals of fluopyram</li> <li>• Establishment of the permitted amount for agricultural chemicals such as Iprovalicarb in ginseng</li> </ul>	Nov. 29, 2012

### (1) Microorganism

Microorganisms will be qualitatively or quantitatively managed in consideration of controllability and risk grounded on the processing processes. As for relatively low-risk food poisoning bacteria (bacillus cereus, clostridium perfringens, Staphylococcus aureus), the right amount was set up for each food in 2007. In 2012, the Ministry introduced the statistical standards for microorganisms applied by the Codex Alimentarius Commission (Codex), Australia, New Zealand, European Union and USA to the area of baby and infant food, which will be gradually expanded. Also, considering the level of contamination and method of food intake, the standards for vibrio parahaemolyticus among food poisoning bacteria were revised reasonably. The Ministry also established the standards for coliform bacillus to strengthen sanitation for Korean cakes called Ddeok.

### (2) Residual Materials

As for agricultural chemicals, the use and registration will be decided under the 「Agricultural Chemicals Control Act」. According to the 「Food Sanitation Act」, they will be subject to risk assessment based on the residual quantities in crops, allowable daily intake (ADI), average national weight and food intake amount, followed by the standards to allow residual agricultural chemicals. In 2012, the residual quantities permitted for 273 agricultural chemicals such as diazinon were established and revised. Among others, six agricultural chemicals such as ametoctradin were subject to new standards in the quantities while six other types such as saflufenacil were subject to the establishment of import tolerance. As of end of 2012, there are the residual quantities permitted for 432 types. Continued

reassessment is in place, including the division of the standards for Korean cabbage into general Korean cabbage and eotgari cabbage.

As for animal medicines, the use and registration will be decided by the Animal and Plant Quarantine Agency according to 「the Pharmaceutical Affairs Act」 and the standards for the residual quantities permitted are established under the 「Food Sanitation Act」. In 2012, the residual quantities permitted for 23 animal medicines such as Flunixin were established and revised.

### (3) Contaminants

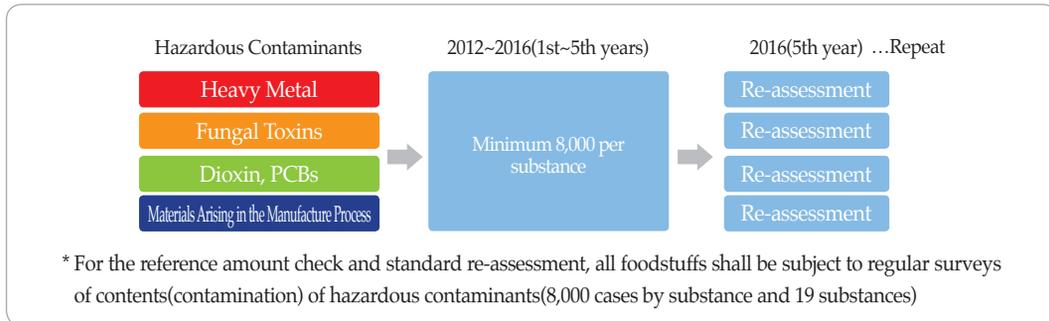
#### A. Management of Amount of Exposure of Hazardous Contaminants

According to the 「Overall Plan for Safety Control of Hazardous Contaminants」 (September 2011), the Ministry has assessed the levels and amounts of food contamination and intake of 19 hazardous contaminants<sup>1)</sup> such as lead and cadmium by monitoring the level of exposure of hazardous contaminants since 2012 every year to ensure the maintenance of safe levels of exposure to human bodies. This will be reassessed regularly, every five years to re-establish the standards.

For optimum management of the total exposure of hazardous contaminants, the standards shall be arranged and hazardous contaminants arising from manufacture shall be reduced. At the same time, there shall be safe intake guidelines for extreme or sensitive groups.

According to the 「Overall Plan for Safety Control of Hazardous Contaminants」, in the first year(2012), the level of contamination of hazardous materials in imported food or others distributed in the country was assessed. Heavy metal in marine products(11,192 cases), dioxin and PCBs in fish(960 cases), heavy metal, fungal toxins and acrylamide in food(743 cases) and fungal toxins in agricultural and processed foodstuffs(10,510 cases) were monitored for the stronger safety control, urging that total hazardous contaminants do not exceed the amount allowed to human body(PTWI, etc.). In the second year(2013), the Ministry will assess the amount of exposure of fungal toxins in agricultural and processed food as well as heavy metal in agricultural products and dioxin and PCBs in shells and crustaceans and maintain safe exposure levels.

1) Heavy metal(6 types including lead, cadmium, arsenic, total mercury, ethyl mercury and tin), fungal toxins(8 types, total aflatoxin, aflatoxin B1, aflatoxin M1, patulin, fumonisin, ochratoxin A, zearalenone, deoxynivalenol), 3-MCPD, benzopyrene, dioxin, PCBs and melanin



### B. Control of the Standards for Hazardous Contaminants

Since the establishment of the standards for heavy metal materials in ten most consumed agricultural products in 2006, the Ministry has set the standards for lead and cadmium in various agricultural products and fruits such as carrot, garlic, chives, onion, cucumber, chili, sesame and grape. In 2012, the standards for tin were revised for liquid canned products in addition to aluminum cans. As it is continuously required to set up the social standards for heavy metal materials in marine products including intestines, the Ministry established the standards for lead and cadmium in octopus and blue crab including intestines. Also, it established the standards for cadmium in laver and the standards for lead and cadmium in crustaceans. For children vulnerable to contaminants, the Ministry established the standards for lead in candies.

Since the opening of the international market developed through the WTO and FTAs, there have been frequent reports on contamination from fungal toxins in the agricultural products imported from warm Southeast Asia, leading to the standards for fungal toxins. In 2012, the standards for ochratoxin A in dried grapes were extended to those for dried fruits. The term for subjects under the application of the standards for fungal toxins was revised from 'simple processed foodstuffs' to 'stuffs processed simply'. Also, the standards for aflatoxin in Meju(block of fermented soybeans) which were categorized as individual standards under the Korean Food Standards Codex were deleted and integrated into the common standards.

As the 「Enforcement Regulations of the Ginseng Industry Act」 designating black ginseng as a type of ginseng was revised on January 26, 2012, for safety control of black ginseng, the standards for benzopyrene in black ginseng powders and concentrated extracts were established for stronger safety control.

### 3) Strengthened Capacity for Food Safety Control

The Ministry invites food-related employees and public officials responsible for food hygiene from 16 cities and provinces to promote the understanding of the standards for hazardous materials in food and to reinforce the efficiency of food safety control under the 'Food-related Standards Explanatory Session'. In 2012, 409 participants came from 13 local governments including Gyeongsangnam-do. Also, the 'Korean Food Standards Codex Understanding' education program was established for 74 public officials responsible for food hygiene from local governments to ensure overall understanding of types of food under the Korean Food Standards Codex and raw materials of food and strengthen the capacity to interpret related standards.



[ Figure 2-2-1 ] Municipal and Provincial 'Visit-based Explanatory Session'

### 4) Expected Effects and Future Plan

The constant intensification of the standards for hazardous materials and the international harmonization will increase the reliability of consumers. The reasonable standards sympathized by consumers will facilitate the market even more on the part of manufacturers. Finally, this will enable us to come closer to the promotion of food industries based on national health and trust.

As for the standards for microorganism in food, statistical concepts will be introduced based on the 「Comprehensive Food Microorganism Standards Management Plan」 and there will be scientific and reasonable revision to extend the standards for food poisoning bacteria and regular quantities.

The import tolerance will be facilitated to fortify the safety control of residuals in imported

food. As for residual materials, scientific reassessment of the standards for import tolerance already available will be continued.

Also, hazardous contaminants will be continuously managed following 「the Overall Safety Control Plan」 and the standards for lead and cadmium in agaric or shiitake much consumed by the nation will be established in 2013 to cover heavy metal control. The standards for benzopyrene will be strengthened for special delicatessen and modified milk powders for babies and infants as well as fungal toxins(aflatoxin M1) in such food will be strengthened. infants as well as fungal toxins(aflatoxin M1) in such food will be strengthened.

## 2. Food Additives Standards Control

Food additives are materials widely in use to maintain or improve the food quality in the process of manufacture, processing or conservation of food. While scientific research proves safety and the necessity of food additives is recognized, consumers are vaguely anxious due to the media reports in violation of food safety. Therefore, the Ministry provides the data wanted by consumers to reinforce proper awareness of food additives, increase the chances for ordinary citizens to participate in academic seminars and forums to cultivate the safety control for food additives.

Recently, the Ministry reorganizes the domestic food additive standards to meet international standards such as CODEX and continuously improve the system for food additive classification with an aim to improve the food additive safety control system.

### 1) Procedure for Establishment and Revision of the Standards for Food Additives

The criteria of food additives were established and revamped for the harmony of the international standards and consumer's safety. As for the procedure, a plan for the revised standards is arranged for an administrative notice(opinions collected for 20 days and notified to WTO within 60 days) and reviewed by the Food Hygiene Review Committee. The standard(plan) as a subject of regulation will be subject to the administrative procedures such as independent regulatory review and regulatory review of the Regulatory Innovation Committee of the Office of the Prime Minister before the final notification.

[ Table 2-2-3 ] Procedure to Establish and Revise the Standards

Procedure	Main Division	Assistive Division	Description	Period
① Arrangement of the Foundation	Additives Standards Division	Ministries Related to the Ministry of Food and Drug Safety	<ul style="list-style-type: none"> <li>The Ministry of Food and Drug Safety-found(individual and corporate opinions, results of monitoring), opinions of municipal and provincial offices and other ministries and consumer's groups to be collected and reviewed</li> </ul>	-
② Drafting	Additives Standards Division	Related Divisions and Bureaus within the Ministry	<ul style="list-style-type: none"> <li>Comparison with overseas standards such as CODEX and EU, monitoring and overall review of the safety data, resulting in the standards</li> </ul>	-
③ Discussion among Related Divisions	Additives Standards Division	Related Divisions and Bureaus within the Ministry	<ul style="list-style-type: none"> <li>Advance discussion among related divisions and advance ministerial review</li> </ul>	-
④ Regulatory Subjects and Corruption Impact Assessment	Additives Standards Division	Regulatory Innovation and Legal Affairs Officer	<ul style="list-style-type: none"> <li>Whether the notice plan pertains to the regulation. Preparation and assessment of the independent impact assessment</li> </ul>	-
⑤ Administrative Notices, WTO Notifications and Opinions	Additives Standards Division	International Cooperation Officer, Stakeholders	<ul style="list-style-type: none"> <li>Domestic : the Administrative Procedure Act(website announcement and public notices in writing)</li> <li>WTO : SPS/TBT regulations</li> </ul>	<ul style="list-style-type: none"> <li>Domestic : 20 days or longer</li> <li>WTO : 60 days or longer</li> </ul>
⑥ Food Sanitation Review	Additives Standards Division	-	<ul style="list-style-type: none"> <li>Review the opinions submitted with related divisions and the established or revised plan shall be reviewed by the Food Hygiene Review Committee</li> <li>Citizen observer system to allow citizens to the review committee meetings</li> </ul>	<ul style="list-style-type: none"> <li>Normally, 10 days</li> </ul>
⑦ Independent Regulatory Review	Additives Standards Division	Regulatory and Legal Affairs Division	<ul style="list-style-type: none"> <li>Review whether to regulate the established or revised(plan)</li> <li>- Necessity, clarity and costs for regulations</li> </ul>	<ul style="list-style-type: none"> <li>No separate rule. Normally, 30 days</li> </ul>
⑧ Regulatory Review of the Regulatory Reform Committee	Additives Standards Division	Office of the Prime Minister, Regulatory and Legal Affairs Division	<ul style="list-style-type: none"> <li>Request the Regulation Innovation Division of the Office of the Prime Minister according to the Framework Act on Administrative Regulations</li> <li>- Request for Review, Regulatory Impact Analysis, Independnet Test Request and Summary of Opinions from Administrative Institutions and Stakeholders</li> </ul>	<ul style="list-style-type: none"> <li>45~60 days(the Framework Act on Administrative Regulations)</li> </ul>
⑨ Notice	Additives Standards Division	Regulatory and Legal Affairs	<ul style="list-style-type: none"> <li>On the Ministry's website</li> <li>The date of enforcement and progress shall be decided in consideration of the preparatory period by issue</li> </ul>	<ul style="list-style-type: none"> <li>About 150~ 180 days until the notice</li> </ul>

## 2) Major Progress

In 2012, the Korean Food Additives Standards Codex was published and distributed in reflection of the improved and revised system for classification of food additives with the standards for components which reinforced the convenient use of the Korean Food Additives Standards Codex. Also, the overall standards were re-established in consideration of the status of designation in other countries and results of domestic surveys. Four items designated only in Korea, 「Mutastein」, 「L-sorbose」, 「crayfish colors」 and 「krill color」 were deleted to harmonize with international standards, promoting more efficient food additives management. Also, the 「polyvinyl alcohol」 was newly designated as an ingredient applied for the purpose of filming when purifying health functional food, removing the cover of such food or making capsules for the development of health functional food industry.

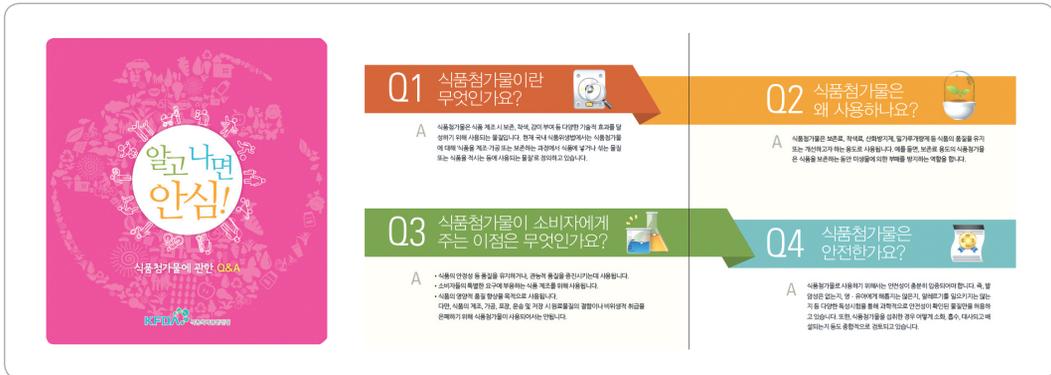
Additionally, the standards for use of eight subjects including sweeteners were additionally revised, following the original materials to the definition of 「5'-adenylic acid」 and 「5'-cytidylic acid」. The current standards for heavy metal such as 70 items including 「cinnamic acid」 were aimed to reinforce the control system of the individual noxious heavy metal standards. This resulted in the settlement of the standards for '2-acetyl-4-tetrahydroxy imidazole' which may occur in the process of manufacture of caramel pigment III among the standards for lead and 「caramel pigments」. The testing methods for 26 items including 「caffeine」 and 「saccharose-fatty acid ester」 were re-arranged while the definition of inactive dried yeasts was added to the definition of dried yeasts, clarifying the subjects of the standards for microorganisms. The standards use of preservatives such as six dried vegetable types including 「sorbic acids」 and 「sulfite」 were newly coordinated. As for six 「benzoic acid」 food additives, three 「sorbic acid」 food additives and one 「sodium diacetate」 food additive were re-classified to meet the Korean Food Standards Codex, improving and supplementing the standards.

[ Table 2-2-4 ] Descriptions about Establishment and Revision of the Food Additives Standards

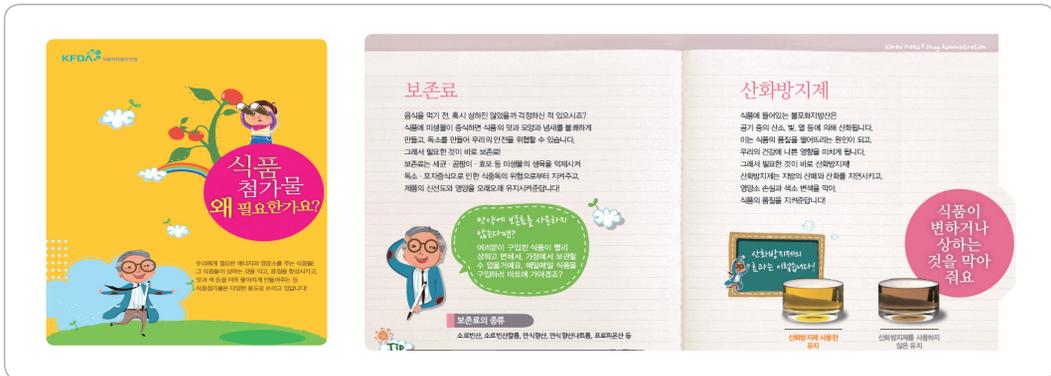
Details of the Established or Revised Contents	Necessary Term
<ul style="list-style-type: none"> <li>• Cancellation of the four items such as Mutastein, L-sorbose, crayfish colors and krill color</li> <li>• New designation of polyvinyl alcohol</li> <li>• Establishment of the standards for lead such as cinnamic acid</li> <li>• Addition of 'original materials' to the definition of two items such as 5'-adenylic acid and 5'-cytidylic acid</li> <li>• Establishment of the standards for 2-acetyl-4-tetrahydroxy imidazole among caramel pigments</li> <li>• Addition of the standards for use of eight food types such as Sodium saccharin sauces</li> <li>• Establishment of the standards for use of six types of sulfite</li> </ul>	Notice (Mar. 27, 2012)

Details of the Established or Revised Contents	Necessary Term
<ul style="list-style-type: none"> <li>• Establishment and revision of the standard ingredients for 12 items such as saccharose-fatty acid ester, etc.</li> <li>• Addition of inactive dried yeast to the definition of yeasts</li> <li>• Arrangement of the food types subject to three types of sorbic acids and the standards for use of spice-applied manufactured goods</li> <li>• Arrangement of the food types subject to Sodium Diacetate Item No. 1</li> </ul>	Notice (Jun. 1, 2012)

Also, the Ministry continued the training and promotion tailor-made to the demanding side of industry sources and general consumers to expand the sharing information for more appropriate awareness of food additives. An advisory committee consisting of experts was set up to establish the strategies to improve awareness of food additives in specific, followed by advisory meetings. Major issues promoted for the improvement of awareness include a leaflet titled 「Knowing and Feeling Safe! Q&A about Food Additives」 published for easier understanding on the part of consumers. This was distributed to 700 recipients such as provincial and municipal governments as well as consumer's groups and associations. The information was made available on the Food Additive Information Website, too. There was a promotional material on the necessity of food additives, titled 「Why Do We Need Food Additives?」 which was distributed to 575 recipients and published on the Food Additive Information Website. It hosted seminars and expert forums to fortify the awareness of food additives such as the 「Proper Dissemination of Data about Food Additives」 which was attended by 420 participants such as academia, industry sources, consumer's groups and ordinary citizens. A leaflet titled 「Information of Food Additives You'd Like to Know」 was published and distributed to 575 recipients including provincial and municipal governments, consumers' groups and associations to provide the required information for the designation of food additives and purposes of use. The information was made available on the Food Additive Information Website, too. The Ministry held international workshops to share information on the trends in the safety control of food additives in Asia. The ILSI-Korea joint international workshop invited about seventy participants from the government, academia and industry. Also, 90 food education instructors from consumer's organizations and elementary school teachers were trained in connection with food additives. Based on a result of the ministerial survey, awareness improved by 75.6%.



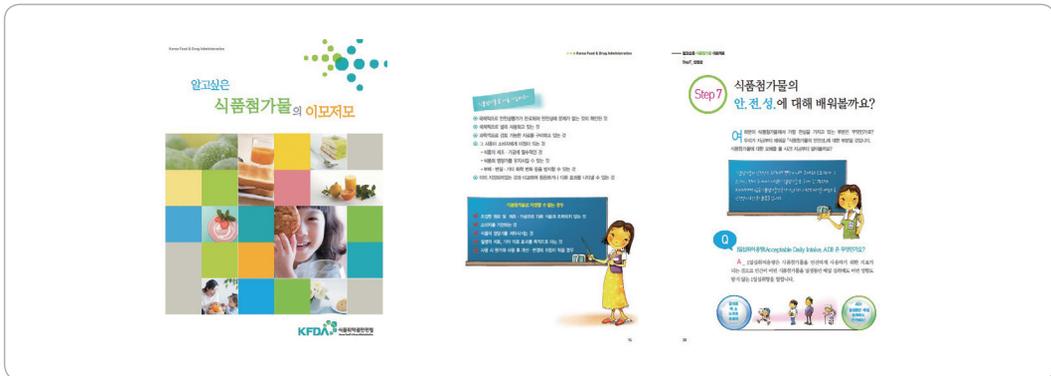
[ Figure 2-2-2 ] Publication and Distribution of the Leaflet Titled 「Knowing and Feeling Safe! Q&A about Food Additives」 (March 2012)



[ Figure 2-2-3 ] Publication and Distribution of a Promotion Leaflet Titled 「Why Do We Need Food Additives?」 (April 2012)



[ Figure 2-2-4 ] Academic Seminar and Expert Form on 「Proper Dissemination of Data about Food Additives」 (May 2012)



[ Figure 2-2-5 ] Publication of a Booklet Titled 「 Information of Food Additives You'd Like to Know 」 (July 2012)



[ Figure 2-2-6 ] International Workshop titled 「 The Trends in the Standards and Harmonization of Food Additives in Asia 」 (September 2012)

### 3) Future Plan

In 2013, food additives will be reclassified based on the purpose of use and comparative analyses along with the Codex Alimentarius Commission and the European Union, resulting in a revised plan for the classification system for food additives in line with advanced countries. Also, with a view to harmonize the international standards, 39 items including 「Polydextrose」 will be subject to component standards and three nutrient supplements. The standards of 18 items will be arranged along with the reclassification of food additives with improved criteria.

Besides, with aims to reinforce awareness of food additives and to provide the consumer-oriented training and information, the Ministry will hold experts' advisory conferences to

establish the communication strategies on food additives from various experts and arrange forums involving ordinary citizens. It will publish the fourth revised the 「A Comparative Handbook for Food Additives Designated」 and Q&A as to complaints on the standards of food additives and provide tailor-made training to consumers. The Ministry will conduct surveys on the rate of improvement in awareness and provide data on food additives.

### 3. Control of the Standards for Apparatuses, Containers and Packaging Materials

As consumers' interest in food safety increases, safety of food apparatuses, containers and packaging materials used in direct contact with food becomes more important. Also, various products are developed with the pursuit of convenience in cooking and technological development. There is a greater focus on safety control of noxious materials which may be transferred to food when these apparatuses, containers and packaging materials are applied. At the same time, other countries such as the European Union member states continuously establish and revise the safety standards for noxious materials originating from apparatuses, containers and packaging materials. In the future, the standards will be continuously established with safety inspection for noxious materials newly found as well as safety issues in other countries. Daily necessary Q&A as to appropriate use of apparatuses, containers and packaging materials will be arranged and continuously promoted so that consumers' anxiety arising from inaccurate data delivery from the media can be reduced.

#### 1) Major Progress

In 2012, the Ministry separated the 「Standards for Apparatuses, Containers and Packaging Materials」 under the Korean Food Standards Codex for the publication of the Korean Standards for Food Apparatuses, Containers and Packaging Materials for the efficient safety control and convenient use of such items. Accordingly, 'the Common Standards' including 'General Provision', common manufacture standards, application of the standards and decision of conformity were arranged. Each testing item under the standards for materials such as synthetic resin(38 types) and cellophane was reclassified as 'the testing method for apparatuses, containers and packaging materials'. At the same time, 'general principles' as to testing methods were arranged for the comprehensively redeemed classification system as to

the standards for apparatuses, containers and packaging materials.

At the same time, migrant specifications for hazardous materials arising from raw materials such as primary arylamine applied as the four types of synthetic resin including polyamide are manufactured to reinforce the control of food containers and packages. Also, migrant specifications for antimony used as enamel and zinc for silicon resin-coated metal materials were added. Additionally, leaching solvents(50% ethanol) were added for alcoholic beverages containing alcohol more than 20% in migrant specifications for devices, containers and packages for alcoholic beverages. The standards for lead, cadmium, mercury and hexavalent chrome among cellophane, paper and starch-based materials were separated as the common manufacture standards.

[ Table 2-2-5 ] Establishment and Revision of the Standards for Devices, Containers and Packages

Details of the Established or Revised Contents	Date
<ul style="list-style-type: none"> <li>• Improved standards and classification for devices, containers and packages</li> <li>• Strengthened safety standards for synthetic resin</li> <li>• Re-arrangement of residual quantities permitted for lead and cadmium in cellophane, paper, or starch-based devices, containers and packages</li> <li>• Leaching solvents for devices, containers and packages containing alcoholic beverages(alcohol by 50%) added</li> </ul>	Notice (Nov. 26, 2012)

Additionally, with an aim to provide safety information based on scientific grounds on containers and packaging materials, issues much questioned by consumers were developed into Q&A such as 「Let's Learn about Melanin Resin Containers!」, 「Let's Share about Multi-layered Food Packaging Materials!」, 「Stop and Learn about Canned Food!」, 「It's about Bisphenol A!」, 「Let's Learn about Microwave Containers and Packaging Materials!」.

## 2) Future Plan

In 2013, the Ministry plans to arrange the safety standards for apparatuses, containers and packaging materials as high as those of advanced countries by establishing the safety control standards for lubricants that may contact food and modernizing testing methods such as elution for polyethylene and metal. Also, there will be consumer-oriented, daily necessary information related to apparatuses, containers and packaging materials such as Q&A pertaining to aluminum containers, PET bottles as well as types and methods of manufacture and types and purposes of use of synthetic resin.

번호	년도	제목	작성일자	등록일	조회수
30	2013	식용용 기구 및 용기포장 안착 질의 답변집	관리자	2013/10/30	111
29	2013	기구 및 용기포장 용출시험에 대한 식용용항밀 횡...	관리자	2013/10/30	90
28	2013	항생수지재에 대하여 알려드립니다	관리자	2013/06/24	298
27	2013	페트(PET)봉에 대하여 알려드립니다	관리자	2013/04/16	489
26	2013	일부리놀 식기에 대하여 알려드립니다	관리자	2013/02/27	534
25	2012	전자레인지용 용기포장에 대하여 알려드립니다	최희주	2012/11/13	807
24	2012	비스페놀 A에 대하여 알려드립니다	최희주	2012/09/21	670

[ Figure 2-2-7 ] Q&A for Safety of Devices, Containers and Packages(February~November 2012)

#### 4. Control of Standards for Disinfectants of Apparatuses

The recent climate change and even the refined food services increased cases of food poisoning. The accidents become larger in scale, making food hygiene more important and increasing the demand for disinfectants for apparatuses. As a safety control method, the Ministry continuously revamps the standards for items under the current temporary criteria pertaining to disinfectants for apparatuses to harmonize with the international standards.

Also, the Ministry has provided Q&A about the safe use of disinfectants at restaurants and hospitality facilities.

##### 1) Major Performance

In 2012, the standards pertaining to 「Formulations of Chlorine Dioxide」 were newly established to standardize the processes of items already recognized as the temporary standards for apparatuses. For the harmonization with international standards, two active components were deleted and ten types of components were amended in comparison with active components of disinfectants available in other countries. Also, the ten items of disinfectants for currently noticed apparatuses such as 「ethanol」 were renamed as formulations.

[ Table 2-2-6 ] Establishment and Revision of the Standards of Disinfectants for Apparatuses, etc.

Details of the Established or Revised Contents	Date
<ul style="list-style-type: none"> <li>• One item newly designated as a disinfectant, 「chlorine dioxide formulation」 for those recognized under the category of temporary standards</li> <li>• Two ingredients applied to manufacture disinfectants of devices were deleted and one ingredient's name changed</li> <li>• Revision of the ten items such as disinfectants of devices, etc., including 「ethanol」</li> </ul>	<p>Notice (Mar. 27, 2012)</p>

## 2) Future Plan

In 2013, the Ministry will newly designate the 「Lactic Acid Formulations」 already recognized as temporary standards for disinfectants applied to apparatuses to diversify the disinfectant products and harmonize with international standards, which will standardize the processes. Also, it will re-arrange the definition of 「hypochlorous acid water」 and standard composition to develop new technologies to manufacture hypochlorous acid water and harmonize with the international standards. There will be daily necessary information such as the proper use of disinfectants for apparatuses.

# 03

## Establishment and Execution of the Pan-governmental Measures to Eliminate Unsanitary Food

### 1. Backgrounds

The new administration changed the national paradigm ‘from state to people’ to materialize a government that prioritizes the national safety. With this aim and to focus on individual happiness of the nation, the new government is establishing and executing policies. The ‘elimination of unsanitary food’ is the strong will to safely control food as a basic necessity for the nation and contains the paradigm shift. At the same time, the Ministry of Food and Drug Safety was established to play the important roles as a ‘control tower for food safety’.

We consume food on a daily basis and the safety is the most basic ‘life security’ to ensure happiness of all people. Therefore, the Ministry of Food and Drug Safety established and announced the comprehensive plan to Eradicate unsanitary food, involving 29 ministries to ensure healthy and happy life of the nation on May 8. The pan-governmental Comprehensive Plan to Eradicate Unsanitary Food contains a close and thorough web of control to cover noxious elements at all stages including production, manufacture, processing, import, distribution and consumption of unsanitary food that has not been removed despite passionate efforts.

## 2. Concept and Social Awareness of Unsanitary Food

### 1) What Is Unsanitary Food?

While there is no legal definition of unsanitary food, unsanitary food means all foodstuffs in the violation of laws<sup>1)</sup> that may occur in all processes of production, manufacture, distribution and food sale. The government defines such noxious food and others in the violation of laws as 'unsanitary food' for easy understanding of the nation. The US Food and Drug Administration(FDA) classifies unsanitary food into 14 types and the Ministry of Food and Drug Safety categorizes into 17 types to make the definition of unsanitary food clear.

[ Table 2-3-1 ] Types of Unsanitary Food

Division	Korea(Divided into 17 kinds)		USA FDA(Divided into 14 kinds. Source : The Federal Food, Drug and Cosmetics Act. Sec. 402)
①	Food likely to go bad or damaged	⇒	① Dirty, bad-smell, or rotten food
②	Food likely to contain noxious or hazardous materials(unapproved agricultural additives, unintentional hazardous substances, fungal toxin, etc.)	⇒	② Food containing noxious or hazardous materials ③ Food containing artificial noxious or hazardous substances ④ Food containing unapproved animal medicine ⑤ Food containing unsafe pigments
③	Food containing materials not to be used(sexual virility improvement, diet, arthritis treatment or other medicinal ingredients and raw materials for animal feeds)	⇒	⑥ Food containing unapproved or prohibited additives ⑦ Food containing hazardous ingredients and that may cause diseases or injuries despite the method of intake taken according to the labeled data
④	Food made of illegally slaughtered or sick animals or their raw materials	⇒	⑧ Food made of illegally slaughtered or sick animals or their raw materials
⑤	Food, containers or packaging materials containing noxious or hazardous materials	⇒	⑨ Food containers containing noxious or hazardous materials
⑥	Food not-conforming with hazardous materials or standards(agricultural chemicals or animal medicine in excess of standards, foods mixed with foreign materials such as insects and metal)	⇒	⑩ Food with agricultural chemicals exceeding the standards ⑪ Food radiated extra-approved or in excess of standards
⑦	Food manufactured, cooked or reused unhygienically(cold noodles with coliform bacillus, food reusing residual side dishes)	⇒	⑫ Food likely to be unsanitary with unsanitary manufacture, packaging or handling
⑧	Food imported without reporting	⇒	⑬ Food whose import has been rejected or with weight, size, company name, reported data falsely represented

1) 「Food hygiene act」, 「Health supplement act」, 「Child food safety management special act」, 「Live stock hygiene act」, 「Marking source of agricultural and marine product act」 etc

Division	Korea(Divided into 17 kinds)		USA FDA(Divided into 14 kinds. Source : The Federal Food, Drug and Cosmetics Act. Sec. 402)
⑨	Food falsely representing ingredients(contents), quality, prices, etc.(forged sesame oil, red pepper powders, and honey)	⇒	⑭ Food overvalued with less essential ingredients, alternative ingredients, and quality deception.
⑩	Food falsely displaying ingredients, nutrients and data to be reported	⇒	⑬ Food whose import has been rejected or with weight, size, company name, reported data falsely represented
⑪	Food likely to be contaminated with pathogenic microorganism(food poisoning germs and viruses)	⇒	⑫ Food likely to be unsanitary with unsanitary manufacture, packaging or handling
⑫	Food with inappropriate ingredients or standards (food non-conforming in ingredients and sizes, health functional food, and livestock products.)	⇒	⑭ Food overvalued with less essential ingredients, alternative ingredients, and quality deception.
⑬	Unapproved or unreported food, etc.	⇒	⑫ Food likely to be unsanitary with unsanitary manufacture, packaging or handling
⑭	Wrong place of origin (Chinese food represented as Korean)	⇒	⑬ Food whose import has been rejected or with weight, size, company name, reported data falsely represented
⑮	Food with forged or false circulation periods		
⑯	Food advertised, inducing misunderstanding or confusion with disease treatment or medicine	⇒	⑬ Food whose import has been rejected or with weight, size, company name, reported data falsely represented
⑰	Cheap, low-quality food that induces children and damages emotional growth(confectionary shaped as cigarettes or playing cards)	⇒	⑭ Food overvalued with less essential ingredients, alternative ingredients, and quality deception.

## 2) Social Awareness of Unsanitary Food

Unsanitary food has always been a social problem. If unsanitary food occurred with the lack of awareness and technology on the part of small shops it occurs with new noxious materials arising from the environmental contamination, the development of detection methods, equipments, manufacture and processing technologies. In addition, the improved national income and more interest in food safety and soundness increased the safety discussions not related to the noxious food.

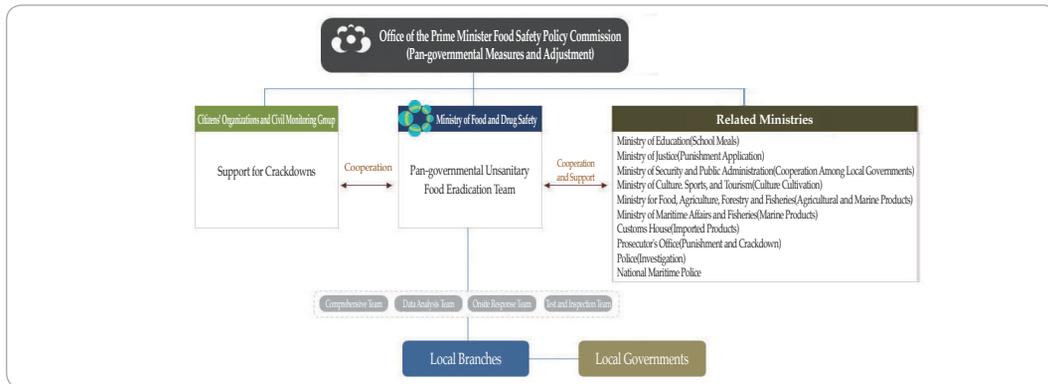
The reports on unsanitary have changed over time. In the 1960s~1980s, there were more cases reported that pertained to lack of knowledge or awareness of manufacturers rather than deliberate acts. These include the include 'Rongalite', a bleaching agent in confectionary goods(1966), soy sauce with chemicals(1985), and bean sprouts containing prohibited agricultural chemicals(1985). Mostly, the deficiency of hygiene awareness caused the unsanitary

manufacture environment, facility and method as well as inappropriate food control. Since the 1980s, inaccurate expressions led to exaggerated reports on unsanitary food, causing serious social problems and economic losses. They include 'beef tallow ramen(1989)', 'formalin cans(1998)', 'wastes-filled dumplings(2004)' and 'hazardous contents in octopus heads(2010)'. As for 'beef tallow ramen', there were major media reports that industrial beef tallow was applied when frying ramen, which steeply decreased the then-high(60%) market share. At that time, the nation blamed manufacturers and campaigned against purchase, claiming that they be removed from the market. 1,000 employees of the company left and products amounting to more than 10 billion won were recalled and destroyed. However, the manufacturer was found not guilty by the Supreme Court in 1997 after eight years of the accident. The case of 'unsanitary dumpling filling(2004)' resulted in problems as residual foodstuffs and filling materials were misrepresented as wastes, which damaged the entire dumpling manufacture industry at large. Finally, one of the manufacturers killed himself and the industry was almost destroyed. As this case shows, unsanitary food results in the national anger as it directly threatens life and health of the unspecified mass. However, there are cases where unsanitary food problems become more serious due to consumer's psychological aspects rather the seriousness of scientific risks. These cases include 'cadmium in octopus(2010)' and 'benzopyrene in ramen(2012)'. While cadmium and benzopyrene are categorized as noxious materials, judging from overall aspects of total food intake and contents that affect human bodies, there may be no problems. Still, negative awareness has been established as the issue has become a social interest.

Over the last ten years, international food-related issues such as safety of irradiated food and genetically modified organism, bovine spongiform encephalopathy in other countries and acrylamide or endocrine disruptors in fried food have become domestic issues, too. As the Belgian 'dioxin problem with livestock products' in 1999 tells, there is no single-country problem but the entire world will suffer from the same issue.

### **3. Establishment and Execution of the Pan-governmental Measures to Eliminate Unsanitary Food**

#### **1) Organization and Operation of the Pan-governmental Unsanitary Food Elimination Promotion Team**



[ Figure 2-3-1 ] Unsanitary Food Elimination Promotion Team

The Ministry of Food and Drug Safety sets up 「the Unsanitary Food Elimination Promotion Task Force Team」 on February 28 and launched 「the Pan-governmental Unsanitary Food Elimination Promotion Team」 inviting 29 governmental offices such as the Office for Government Coordination, the Ministry of Education, Ministry of Justice, Ministry of Food, Agriculture, Forestry and Fisheries, the Ministry of Maritime Affairs and Fisheries, Prosecutors and Police, Maritime Police and Customs Office.

The Promotion Team will execute 46 strategic tasks including the national policies, pan-governmentally shared issues, projects supported by the Ministry of Food and Drug Safety and tasks involving ministerial participants with an aim to ensure a safe food environment by eliminating unsanitary food based on the 「Comprehensive Plan to Eradicate Unsanitary Food」. The focus is laid on preventive problem-solving and the systemic management with the strengthened inter-ministerial connection and analysis of fundamental causes rather than the special control, monitoring and crackdowns conducted by respective Ministries.

## 2) Elimination of Unsanitary Food and Safe Food Culture

Unsanitary food does not disappear as long as there are people who make and sell it. The government plans to improve the system in a way to eliminate any chance of manufacture by systemically enforcing the 「Comprehensive Plan to Eradicate Unsanitary Food」 and establish a close safety network to prevent any sale in the country. However, the governmental efforts shall have the limitation to eliminate the wide-spread generation of unsanitary food. The fundamentals to eliminate unsanitary food is to cultivate cultures 'not to make

or buy unsanitary food' by changing consumer behaviors and by reinforcing the sense of responsibility on the part of manufacturers.

The Ministry of Food and Drug Safety will promote national campaigns such as the Consumer Forum and the Open Forum and Don't Buy Unsanitary Food to spread the safe eating culture. There will be an education in collaboration with consumer's groups to ensure that the level of interest and preference of each subject can be met in terms of the methods of identification, reporting and dietary life at schools. Seven ministries including the Ministry of Security and Public Administration, the Ministry of Gender Equality and Family, and the Ministry of Culture and Sports will divide the roles to promote safe culture campaigns against the Four Social Problems designated by the government. Also the national promotion and education will be expanded with the facilitation of communication with consumers, businesses and the media through SNS.

### 3) Pan-governmentally Planned Monitoring

The pan-governmentally planned monitoring aims to remove the fundamental causes of unsanitary food in all food stages beyond the joint daily food safety control. To achieve this aim, the interministerial cooperation will be reinforced to remove any loophole by area and industry under structurally poor monitoring system, followed by institutional improvement based on the surveys of all stages.

The stages include the following: First, the subject issues will be decided based on the advice of the advisory group consisting of ten food experts and the sharing of data pertaining to unsanitary food among the ministries. Second, joint squads will be flexibly set up and managed based on the importance of issues of the prearranged inspection.

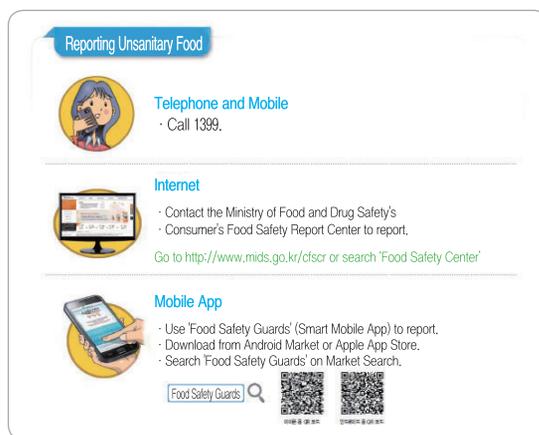
Third, like the Citizen Monitoring Team, the Joint Squad including the Ministry of Food and Drug Safety and civilians will work together for crackdowns. Fourth, the results of the joint crackdowns will be shared and the institutional systems will be bettered.

The Ministry of Food and Drug Safety expects that this systemic pan-governmentally planned monitoring can clarify each Ministerial duties by creating the synergistic effects.

[ Table 2-3-2 ] Method of Joint Monitoring and Crackdown by Case

Division	Importance	Participation	Comment
1st Grade	Nationwide monitoring in consideration of the status of dissemination and degree of hazards	All Ministries	
2nd Grade	Needs for cooperation in specific data areas	Related Ministries in cooperation	Data sharing
3rd Grade	Simple affairs such as complaints and reports	Relevant Ministries(Single)	Data sharing

#### 4) Unified Unsanitary Food Reporting System



[ Figure 2-3-2 ] Unsanitary Food Reporting

The Ministry of Food and Drug Safety combined and integrated the report-receiving centers(1399) managed separately by 17 respective local governments in July. The integrated system is the 'Integrated Unsanitary Food Report Center'. This has enabled the government to resolve civil complaints and to take quick measures to all consumer reports.

If there is any doubt of unsanitary food, do not hesitate to report by using a telephone, the internet or a mobile and take part in the nationwide efforts to ensure a safe country without unsanitary food.



2013 MFDS Report Ministry of Food and Drug Safety



# 03

## Food Nutrition and Dietary

01. Secure Public Health by Nutrition Management Including Foods for Children
02. Promote Public Health by Foodborne Disease Prevention
03. Secure Safety and Functionality of Health Functional Food and Novel Food



## 01

**Secure Public  
Health by Nutrition  
Management  
Including Foods for  
Children****1. Enhancement of Children's Food Safety Management****1) Conditions and Prospects for Enhancement of Safety Management on Children's Food**

With the recent westernization of lifestyle, the rate of chronic diseases such as obesity and hypertension is increasing due to an imbalance of nutrient intake and reduced physical activity. Especially, as obesity rates of children (elementary and middle school students) continue to increase every year from 11.2% in 2008 to 14.7% in 2012, 40% of childhood obesity and 70% of adolescent obesity are likely to turn into adult obesity. Thus, children's health needs to be protected from obesity.

Based on the advancement in medical technology along with abundant food, national life expectancy reached 60 years in 1970 and it exceeded 80 years in 2010. A hope to live longer as well as live healthy changed the paradigm on food safety to the supply of superbly nutritious food rather than merely securing safe food supply; it now focuses more on securing nutrition-related safety.

Under the given circumstances, the Ministry recognized the necessity for comprehensive and systematic measures upon the safety of children's food at the level of government, which led to the announcement of 'Comprehensive Safety Measure for Children's Food' in 2007. Based on

this measure, 「the Special Act on Safety Control of Children's Dietary Life」 was established in 2008 and enacted in March of 2009.

The Ministry of Food and Drug Safety developed the 「Second Comprehensive Plan for Safe Management of Children's Dietary Life」 (2013~2015) and notified local governments to provide execution plans in order to secure food safety, to procure a safe environment for children's food where children are allowed to choose their own safe and nutritious food, to promote voluntary participation amongst business organizations along with regulations upon them and to improve safety on children's dietary life as well as nutrition level in September, 2012, in accordance with 「Special Act on Safety Control of Children's Dietary Life」.

Key issues are as follows ▲ formation of safe sales environment for children's preferred foods, ▲ construction of safe supply system to guarantee children's safe dietary life, ▲ warranty for children's right food selection, ▲ active participation and communication for safe management of children's dietary life.

The Second Comprehensive Plan was developed to ensure further practical, as well as meticulous safe management, of children's dietary life while maintaining continuity of the policy based on the previous First Comprehensive Plan (2009~2012).

## 2) Designation and Management of Green Food Zone for Children

The Ministry of Food and Drug Safety designates and manages the 'Green Food Zone', a zone within 200 meters from a school in order to teach children a right eating habits as well as to ensure a balanced dietary life by improving the environment of food sales near the school zone where parents' supervision can hardly be effective.

The Green Food Zone is designed to protect children from food that is unsanitary or harmful to health where specially assigned personnel are deployed to each zone to ensure safe and sanitary food supply.

Amongst stores preparing and selling children's preferred foods within the Green Food Zone, the 'Exemplary Stores for Children's Preferred Foods' is to be designated for those stores which fulfill the sanitary facility standard stipulated by the 「Special Act on Safety Control of Children's Dietary Life」 and do not carry high-calorie low-nutrient foods in order to offer nutritious and balanced food; and such selected stores are allowed to utilize a special logo prepared by the Ministry.

To help more retail stores within the Green Food Zone to be named 'Exemplary Stores', 「Special Act on Safety Control of Children's Dietary Life」 clearly states that the retail stores which intend to be designated as 'Exemplary Stores' are entitled to be subsidized from the National Treasury or a Food Promotion Fund to pay for a part of the expenses for renovation.

As of December 2012, there are 9,828 Green Food Zones and 1,904 Exemplary Stores for Children's preferred Foods.

### 3) Improvement on Distribution Environment for Children's Preferred Foods

Due to the change in a dietary life where snacks with high-sugar, high-fat and high-sodium such as cookie, beverage, bread and Ramen are more favored than fresh fruit and milk, it is evident that child obesity continues to increase. Especially, children's consumption of carbonated drinks and sweet processed food has increased by 1.8 times comparing to the consumption in 1998. WHO/FAO reported that a risk for chronic illnesses such as obesity is to greatly increase unless sugar intake is sustained below 10% of the whole calorie.

To encourage children to choose the right food, the Ministry of Food and Drug Safety defined the children's preferred foods with higher calorie and low nutrition than specified level which is prone to cause obesity or nutrition imbalance('High-calorie low-nutrient foods' hereafter) and subsequently banned its sale at school or Exemplary Stores. Nutritional ingredients standard for high-calorie low-nutrient foods was defined after gathering inputs from experts at various levels and interested parties and high-calorie low-nutrient foods can be identified by using the information of food type and labeling information of the food which indicates nutritional ingredients per one serving amount.

Moreover, in order to ensure consumers and business owners to easily notice high-calorie low-nutrient foods, the Ministry of Food and Drug Safety posted high-calorie/low-nutrition distinction program for single-item and simultaneous multi-items at the official website, (<http://mfds.go.kr/jsp/page/decintro.jsp>). In 2012, application, 'New High-calorie/low-nutrition Food Alert-e' was distributed to help easy access through cell phones.

Thanks to the efforts made by the children's preferred foods manufacturers to lower the ratio of high-calorie low-nutrient foods including the improvement on ingredient mix proportion and the modification of manufacturing process the ratio of high-calorie low-nutrient foods in children's preferred foods keeps decreasing.

[ Table 3-1-1 ] Summary of Children's Preferred Foods

(December, 2012)

Total	High-calorie Low-nutrient Foods	High-calorie Low-nutrient Foods
7,378(100%)	1,565(21%)	5,813(79%)

[ Table 3-1-2 ] High-calorie Low-nutrient Foods by Type

(December, 2012)

Classification	Total	Cookie	Bread	Chocolate	Milk Product/ Ice Cream	Fish Meat Sausage	Beverage	Noodle	Instant Intake	Precooked Food
High/Low	1,565	558	35	128	71	0	363	107	22	281
None-High/ Low	5,813	1,797	1,473	524	833	11	303	37	324	511
Total	7,378	2,355	1,508	652	904	11	666	144	346	792

At the same time, in order to ensure consumers' right to know and business owners' convenience, the Ministry posts the list of high-calorie low-nutrient foods at its official website every month.

Meanwhile, the quality certification system has been implemented to enhance parents and children's right to choose children's preferred processed food as well as to encourage manufacturers to voluntarily produce, process, distribute and sell well-balanced children's preferred foods. When the product is deemed to fulfill the standards for safety, nutrition and the use of additives based on the review, labelling of quality certification can be placed on the containers and packaging of the product. In 2012, 70 products including fruit and vegetable juice and frozen desserts were certified for their quality and are currently being distributed in the market. Also, in 2013, the Ministry is determined to invest further effort to expand the number of products with quality certification for safety and nutrition by revising the quality certification standard for children's preferred foods.

#### 4) Survey for Children's Dietary Life Safety Index and Assessment on the Safety and Nutrient Level of Dietary Life

Children's dietary life safety index is a set of objective value to compare and evaluate the level of efforts made by local governments to manage dietary life safety in accordance with Article 23 of the 「Special Act on Safety Control of Children's Dietary Life」. It derives 3 policy indexes on the level of safety, nutrition and awareness/implementation of children's

dietary life safety based on 9 strategic indexes which are ▲ the level of support for dietary life safety management, ▲ the level of safety management on children's preferred foods, ▲ the level of safety management on school meal system, ▲ the level of management on hunger and obesity, ▲ the level of nutrient management on children's preferred foods, ▲ the level of nutrient management on school meal system, ▲ the level of awareness on dietary life safety and nutrient system, ▲ the level of awareness and implementation on dietary life safety management and ▲ the level of awareness and implementation on dietary life nutrient management. The Ministry investigates children's dietary life index from all over the nation in every year.

### 5) Restriction on Advertisement of Children's Preferred Foods

The Special Act on Safety Control of Children's Dietary Life clearly states, 'Those who manufacture, process, import, distribute and sell children's preferred foods shall NOT run an advertisement containing contents where toys or other objects which are not food but prone to encourages children to purchase via broadcasting, radio or internet media'. And it also stipulates, 'When those who manufacture, process, import, distribute and sell children's preferred foods advertise high-calorie low-nutrient foods through TV broadcasting, the said advertisement may be banned or partially restricted'. Therefore, monitoring on advertisement via TV(including cables) and internet is being conducted every month for the purpose of the follow-up management on broadcasting advertisement. In 2013, the Ministry continues to make efforts to focus on children obesity prevention and to nurture environment for healthy dietary life. Most of all, the Ministry plans to pursue to revise the 「Special Act on Safety Control of Children's Dietary Life」 in order to impose a restriction on high-caffeine beverage advertisements.

### 6) Establishment and Operation of Center for Child-care Foodservice Management

In addition to low birth rate and increasing double-income families in recent years, parents' expectation toward food safety and nutrient management at children's meal service center gradually increases to the next level. Hence, in order to support the systematic and meticulous sanitary and nutrient management at nurseries and kindergartens, the Ministry has established and operates 'centers for child-care food service management'. A total of 22 of these centers for

child-care food service management in the nation were either established as a corporate body by local governments or managed by relevant agencies or organization under the contracts on consignment.

To establish ‘centers for child-care food service management’, the Ministry of Food and Drug Safety has conducted a series of projects and studies including the ‘Development of Establishment Models and Feasibility Study for Centers for Child-care Food Service Management(2008)’, the ‘Development of Manual and Contents to Operate Centers for Child-care Food Service Management(2009)’ and ‘Feasibility Study on On-site Application of Operation Manual and Guideline for Centers for Child-care Food Service Management’. At the same time, the Ministry implemented test-establishment and on-site application to the food service management center affiliated to local colleges under selected local governments(Guro-gu of Seoul City, Jeonju-si and Jeju-si).

Specialized personnel on meal service including 6 to 10 dieticians are assigned at ‘the centers for child-care food service management’ to support the management of the food service centers for children at nurseries and kindergartens within the jurisdiction. Key roles of the centers are to sanitarily manage safe food supplies at nurseries and kindergartens, to assure the meals to be scientifically designed to comply with nutritional requirements by age and to teach children to develop healthy dietary habits through door-to-door guidance.

The Ministry plans to further expand ‘centers for child-care foodservice management’ nationwide to establish and operate; and it also envisions supporting meal-service management of the small-scale facilities for less than 50 people and local child-care centers which are in need of practical safety management.

And it is more meaningful as ‘the centers for child-care foodservice management care’ for life-long nutrient safety rather than merely focusing on sanitation for the sake of short-term safety management. Thus the level of dietary life management for children should be eventually improved through various activities provided by the center.

### 7) Education and Promotion for Safety Management of Children’s Dietary Life

In order for children to choose the right foods by themselves, children not only should be provided the environment for healthy dietary life but also must be able to develop their own skill to choose the right foods. Therefore, the Ministry has implemented on education and

promotion for food safety and nutrition.

Starting with the pilot project of nutrition education for elementary schools in 2008, the Ministry of Food and Drug Safety has been consistently implementing on education programs for food safety and nutrition at elementary schools. By utilizing the teaching materials of 'Nutrition/Dietary Life'(for low / mid /high graders) for each level developed by the research group for safety management of children's food in 2010, the Ministry conducted the education programs for food safety and nutrition at 115 elementary schools in 2011 as well as 175 elementary schools in 2012. After the education programs were performed, children in all grades scored higher points in dietary life behavior and nutrition knowledge than they did before the education. Especially, the children in 3rd and 4th grades exhibited the biggest improvement.

Meanwhile, the Ministry made efforts to raise the awareness for the 「Special Act on Safety Control of Children's Dietary Life」 and the dietary life management by distributing promotional literature and posters throughout children and consumers as well as hosting exhibition contest for the practice of safe dietary life. Moreover, by exhibiting the award winning posters from the '4th Contest for Children's Dietary Life Safety Poster' at schools and local communities, the Ministry not only promoted the practice of healthy dietary life but attempted to inspire children to practice safe dietary life. The Ministry also prepared promotional literature on prevention for erratic intake of highly concentrated caffeine foods and distributed them throughout middle and high schools all around the nation.

To establish environment for children's healthy dietary life and to improve children's capability to make smart decision on selection and purchase of the food, the Ministry plans to implement an education program for dietary life and keep developing educational media that accommodate children's viewpoints.

## 2. Public Nutrition Management

### 1) Background

With the recent change in lifestyle, the rate of chronic diseases such as obesity and hypertension is increasing due to the imbalance of nutrient intake and the lack of physical activities. According to the National Health and Nutrition Examination Survey, the adult

obesity rate over the age of 19 continues to increase with 30.8%(men 36.3%, women 24.8%) in 2010 and the Health Insurance Research Center reported in 2008 that socioeconomic costs for obesity in Korea reached a total of 1 trillion 823.9 billion KRW with the direct cost of 1 trillion 108.7 billion KRW and indirect cost of 715.2 billion KRW, which was equivalent to 0.22% of GDP as well as 3.5% of total national medical cost in 2005. Moreover, 1 out of 7 students between elementary school and high school suffers from obesity and a truly serious problem lies in where most children and youth with obesity are highly likely to become adult obesity patients.

The national sodium intake in Korea was at 4,878mg in 2010 which is 2.4 times higher than 2,000mg, recommended amount by WHO, while the number has been continually increasing from 4,388mg in 2007. While medical expenses for 4 major chronic diseases related with excessive sodium intake(hypertension, cerebrovascular disease, heart disease, diabetes) takes up 15.1% of total medical expenses, insurance payment for 4 major diseases was doubled in 5 years from 2 trillion 550 billion KRW in 2005 to 4 trillion 10 billion KRW in 2010 and the market cap for hypertension drugs surpassed 30 trillion KRW last year as it was reported that 1 out of 3 adults over the age of 30 is currently viewed as a hypertension patient(32%).

To secure healthy dietary life for the general public, environment for calorie count within dietary life should be first established to ensure the intake of balanced nutritive components through the minimization of risk-potent nutritive components and nutrition labeling on processed food.

## 2) Priority Control of Potentially Hazardous Nutrients Including Sugar, Sodium and Trans Fat

### (1) Pursuing Reduction of Trans Fat and Saturated Fat

Amongst nutritive components, those components such as sugar, sodium and trans-fat are classified as risky nutrients, which are likely to cause risks to health with their excessive intake. Thus applicable policies upon these components have been pursued. Regarding trans fat, its reduction policy was first planned in 2003 followed by fact-finding studies in 2004 and the policy to reduce trans-fat has become effective since 2005 subsequently in 2006, the government procured a relevant management policy and imposed a mandatory nutrition labeling for the first time in Asian nations.

Reduction policy on trans-fat in processed food, which was pursued in collaboration with food industry, started to garner a feasible achievement as the said policy was included in the campaign themes of the 17th Presidential Election in 2008. In December of 2012, 99% of the confectionery circulated in the market indicated '0 g' of trans fat and such market trend appeared to be still remained according to the survey conducted in December, 2012. Upon saturated fat which was increased by reducing trans-fat, the 'Project to Support Technology Development for Maintaining Low-saturated and Non-Trans Fat' has been initiated along with the 'Project to Support Technology Development for Maintaining Non-Trans Fat' since 2008 in order to induce voluntary reduction from the industry. And the Ministry plans to keep supporting the industry for voluntary reduction in the future.

## (2) Promotion of Nationwide Sodium Reduction Movement

With the national daily intake of sodium at 4,831mg in 2011, the number was still 2.4 times higher than WHO's recommended daily amount of 2,000mg, where men aged between 30 and 50 years were particularly 3.3 times higher than the recommended amount with 6,674mg.

[ Table 3-1-3 ] Yearly National Daily Sodium Intake Amount

Year	2007	2008	2009	2010	2011
Average Sodium Intake	4,388	4,553	4,646	4,878	4,831

(Unit : mg)

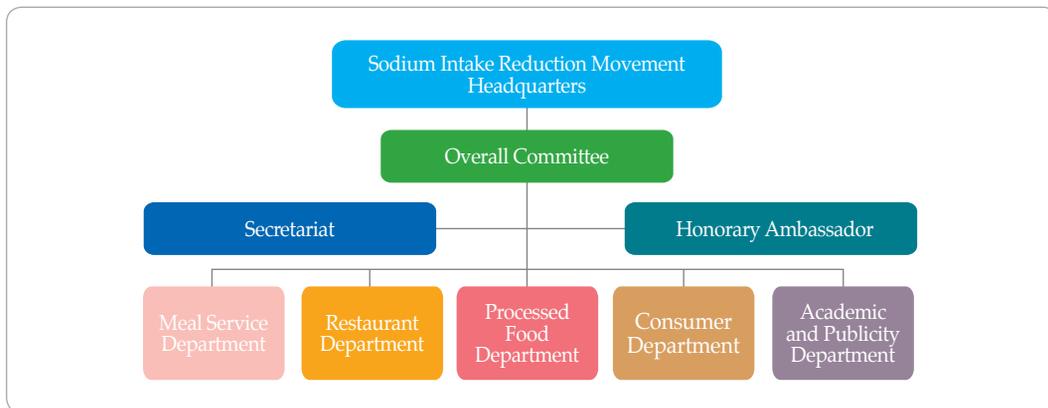
To resolve ongoing problems, the Ministry of Food and Drug Safety accumulated scientific data through studies on sodium contents in restaurant, meal services and processed food as well as studies on national sodium sensitivity since 2005, which led the Ministry in 2006 to lower the standard daily sodium intake amount from 5,300mg to 2,000mg.

Since 2011, the Ministry conducted pilot projects on each venue to reduce sodium intake at meal-service, restaurant industry, processed food and home-cooked meals. In the field of meal services, the Ministry performed a pilot project of 'A Week of Low-sodium Meal Service', while the Ministry designated 114 restaurants for 'Healthy Restaurant Participating in Sodium Reduction' from Seoul, Chungcheong and Youngnam regions in the field of restaurant industry. Also, in the field of processed food, the Ministry encouraged the industry to set the goal for sodium reduction upon the items with high sodium.

The Ministry also posted 70 low-sodium recipes for popular home-cooked meals at its official

website. Moreover, in order to improve consumers' awareness and behavior, the Ministry launched campaigns to reduce soup of including 'Reduce Sodium, Elevate Health' and it also offered training programs for housewives, parents and office workers in collaboration with consumer groups.

'Sodium Intake Reduction Movement Headquarters' was launched to lead the national movement for the whole country to participate in reducing sodium in March, 2012. This H.Q. is to assume a society-wide key role to improve public health and spread healthy dietary culture by unifying the resources of various industries and promoting nationwide voluntary participation along with continuing practice.



[ Figure 3-1-1 ] Organization Structure of Sodium Intake Reduction Movement Headquarters

In 2012, education and promotions were enhanced in order to have suppliers to continue sodium reduction movement and to encourage consumers to change their awareness and practice behavior. In the field of restaurant industry, 'Healthy Restaurant Participating in Sodium Reduction' was also expanded as 99 additional restaurants were newly designated; and 202 restaurants from all over the country were named as its participants after monitoring process was conducted. In the field of processed food, 5 manufacturers of seasoning, dressing and instant-processing food announced their sodium-reduction execution plan upon 51 products and their effort for sodium reduction still continues. At the same time, the Ministry developed and provided 'sodium reduction guideline for the food industry' in order for the whole industry to easily implement sodium reduction plan, while taste corners with low-sodium food were introduced at department stores and hypermarkets.

In 2012, the Ministry developed promotional plan for Sodium Intake Reduction Movement,

constantly educated the seriousness of excessive sodium intake and executed extensive PR activities to promote the changes in dietary habits; at the same time, the Ministry oversaw Sodium Reduction campaigns including a test for salty taste, quiz competition, exhibition of promotional panels and distribution of promotional literature in order to heighten the awareness for excessive sodium intake. Lectures on sodium reduction policies were also offered for various policy-makers at schools and military units. A website([www.foodnara.go.kr/Na\\_down](http://www.foodnara.go.kr/Na_down)) to interact and share the information on sodium reduction was developed to form social consensus with consumers and low-sodium cooking contests were held to popularize the recipes with low sodium furthermore, academic symposium was also held to enhance social responsibility as well as to share success stories with food suppliers.

Aiming to further lower sodium intake by 20% by 2017, the Ministry of Food and Drug Safety is determined to pursue more efficient and sustainable policies such as enhancement of consumer education programs, continuous implementation of sodium content reduction throughout suppliers of meal-service, restaurants and processed food, operation of tailored sodium reduction programs accommodating each life-cycle and cooperation and supports for sodium reduction projects of local governments in order to spread the movement nationwide.

### (3) Reduction of Sugar Intake

The reduction policy of sugar intake is designed to pursue its reduction step by step considering the conventional sugar intake practice of the general public while maintaining the basic frame of the trans fat reduction policy(fact-finding study→management measures→education/promotion). In 2006, content of sugar was included in the nutrient labeling in processed food and it became mandatory for hamburger, pizza, ice cream, cookie and bread(more than 100 stores) among children's preferred food to include sugar in the labeling.

In 2008, the Ministry started to make efforts to reduce sugar at schools by developing and distributing 'Recipes with lowered sugar for school meal service'. To learn precise sugar intake by general public and prepare responsive measures, the Ministry in 2012 analyzed national sugar intake by utilizing the National Health and Nutrition Study between 2008 and 2010 as well as database of nutritive components in restaurant industry; and the analysis results indicated that national daily sugar intake was increased by 23% in 2010 with 61.4g from 2008. National average daily sugar intake amount(excluding fruit and milk) was 59~85% of the

recommended amount by WHO, which was not particularly serious; however, preventive measure is still required to manage national dietary habit as the average sugar intake has been consistently increasing since 2008.

Therefore, the Ministry pursues the sugar reduction project mainly on specialty stores of coffee and beverage to heighten the risk of sugar intake. Majority of children and teenagers with obesity are highly likely to move on to adult obesity and the excessive sugar intake is also likely to raise morbidity rate for adult diseases such as diabetes and cardiovascular disease. Thus, the Ministry is determined to continue investing efforts to reduce sugar intake.

### 3) Promote the Environment for Calorie Count in Daily Dietary Life

The Ministry of Food and Drug Safety is trying to promote an environment for calorie count in daily dietary life to ensure the balanced nutrition intake through nutrient labeling at processed food and restaurants in order to secure healthy dietary life for entire general public.

In 2012, 'Foods Labeling Standards' were revised for products that are packaged and sold for a single intake to indicate nutritive components of the entire contents as a single serving size; and the Ministry also ensured the convenience for the suppliers where they can easily define a single serving size by providing them a 'Single Service Size Configuration and Notification System'. And 'Nutrient Reference Values' used at the food labeling were revised based on the international as well as Korean nutrient intake standards, while the 'Survey on food for special medical uses and its demand' was conducted in order to vitalize the food for special dietary uses.

As a part of comprehensive measures for children's food safety, a voluntary nutrient labeling has been implemented for the stores carrying pizza, coffee, cookie and bread since 2008. Pursuant to 'Special Act on Safety Control of Children's Dietary Life', the content labeling of calorie, sugar, protein, saturated fat and sodium contained in a single serving size has become mandatory for those (more than 100 stores) who prepare and sell hamburger, pizza, ice cream, cookie and bread amongst children's preferred foods since 2010.

As consumers and media have continued to demand the expansion of labeling to conventional restaurants since the mandatory labeling was imposed on cooked food amongst children's preferred foods, the Ministry formed practical consultative groups by each business type such as family restaurants, flour-based food restaurants, expressway service areas and

children entertainment facilities in order to pursue voluntary nutrient labeling for restaurants.

With increasing leisure hours largely due to 5 business days a week, the Ministry signed a business alliance agreement with the Korea Highway Corporation in order to improve food safety and nutrient quality at highway rest areas where an average of 1.2 million people stop by every day(438 million people a year). Subsequently, the Ministry promoted the expansion voluntary nutrient labeling by offering rewards and incentives including the designation of superior service areas of nutrient labeling as well as tailored technological assistance with distribution of 'Nutrient labeling guideline for a highway rest area' after operating a committee for voluntary nutrient labeling at a highway rest area. Starting with voluntary nutrient labeling on processed and conventional food products at highway rest area(Jukjeon Rest Area) for the first time in the world in March of 2010, such movement expanded throughout 40 additional rest areas in December, 2010. Eventually, the nutrient labeling practice has been in place at all 170 rest areas(excluding rest areas on private highway) nationwide since the late October of 2012.

The voluntary nutrient labeling is being implemented at the entire outlets of the family restaurant franchise VIPS(83 stores), Outback Steakhouse(106 stores) and Ashley(110 stores), and it also has been in place at MI-Mandoo(20 stores) and GIMGANAE(22 stores) since 2011. Thus the Ministry plans to gradually expand the system further. In addition, nutrient labeling has been available on all food products prepared and sold at Samsung Everland, Seoul Land, Seoul Children's Grand Park, Seoul Grand Park(Gwacheon) and Lotte World since 2012. Nutrient labeling has been also visible on popcorn and beverage sold at snack shops of movie theater franchises such as CGV, Lotte Cinema and Megabox since December of 2012.

Since March of 2011, the Ministry introduced and implemented a voluntary nutritional ingredient color / content / shape index(also known as 'Nutrition Signpost Labeling'), which indicates the level of contents by colors in order for children to easily recognize nutrient ingredients that may cause obesity, on children's preferred foods. This index is designed to indicate the contents of 4 nutritional ingredients(sugar, fat, saturated fat, sodium) from a single serving size of the product on the main display surface, where one of three available designs may be employed.

### 3. Nationwide Service for Public Nutrition Management

#### 1) Background

In recent years, family dining-outs are rapidly increasing due to the changes in dietary life environment caused by the increase of incomes and double-income families. At the same time, due to the changes in public dietary lifestyle such as westernized dietary habits, chronic diseases like obesity or cardiovascular disease caused by excessive or imbalanced nutrition became on the rise for leading causes of death.

To promote the environment for the general public to choose healthy food, the Ministry not only expands nutrient labeling from processed food to restaurant food but builds a nutritional ingredient analysis system, the foundation for nutrient labeling on restaurant food, to provide reliable nutrition information through websites and mobile services.

#### 2) Construction of System for Nutrition Assessment and Management

Since 2009, the Ministry of Food and Drug Safety developed and implemented the 'National Laboratory System for Food and Nutrient Databank' to generate a reliable national nutrient component database for nutrition information so that the public can choose healthy food products. The Ministry has been offering an e-book of nutrient component data on 130 most consumed restaurant food products in life size; and it also built the 'Food and Nutrient Data System(FANTASY)' and launched its service for the general public who develops a diet menu, evaluates and calculates a nutrient index by utilizing the database of food nutritive components.

The 'Calorie Coordi', individual nutrition assessment and management program used on mobile and website, allows individuals to easily calculate nutrition information such as calories of the daily food intake through mobile phones, where the program has been warmly accepted by the public as its number of download reached to 338,595. According to the survey of 7,000 middle and high school students on obesity-related dietary habits, the 'high risk group for eating disorder' took up 12.7%(men 10.5%, women 14.8%) of total students, which demands solutions to prevent eating disorder along with obesity. Subsequently, the Ministry launched a 'Calorie Coordi II' service embedded with cartoon-like educational materials and self-diagnosis/assessment feature for eating disorder in order to enable users to conduct self-

health management.

The Ministry has been providing a service of 'Gungangi's Food Bicycle Journey', a game program for the nutrition management designed for children to easily learn healthy nutrition and dietary life by using food-organizing bicycle, through the home page of nutrition index information and children's portal site(Juniver) since August, 2011.

As a part of information provision for the nutritional dietary life management, the Ministry in 2011 developed and distributed a 'Nutrition/Dietary Life Guide for Healthy Soon-to-be-mothers' throughout hospitals and clinics nationwide and its service is also available in the form of e-book via the official website. At the same time, this e-book is equally available in foreign languages including English, Chinese, Vietnamese, Cambodian and Pilipino Tagalog language with the help of the Korean Institute for Healthy Family to accommodate soon-to-be-mothers in multi-cultural families.

In 2012, the Ministry developed and provided contents for children, teenagers, fertile women, breast-feeding women and adults through the 'Life-cycle Nutrition Management Library' of the internet. Also it plans to translate and offer a Nutritional Dietary Life Guide for multi-cultural families and vulnerable social groups along with continuing general provisions of nutritional dietary life contents tailored for various groups.

## 02

## Promote Public Health by Foodborne Disease Prevention

### 1. Establishment of Constant Surveillance System for Foodborne Diseases

#### 1) Latest Trends

An outbreak of foodborne diseases has been continuously decreasing since 2007. Meanwhile, comparing to 2011, the number of foodborne disease outbreaks was increased by 6.8%, but the number of patients was decreased by 14.7% in 2012.

[ Table 3-2-1 ] Outbreak of Foodborne Disease for the Past 5 Years

Classification	2008	2009	2010	2011	2012
Cases	354	228	271	249	266
Patients	7,487	5,999	7,218	7,105	6,058

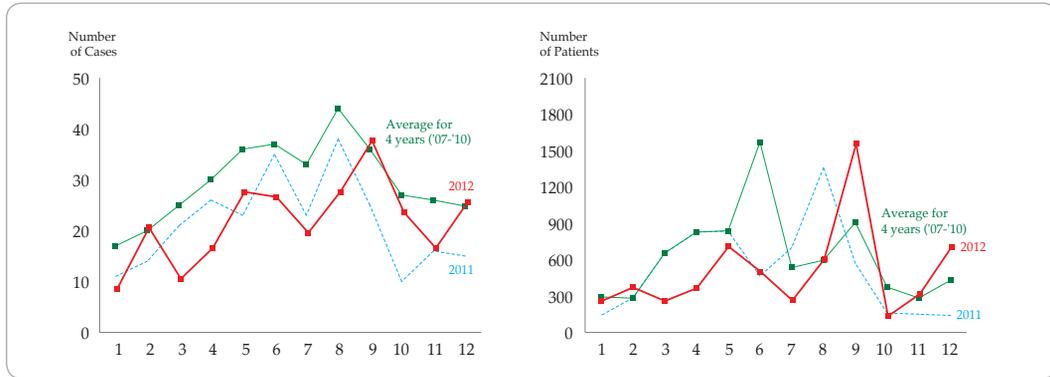
\* 2009 was an exception as the number decreased because of nationwide prevention efforts with hand-washing due to the outbreak of swine flu.

The number of patients per million by each country a potent comparison tool for the frequency of foodborne disease outbreaks, was 119 which were less than its number in Japan.

\* Japan : 174 patients(2010)

Examining the characteristics of foodborne diseases by each month in 2012, the number noticeably decreased in the first half comparing to the first half of 2011; however, the number

greatly increased in the second half because of food poison incidents caused by contaminated Kimchi.

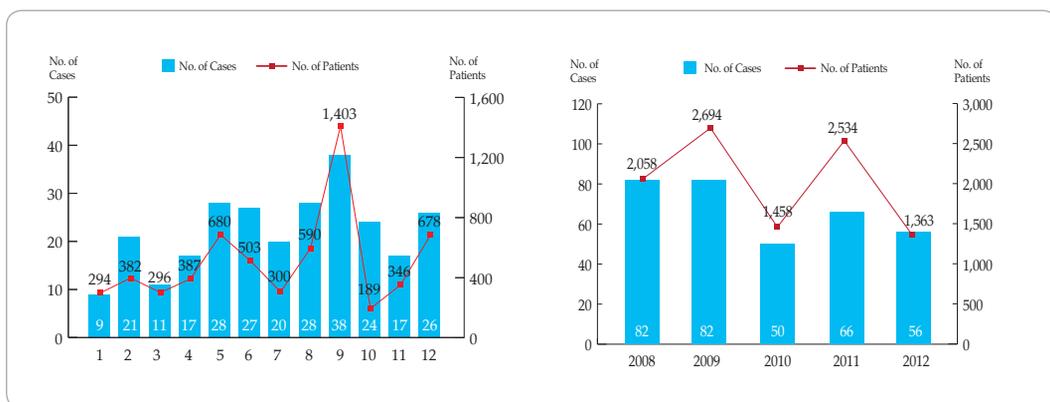


[ Figure 3-2-1 ] Number of Cases of Foodborne Disease and Its Patients by Month in 2012

[ Table 3-2-2 ] Cases of Foodborne Diseases by Month in 2012

Classification	Total	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
Cases	266	9	21	11	17	28	27	20	28	38	24	17	26
Patients	6,058	294	392	296	387	680	503	300	590	1,403	189	346	678

Also, the number of foodborne disease cases(15% in cases 46% in patients, 22.4% of all patients) decreased greatly during spring season(March thru May) in 2011(66 cases and 2,534 patients) comparing to the in 2012(56 cases and 1,363 patients).



[ Figure 3-2-2 ] Foodborne Disease Cases by Month in 2012

[ Figure 3-2-3 ] Foodborne Disease Cases in Spring by Year

Looking into the foodborne disease cases based on outbreak of each facility during the year of 2012, restaurants recorded the highest incidence rate(95 cases, 35% of all cases) and the highest number of patients were reported from the meal service places serving one-time visitors(3,431 patients, 56.6% of all patients).

The number of patients at school increased only slightly and its main cause was the contaminated food supplies(such as Kimchi) which caused a number of cases all at once.

[ Table 3-2-3 ] Foodborne Disease Cases by Facilities in 2012

Classification	Total	Meal Service			Household	Restaurant	Others*	Unidentified
		Subtotal	School	Business				
Cases	266	63	54	9	95	14	22	72
Patients	6,058	3,431	3,185	246	1,139	54	758	676
Patients per Case	22.8	54.5	59	27.3	12	3.9	34.5	9.4

\* Others : Households & Packaged Meal Manufacturers

At restaurants, the biggest contributors for foodborne diseases were vibrio(11 cases), perfringens and Noro virus(7 cases for each), which totaled in 25 cases and 26.3% of all etiologic agent-identified cases.

Upon the foodborne disease cases by region, Gyeonggi and Incheon as population saturated regions, recorded the highest number of cases; and the highest number of patients per 100,000 populations was reported from in the order of Gangwon, Jeju and Incheon.

[ Table 3-2-4 ] Foodborne Disease Cases by Region in 2012

Total	Seoul	Bu san	Dae gu	In cheon	Gwang ju	Dae jeon	Ulsan	Sejong	Gyeong gi	Gang won	Chung buk	Chung nam	Jeon buk	Jeon nam	Gyeong buk	Gyeong nam	Jeju
266(Cases)	35	11	12	19	4	3	8	1	90	17	9	8	4	13	13	13	6
6,058(Patients)	837	325	238	986	91	22	123	33	1,078	929	168	154	98	243	196	333	204
Patients Per 100,000 people*	8.2	9.2	9.5	34.7	6.2	1.4	10.7	29.2	8.9	60.4	10.7	7.6	5.2	12.7	7.3	10.0	34.9

Amongst causative organisms causing foodborne disease, Noro virus caused the most foodborne disease cases and it was followed by in the order of pathogenic Escherichia coli, perfringens, vibrio and salmonella. Noro virus caused Foodborne disease all year along without any seasonal traits and it was found that extra caution for Noro virus was required as the Noro virus-causing foodborne diseases were heavily concentrated during January through

May(81%) however, the detection rate of Noro virus-causing cases(51.5%) in 2012 was lower than the average detection rate for the past 4 years(2008~2011).

[ Table 3-2-5 ] Foodborne Disease Cases by Etiologic Agent in 2012

Etiologic Agent	Case	% of Cases (%)	Patients	% of Patients (%)	Etiologic Agent	Case	% of Cases (%)	Patients	% of Patients (%)
Noro Virus	50	18.8	1,665	27.5	Bacillus Cereus	6	2.3	111	1.8
Pathogenic Escherichia Coli	31	11.7	1,844	30.4	Staphylococcus Aureus	5	1.9	35	0.6
Vibrio Parahaemolyticus	11	4.1	195	3.2	Other Viruses	1	0.4	22	0.4
Foodborne Clostridium Perfringens	13	4.9	297	4.9	Shigellosis	0	0.0	0	0.0
Salmonellosis	9	3.4	147	2.4	Natural Toxicant	3	1.1	13	0.2
Campylobacter	8	3.0	639	10.5	Non-detection	129	48.5	1090	18.0

Amongst food of a probable cause(70 cases), the processed food products(24cases) reported the highest number of cases followed by fishery / meat(16 cases) and its processed product(6 cases), while foodborne diseases were mostly caused by pathogenic Escherichia coli and Noro virus through Kimchi amongst vegetables(24 cases). It was presumed that foodborne diseases were caused when people ate fishery and vegetable food products without cooking or heating.

## 2) Accomplishments of Preventive Management upon Foodborne Disease in 2012

### (1) Operation of Pan-governmental Committee for Comprehensive Measure against Foodborne Disease

The Pan-governmental Committee for Comprehensive Measure to prevent and manage foodborne disease nationwide was established and has been operated since 2007; and a total of 32 agencies including central departments, local governments and private institutions came together 3 times and they developed and oversaw countermeasures to prevent foodborne diseases in 2012. Regarding major achievements by each agency, the Ministry of Education, Science and Technology focused on and pursued preventive activities for school meal services through the unscheduled inspection on sanitation and safety management at school meal services, modernization projects on outdated meal service facilities and appointment of

directors to manage school meal service. The Ministry of Justice developed standard criteria upon kitchens for school meal service and pursued modernization of meal service facilities and equipments, whereas the Ministry of National Defense concurrently conducted inspections both on military cookhouses and winter-season military food supplies. The Ministry for Food, Agriculture, Forestry and Fisheries enhanced the map indicating the use of oyster upon the detection of Noro virus and its guidance and the Ministry also pushed for the revision of fisheries license regulation mandating the installation of incineration-type bathrooms.

The Ministry of Health and Welfare distributed the standards on a joint-inspection/guidance for social welfare facilities of children meal services and nurseries before-and-during vacations as well as the standards for sanitary safety and facilities of small-scale meal-service places. The Ministry of Environment strengthened the inspection and management on contamination of underground water near burying sites of livestock by operating the surveillance system of Noro virus at 4 major regions in the country and pursued improvement projects for 572 small-scale water supply facilities. The Korea Centers for Disease Control and Prevention distributed stool collection kits to heighten the cause clarification rate and revised the guideline for the epidemiologic investigation. Also, local governments efficiently performed the 'Diagnosis Service for Foodborne Disease Prevention', the guidance/inspection of sanitation-vulnerable facilities, the enhancement of foodborne disease prevention training/promotion and emergency duties during the summer season.

## (2) Comprehensive Guidance/Inspection based on the Traits of Foodborne Disease Incidents(by Facility or by Season)

An outbreak of foodborne disease exhibits traits based on the four seasons and facilities as the year starts out with the disease caused by Noro virus during the winter season followed by foodborne diseases at school meal service places during March through April and August through September, picnic-related foodborne disease during April through May and September through October and vibrio-causing foodborne disease at restaurants during July through September. Based on this finding, foodborne disease incidents are being efficiently prevented by enhancing advanced inspection and guidance before the disease breaks out. The Ministry of Food and Drug Safety, along with local governments and school boards, conducted extensive inspection and guidance on school meal service centers and food material suppliers in February and August, which resulted in issuing 98 orders of improvement after inspecting

6,782 relevant sites and facilities. In April and May, the Ministry performed the sanitation guidance and inspection on 368 group meal service centers at youth training facilities where students went through 'experience classrooms' field trip facilities and subsequently took administrative measures against 25 inadequate training facilities along with the issuance of the order for improvement.

### (3) Nationwide Fact-finding Study upon Noro Virus at Group Meal Service Centers using Underground Water

Noro virus is the etiologic agent which causes the most cases of foodborne diseases as well as the patients of the disease in Korea, where its main cause is believed to be vegetables, fruits and shellfish washed by the contaminated water while stools or vomitus of the patients infected by Noro virus are transmitted into seawater through underground water or rivers. Hence, the Ministry of Food and Drug Safety has been pushing for the foodborne disease reduction by extensively monitoring Noro virus at group meal service centers of youth training and social welfare facilities using underground water for food-making water since 2009. Also, after examining 2,200 group meal service centers nationwide including the ones at schools using underground water in 2012, Noro virus was detected from 14 different locations including 1 school, 1 training facility, 4 social welfare facilities, 8 contracted foodservice management companies. Subsequently, the Ministry took necessary measures of improvement to prevent foodborne diseases by banning the use of food-making water, ordering to provide boiled water, banning the menu serving raw food and ordering to clean up the water tanks as well as to improve the equipment at the facilities in question.

### (4) Specialized Training and Public Education on Foodborne Disease Prevention

What was notable in public education for foodborne disease prevention in 2012 is to enhance the training and education to strengthen the competence of foodborne disease management. First, the Ministry opened up a specialized education program to develop expert lecturers on investigation of causes for foodborne disease and its prevention, which was held 6 times to provide 188 professional lecturers.

For the public education on foodborne disease, the Ministry diversified its media outlets where it utilized TV(91 times), radio(122 times), bus, KTX and subway to extensively educate the public. The Ministry also produced and distributed 1.55 million stickers using Pororo,

popular cartoon character, upon 3 major foodborne disease prevention techniques such as 'hand-washing, cooking before eating and boiling before eating'. And during the event of, 'A Day of Food Safety', the Ministry also distributed 120,000 promotional notebooks along with wet tissues throughout the general public.

On the other hand, the operation of foodborne disease prevention App(<http://m.mfds.go.kr/fm>) is being initiated to serve smart phone users who are now able to easily access a variety of information upon self-diagnosis and preventive measures for foodborne disease.

### 3) Foodborne Disease Prevention and Management Plan in 2013

To accomplish this goal, it is to develop a detailed operating regulation of the Pan-governmental Committee for Comprehensive Measure against Foodborne Disease to ensure the stability of the committee. Also, it is also expected to conduct mock training for nationwide health clinics to respond to foodborne disease in order to improve the competence of the reporting system on foodborne disease.

The Ministry plans to enhance the management of food products causing foodborne diseases and to perform year-round inspection and guidance upon target facilities including schools for the intensive management of foodborne diseases and vulnerable facilities. Also, it plans to continuously expand the projects to install sterilization and sanitation devices for underground water in order to help out group meal service centers using underground water.

Moreover, the Ministry aims to improve the cause clarification rate of foodborne disease by enhancing the inspection for foodborne disease bacteria and the collection of its strains upon imported products and food products in circulation including agriculture, stock farm and fishery products as well as instant food products. By analyzing the genotype of collected foodborne disease bacteria, it plans to continue sharing the information with all the local governments by establishing nationwide network.

For the public education on foodborne disease prevention, the Ministry plans to greatly expand the number of airings of foodborne disease prevention campaign by using general service broadcasting companies and news channels such as YAN and MBN to improve the restrictions on the number of advertisements caused by the hike of the airing fee of national TV's. At the same time, to heighten the nationwide awareness for foodborne disease prevention rather than merely focusing on the capital area, the Ministry aims to run intensive

advertisements during the vacation season by developing local media outlets capable of promotion tailored to each region while diversifying media outlets utilizing LED outdoor billboard signs alongside of the roads and buildings.

## 03

**Secure Safety and  
Functionality of  
Health Functional  
Food and Novel Food****1. Safety Management of Health Functional Food****1) Background and Prospects**

Recently, due to the increase of lifestyle disease and chronic degenerative disease a result of dietary life as well as the entry into an aging society, it has been proved that health functional food plays a significant role in preserving health. Therefore, advanced countries such as the United States and Japan aggressively support the development of policies and researches on health functional food as they prepare scientific criteria upon the display of functionality by establishing the special ordinance upon health functional food for the purpose of improving public health and saving medical costs.

With expanding the national consensus for the needs to promote the development of health functional food industry along with the application of state-of-the-art biotechnology by establishing separate legal regulations, the Ministry reestablished a new legal concept of 'health functional food' within the dichotomous legal system of food and drug and prepared its management and operational system. Subsequently, the Ministry proposed the 'Health Functional Food Act' which was eventually enacted in August 2002 and has been enforced since January 31, 2004. Also, the Ministry of Food and Drug Safety nurtures the environment where high-quality health functional food equipped with safety and functionality can be

produced and supplied through industrial supports and the advancement of health functional food system.

The sales volume of health functional food started out with 250.6 billion KRW in 2004 and reached 1 trillion 409.1 billion KRW in 2012, 3.0% increase from the previous year, while it is expected to continue growing in the future.

## 2) Advanced Criteria, Standard Management and Assessment upon Health Functional Food

### (1) Health Functional Food Accreditation System

Raw materials or ingredients containing functionality are classified into two types: one is a functional material which the Minister of the Ministry of Food and Drug Safety defines and notifies the criteria as a standard and a raw material or an ingredient of the health functional food for sale. The other one is the functional material which the Minister individually recognizes after reviewing the data submitted by business operators upon criteria. However, the standard, safety and functionality of the health functional food was not previously notified by the Minister. Functional materials individually recognized are the substances with functionality which are used to manufacture health functional food, where those substances are either processed with raw materials originated from animals, plants or microorganism or they are extracted, purified, synthesized or compounded from those raw materials. Those individually recognized functional materials are currently being converted into the notified materials when 3 years have passed since the import declaration or the report of the item production, when 3 or more business operators file a report of item production or import declaration since its accreditation or when more than two-third of recognized parties request for code registration. It is designed to promote the development of various products. However, if business operators to protect the data, up to 5 years of probation period may be granted.

Recently, applicable regulations have been revised to maintain the identical sentence type(it may provide assistance to ○○○) to preserve the consistency within the contents upon functionality of each raw material, while the maximum value of daily intake amount for each description of functionality was expanded with the scope where the safety is secured. At the same time, the vitalization of health functional food industry was pursued through the new establishment of criteria and standards for 8 items including guava leaf extract, banana leaf

extract and ginkgo leaf extract.

In 2012, requirements for data to submit upon safety became simplified, and data to submit upon functionality was clearly defined. Thus, the submission of test report on toxicity was exempted when the raw materials to be used for food products or additives are filed for the accreditation of functional raw materials. Also, the scope of both Korean and international science journals to prove the functionality became clearly defined by specifying those which are registered at 'Science Citation Index(SCI including SCIE)' or 'Korea Citation Index(KCI)'.

In 2012, the number of individually recognized raw materials was increased by 9.7%(from 388 to 426) while the portion of the materials domestically developed appeared to be increasing. It suggests that the know-how of health functional food development have been accumulated while the infrastructure for research and development in Korea continues to advance.

The newly recognized functionality in 2012 was 'skin moisturizing(Collective, collagen peptide)', and milk thistle extract amongst functional raw materials was mostly recognized as the raw material for 'liver health'. And it was followed by green tea extract recognized for its functionality of 'fatigue improvement', tomato extract for 'anti-oxidation' and Dimethylsulfone for 'healthy joint'. Amongst health functional food that became commercial products using the functional raw materials recognized last year, the products for blood circulation improvement, memory improvement and liver health were mostly produced, while a variety of products were developed for body fat reduction, fatigue improvement, healthy joint/bone, health of climacteric woman, serum triglyceride improvement and relaxation of tension.

Consumers gradually exhibit more interests in health functional food, which led the industry to develop various functional materials including natural substances. However, some of the raw materials with pharmacologic effects or strong toxicity are often inadequate to health functional food. Thus, the Ministry prevents unwanted R&D in advance and secures the safety of health functional food by notifying 'Raw Materials Unsuitable for Health Functional Food' as the list of inadequate raw materials which are prone to cause side effects and contain a cautious level of toxicity because of powerful biological activities.

The Ministry of Food and Drug Safety plans to continually expand the notified health functional food to promote the development of various health functional food products and to vitalize the market. Also, it also aims to develop and distribute manuals and guidelines upon individual accreditation of functional raw materials. Moreover, the Ministry is determined to

make efforts to accomplish early commercialization of health functional food along with the expansion of consumers' right to choose and the protection of consumers' right to know. At the same time, the Ministry is to provide training programs for specialists in order to promote a higher value-added health functional food industry, and it is also to continue pursuing business projects to vitalize on-site technical consultation for product commercialization while working for the accreditation of functional raw materials for health functional food through the cooperation with relevant agencies such as the Ministry of Agriculture, Food and Rural Affairs and the Ministry of Trade, Industry and Energy.

### 3) Safety Management upon Production and Distribution of Health Functional Food

#### (1) General Information

Regarding business entities related to health functional food in Korea as of the end of December 2012, there are 435 manufacturers, 2,926 importing companies, 82,246 general retail businesses and 1,736 distribution/sales businesses. Also, a total of 12,495 articles were reported for the manufactured items of health functional food where the number was increased by 20.2% from 10,394 items in the previous year. There were 185 manufacturers which were designated as 'Business with Good Manufacturing Practices(GMP) of Health Functional Food' to ensure the supply of superb and safe health functional food and this number represents 46.7% of all health functional food manufacturers(396 businesses).

Since the inception of the system in 2004, the total manufacturing output of health functional food reached to 1 trillion 67.1 billion KRW in 2010 where it first eclipsed 1 trillion mark and it also marked 1 trillion 409.1 billion KRW to increase by 3.0% from the previous year. The manufacturing output of red ginseng products was 648.4 billion KRW which is equivalent to 46.0% of all health functional food products to maintain continuous strength over the market. Also, it was followed by individual recognized products with 180.7 billion KRW(12.8%), vitamin/minerals products with 164.6 billion KRW(11.7%), aloe products with 68.8 billion KRW(4.9%) and probiotics products with 51.9 billion KRW(3.7%).

#### (2) Construction and Support of Foundation for Outstanding Manufacturing

The Ministry of Food and Drug Safety developed and has been operating 'Business with

Good Manufacturing Practices(GMP) of Health Functional Food' to secure the safety and the quality of health functional food by to systematically managing the manufacturing process and quality of health functional food. Once being recognized as GMP business, the company becomes qualified to accept contracted manufacturing from venture manufacturers or distribution-specialized sales companies of health functional food, while the company is allowed to attach GMP design on the products.

As of the end of 2012, the total number of businesses with GMP designation is 185, 46.7% of all 396 manufacturers. Moreover to develop the professional workforce in providing GMP technological guidance, the Ministry appoints the GMP director for health functional food only from those who completed the 'Training Course for GMP Director of Health Functional Food' amongst employees of the Ministry and local agencies.

### (3) Establishment of Healthy Distribution Order

As the environment demanding health functional food continues to expand due to the elevation of income level, the increasing urge of the general public for a healthy life and the increase of elderly population, a variety of products are being produced and distributed, which subsequently calls for aggressive measures for the safety management of health functional food. Also, due to the advancement of scientific technology and environmental changes and as various risk factors continue to increase the Ministry invests efforts to prevent damages from false or exaggerated advertisement by establishing the safety of standards and criteria through the follow-up management. At the same time, the Ministry is determined to strengthen the procedures of collection, inspection and monitoring, including the close collaboration with applicable agencies for the safety of health functional food and the consumption of the products with improved quality.

#### A. Improvement of Labeling System

To help consumers to make right decision when purchasing health functional food, the Ministry developed and operates the 'Labeling Standards for Health Functional Food'. And it also not only enforces the labeling of the text and design saying 'health functional food' only on the products recognized as health functional food but provides product information through the 'Official Website of Health Functional Food(<http://www.foodnara.go.kr/hfoodi>)' so that consumers enable to confirm the validity of health functional foods before purchasing.

In 2012, the Ministry abolished the regulation on mandatory labeling of the temperature of refrigerated/frozen health functional food while allowing the labeling of actual value of nutritive components, and it also revised the regulation to permit the deletion of the labeling when the calorie and sugar contents are '0'. Also in the future, the Ministry aims to continue revising the regulation to improve unnecessary restrictions which hinder businesses from their business activities and it is determined to prevent consumers in advance from being victimized because of insufficient information in order to protect consumers' rights to know and choose.

#### B. Functionality Labeling/Preliminary Review of Advertisement

The Ministry sternly oversees the preliminary review system on advertisement to prevent consumers from being victimized by false or exaggerated advertisement on the functionality of health functional food and to promote healthy distribution and sales as well as fair competition through proper labeling and advertisement upon the functionality. When anyone hopes to label or advertise the functionality of health functional food, they are obliged to go through the process of preliminary review conducted by the 'Review Committee on Labeling and Advertisement of Functionality' under the Korea Health Supplements Association. This committee is formed with various professionals on health functional food including experts from academic community, food-specialized institutes, consumer groups and the relevant industries for the fairness and objectivity where the committee reviewed a total of 3,624 cases(50 meetings) in 2012. Within the scope of consumer protection, the committee aims to contribute to the industry-wide advancement of health functional food by developing a guideline for functionality labeling and advertisement of health functional food with characteristics and marketing of the product taken into consideration.

#### (4) Monitoring upon Adverse Events of Health Functional Food

The Ministry of Food and Drug Safety currently operates the 'Adverse Event Reporting System on Health Functional Food' based on scientific facts for the purpose of the safety follow-up management on health functional food. Since January of 2013, the Ministry rearranged the system for National Food Safety Information Service to be the only agency to receive the reports on suspected adverse events of health functional food which used to be accepted by a number of agencies including the Consumers Union of Korea, the Korea Health Supplements Association(businesses) and the Ministry of Food and Drug Safety(experts).

All the reports on suspected adverse events accepted are to be investigated for statistically significant clues by applying data mining technique. Subsequently, the causality between the intake of health functional food and the associated adverse event is to be evaluated through the algorithm analysis. For this very purpose, the Ministry developed and is operating a system for the efficient management and prompt evaluation of all information on adverse events by building the 'Korea Integrated System for Signal Manipulation & Evaluation(KISSME)'. Also, the 'Expert Committee on Health Functional Food Safety Assessment' was formed and being operated to complete the third party verification upon cause analysis reports. The committee consists of approximately 20 experts from various fields of clinical science, pathology, toxicity, food and statistics to verify the results of cause analysis by each symptom of the side effects. A total of 484 reports were received on suspected adverse events between 2008 and 2012; however, no causality with the intake of the product was ever identified based on the analysis of the correlation with the intake of health functional food.

#### (5) Tailored Training and Public Education

The Ministry tries to ensure consumers to have better understanding on health functional food to make the right purchasing decision by continually providing proper information of health functional food and public education on false/exaggerated advertisements through various ways and means of the public education.

In 2012, 50 sessions of group training were offered for 5,323 middle-aged and elderly consumers which is the main consumer groups by the responsible agency of the Korea National Council of Consumer Organizations.

Business entrepreneurs and their employees have to take the separate trainings according to their business venues or job descriptions such as manufacturing, importing, sales and quality control. Furthermore, the Ministry also developed and provided online training programs to help them to take the training via internet for the efficient legal training and the convenience of business operators.

A variety of information on legislation, permits, approval, reports and product information(name, function, cautions for intake, etc) can be checked directly through the 'Official Website of Health Functional Food(<http://www.foodnara.go.kr/hfoodi>)'. And for the popularization of the information, the Ministry not only newly established 'Information Chamber for Health Functional Food' at the portal site(Naver) but also developed and

distributed a mobile website of health functional food([m.foodnara.go.kr/hfoodi](http://m.foodnara.go.kr/hfoodi)) in order for consumers to instantly access the product information and its functionality for the purpose of strengthening the provision of information on health functional food.

#### (6) Future Plans

In the future, the Ministry aims to further focus on consumer protection and to promote the public health by encouraging procurement of safety, quality improvement and healthy distribution/sales of health functional food through the policies tailored to each target and level. To accomplish the said goals, the Ministry plans to develop and enact the measures to support and nurture the industry for the promotion of the system securing the functionality of health food and while strengthening the competitiveness. Moreover, the Ministry is determined to aggressively develop and distribute the e-information system through the enhancement of the official website of health functional food, the development of application for product information as well as the preliminary verification system for advertisement review to improve information accessibility and usability of the consumers .

### 4) Enhancement of Technical Support to Improve Competitiveness of Health Functional Food Industry

The Ministry prepared a guideline on the data to submit for the accreditation of functional raw materials in order for business operators who hope to have functional raw materials used for health functional food and it also provided uniformed document forms for submitting data through the information fair to educate how to efficiently prepare the documents. Also, the Ministry plans to continue offering the training programs focusing on case studies to help business operators preparing documents for the accreditation review of functional raw materials.

#### (1) Technical Support and Infrastructure Construction for Health Functional Food

There are currently 13 consulting firms specialized in health functional food, and their information is now available at the official website of Korea Health Supplements Association([www.hfood.or.kr](http://www.hfood.or.kr)). At the same time, information on relevant regulations is being continually provided in order to enhance the responsibility and competency of consulting

firms, while specialized trainings upon approval/licensing works are also being offered to continue improving the competence of consulting firms.

## (2) Expert Training Courses Including Regional Training Academy

As the development of novel substance for health functional food draws more attention, it leads to increasing demands for training and consultation on the regulation to obtain approval of functional raw material for health functional food. Moreover, with unceasing demands for the training where business operators preparing for individual accreditation of health functional food can learn how to prepare required documents and data, the Ministry attempted to present proper direction how to obtain approval for functional raw materials of health functional food by having special training institutes to develop training contents.

By designating training institutes, the Ministry provided trainings upon requirements for individual accreditation including the understanding of regulation on accreditation of functional raw materials for health functional food, development of functional raw material, manufacturing procedure along with necessary consideration, method to set up criteria and standard of functional raw material, animal testing to verify functionality, toxicity test using animal and the understanding of human study.

Moreover, the 'On-site Technical Consultative Council' was founded to present objective and reasonable research direction to secure scientific grounds for functional substance domestically developed and researched. And through this council, the Ministry provided a preliminary information fair of consulting business for regional industry promotion institutes before offering technical consultation to encourage industry-wide participation. Until 2012, there have been a total of 5 functional raw materials that were approved after the on-site Technical Consultative Council performed tailored technical consultations upon 367 petitioned substances at 12 different regional locations including Seoul through door-to-door consultation.

Meanwhile, the Ministry hosts the 'Strategic Seminar for Successful Development of Health Functional Food' every year, presents an improvement direction based on the results of technical consultation and provides case studies upon successful R&D efforts by the industry. At the seminar in 2012, its topics were as follows: ▲ Measures to support and vitalize the development of health functional food, ▲ outcome of on-site technical consultation in 2012, ▲ applicable regulations of major nations upon health functional food, ▲ development of raw materials for health functional food by major nations and ▲ case studies upon successful R&D

of raw materials in Korea.

### (3) Operation of Development Course for Health Functional Food Experts

To help the industry to better understand the health functional food accreditation system and to promote industrial vitalization, the Ministry opened and operates the 'Development Course for Health Functional Food Experts' to have them better understand the assessment practice and the required data to obtain the accreditation for functional raw materials by providing in-depth training for business operators. This course was also offered, while focusing on actual cases, to the researchers and developers from the industry and academic communities preparing to apply for the individual accreditation.

To promote the improvement on the level of business operators, the Ministry in 2012 provided separate development courses of 'Intermediate Course(in May)' and 'Advanced Course(in October)' for health functional food experts to accommodate various levels of the trainees, where it produced high level of satisfactions from the trainees with average index score of 3.34 points(out of 5 point scale).

### (4) Future Plan

The Ministry continues to pursue on-site technical consultative projects in order promote domestic investments through early entry into the market by elevating the understanding of the systems in Korean industry, resolving complaints related to R&D of functional substances and lightening the financial burden on small businesses for their R&D; and the Ministry also aims to enhance the support for commercialization of Korea native substances by building cooperative system amongst relevant agencies and departments.

## 2. Safety Management Enhancement on Novel Food Including Genetically Modified Organism(GMO)

Genetically modified food represents food and additives produced and processed with agriculture, stock farm and fishery products developed and cultivated using 'Recombinant DNA Technique' which takes only useful genes from an organism and combines them with the genes of other organism. As genetically modified agricultural products began to be produced since 1996 based on the advancement of bio-technology, cultivation areas have also been

gradually increased where a total of 25 agricultural products and 319 genetically modified agricultural products were known to be cultivated at 170.3 million hectares in 28 nations in the year of 2012.

[ Table 3-3-1 ] Areas and the Nations Cultivating Genetically Modified Agricultural Product by Year  
(Dec. 31, 2012, Unit : x10,000 ha, Source : International Service for the Acquisition of Agri-biotech Applications)

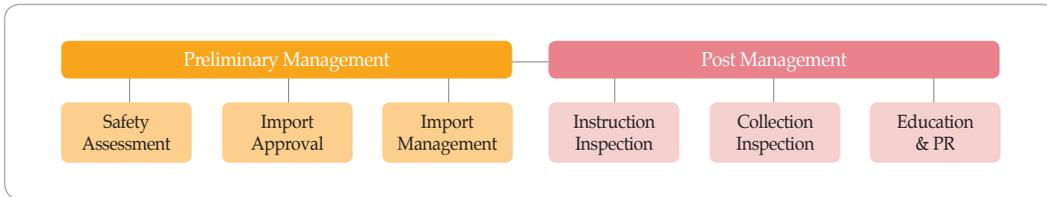
Classification	1996	1997	1998	1999	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012
Area(10 Thousand ha)	170	1,100	2,780	3,990	4,420	5,260	5,870	6,770	8,100	9,000	10,200	11,430	12,500	13,400	14,800	16,000	17,030
# of Nations	6	6	9	12	13	13	16	18	17	21	22	23	25	25	29	29	28

Recently, it became even harder to balance the supply and demand of general agricultural products because of the decreases in agricultural crops due to droughts and the declining cultivation of agricultural products for food. Especially in Korea, because the self-sufficiency rate of grain is relatively low(soy 6.4%, corn 1%: the Korean Rural Economic Institute, 2013), it is inevitable to import genetically modified agricultural products such as soy and corns.

Therefore, the Ministry of Food and Drug Safety grants approvals only to the products of which safety is confirmed based on the strict reviewing process in accordance with Article 18 of 'Food Sanitation Act' in order to secure the safety of genetically modified food and it has been managing a labeling system since 2001 to ensure the public's right to know.

### 1) Safety Management of Genetically Modified Food

In general, the management of genetically modified food consists of two parts such as, pre-safety management and post-safety management. For the sake of the pre-safety management, the Ministry implemented a safety assessment system which allows only the safe food products after going through scientific and thorough review process on them. Also, the Ministry inspects the unapproved products during the process of import and custom to crack down on them from entering into domestic market. With the post-safety management, the Ministry not only secures safety by confirming the propriety of labeling of genetically modified food approved for import but also ensures the provision of correct information through the official guidance, inspection, collection and examination upon relevant businesses Preliminary Management to accomplish the said goals.

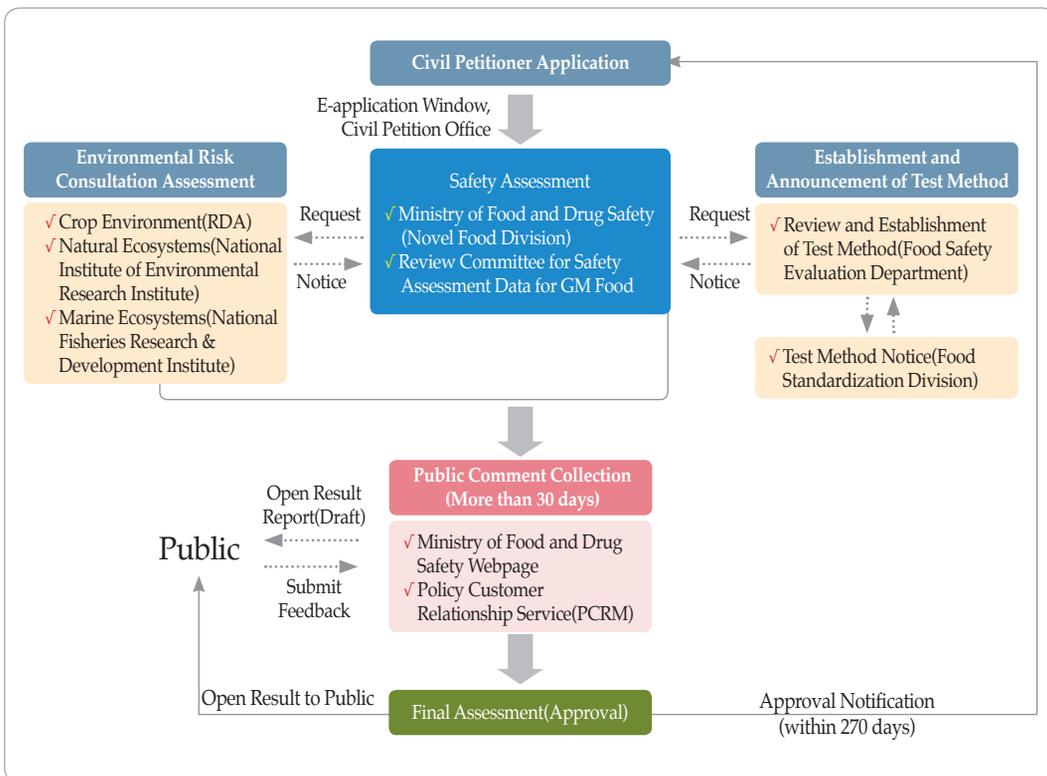


[ Figure 3-3-1 ] Safety Management System on Genetically Modified Food

### (1) Preliminary Management

#### A. Preliminary Safety Assessment Review

Safety assessment review on genetically modified food is being implemented pursuant to the ‘Regulations of Safety Assessment Review on Genetically Modified Food’ in accordance with Article 18 of the ‘Food Sanitation Act’. And the ‘Safety Assessment Data Review Committee on Genetically Modified Food’ led by experts is to review after the Novel Food Division examines the required data. Subsequently, the final approval is to be determined after gathering the



[ Figure 3-3-2 ] Safety Assessment Review Procedure on Genetically Modified Food

public opinion. The safety review procedure is illustrated at Diagram 2 below.

### B. Import Approval

To import genetically modified agricultural products ('Genetically Modified Organism(GMO)' hereafter) capable of surviving and proliferating amongst the approved agricultural products, the application for import approval should be filed on every import attempt in accordance with Article 8 of 'Transboundary Movement, etc. of Living Modified Organisms Act'. Documents required to file for import approval include a transportation contract containing purchase order, transportation route, transportation means and freight forwarder or self-transportation plan, safety management measure upon handling/storage and safety management plan upon professional workforce/facility required for safety management. Approval is to be determined after reviewing submitted documents followed by on-site inspection upon the propriety of safety management plan within import approval application; and the certificate of import approval shall be issued if deemed adequate.

### C. Import Declaration

Upon the completion of import approval, importer shall file for the import declaration along with import license previously issued by the import management department of the local Korea Food and Drug Administration with the jurisdiction over the custom location of GMO in accordance with Article 19 of 'Food Sanitation Act'. Once the import declaration is accepted, the propriety of submitted documents is to be examined followed by sensory test, complete examination or random inspection. Also, based on its outcome, the approval of the import declaration shall be determined and its custom clearance is to be followed if approved.

### D. Management of Unapproved Articles

Article 18 of the 'Food Sanitation Act' stipulates that genetically modified agriculture, stock farm and fishery products for human consumption are to take safety assessment review, whereas Article 4, Section 5 of the same act prohibits the import, distribution and sales of the agriculture, stock farm and fishery products, which either failed to go through the safety assessment review or were found inadequate by the safety assessment review, as well as the food products made of such inadequate products as raw materials.

Subsequently, the Ministry has strengthened the collection and analysis of relevant

information to prevent unapproved articles from entering into domestic market in advance. Also, based on such information, the Ministry thoroughly blocks the articles by examining them for the containment of unapproved GM articles during the process of custom clearance. Under the current reality where development and production of GM agricultural products continue to increase, the Ministry takes all possible preventive measures to complete pre-safety management on the unapproved articles by developing a relevant manual to take prompt responsive measures upon the outbreak of the incidents through the collection and analysis of risk information on regular basis as well as information exchange with foreign nations for the protection of the general public against such incidents.

## (2) Follow-up Management

Follow-up management is to be performed as proper labeling is being inspected for the products of which import declaration was made with the labeling of GM food. While, import products made of raw materials for production is notified to the local government agencies with jurisdiction. Also, upon manufacturers and processing facilities using the raw materials subject to the labeling of GM food, the inspection of their Identity Preservation Handling Certificate and raw material receipts as well as payments ledger shall be performed along with the inspection of the storage and the usage of raw materials to confirm the compliance of such labeling practice. In addition, local government agencies also develop independent management plans and implement guidance/inspection upon GM food currently being produced and distributed. Most of all, they extensively pursue the collection/inspection of the food prone to cause consumers confusion with GMO-Free, Non-GMO or similar labeling.

Moreover, in order to systemize the adequate management of living modified organism(LMO) as well as to help relevant businesses to efficiently practice self-management, the guidance/inspection is being performed on regular basis upon the proper labeling and compliance of safety management plan for the entire process of storage/transportation/distribution of the LMO for food after its custom clearance is completed.

## (3) GM Food Labeling System

The GM Food Labeling System is being implemented in order to provide consumers correct information in 20 nations world-wide including Korea, Japan and EU nations. This labeling system varies with its target articles and execution measures depending on the degree of food

self-support and social/economic situations in each nation, while the system has been in place since 2001 in Korea.

Details of applicable regulations upon labeling and labeling methods on GM food are represented at Table 2 below. Regarding regulations upon labeling, living modified agricultural and marine products are regulated by the 'Agricultural and Marine Products Quality Control Act' whereas GM processed food is regulated by the 'Food Sanitation Act'. Also, the LMO for food such as corn capable of self-growing is mandated to display labeling by the 'Transboundary Movement, etc. of the Living Modified Organisms Act'.

[ Table 3-3-2 ] Applicable Regulation and Labeling Method of GM Food

Classification	Agricultural and Marine Products Quality Control Act	Food Sanitation Act	Transboundary Movement, etc. of Living Modified Organisms Act
Legal Provision	Article 52(Labeling of Living Modified Agricultural and Marine Products)	Article 12.2(Labeling of GM Food)	Article 24(Labeling)
Relevant Ordinance	「Outline for Labeling of Living Modified Agricultural and Marine Products」	「Labeling Standard for GM Food」	「Integrated Notification upon Transboundary Movement, etc. of Living Modified Organisms」
Parties Subject to Mandatory Labeling	Those who produce and ship or sells living modified agricultural and marine products and those who store and display them for sales purpose	Business operators who work on food manufacturing / processing business, instant sales / manufacturing / processing business, food subdivision, distribution-specialized retail business, food import / retail business, health functional food manufacturing business, health functional food import business and health functional food distribution-specialized retail business	Those who develop, manufacture or import LMO
Labeling Method	Labeling is allowed with label or tag if the products are tied or weaved with mesh or non-packaged. When sold by piece or in the form of product, labeling shall be performed with signpost or information signage. Labeling shall be clearly illustrated with the text font larger than 10 points in conspicuous colors clearly different from the color of the package.	Labeling shall be displayed as 'Genetically Modified Food' or 'Food containing Genetically Modified ○○' with the text font larger than 10 points at the main display surface or right beside the name of original material of the GM food to help consumers easily identify. If the use of GM raw material is unclear, labeling shall be displayed as 'Possible containment of GM ○○.'	Name, type, use and characteristics of GMO, cautions for handling, developer or manufacturer of GMO, name / address / phone number of exporter and importer, facts complying with GMO and conformity of GMO used for the release into environment



2013 MFDS Report Ministry of Food and Drug Safety



# 04

## Agro-livestock and Fishery Products

- 01. Strengthened Safety Control by Properties of Agricultural and Marine Food Products
- 02. Expanded HACCP Application
- 03. Safety of Imported Livestock and Marine Products
- 04. Expansion in International Cooperation for Hygiene and Safety of Agricultural, Livestock and Marine Products



## 01

**Strengthened Safety  
Control by Properties  
of Agricultural and  
Marine Food Products****1. Current Status and Problems**

Recently, environmentally harmful materials leave hazard elements in all stages of manufacture, storage, distribution and sale due to a climate change such as global warming or industrial development. Accidents from hazards of agricultural and marine products occur continuously and widely every year with potential risks(such as fungi, poison and others) increasing. This makes safety control of agricultural and marine food as major sources of food very important. Also, an increase of imported agricultural and marine products lead to more accidents, necessitating more thorough safety management of imported products.

**1) Safety Management System for Agricultural and Marine Food Products**

As the National Government Organization Act is revised, the Ministry of Food and Drug was established anew under the Prime Minister. Safety control of agricultural and marine food products was transferred from the Ministry for Food, Agriculture, Forestry and Fisheries. Based on Article 60(Safety Management Plan) of the 「Act on Quality Control of Agricultural and Marine Food Products」, the Minister of Food and Drug Safety shall establish and implement a safety management plan for quality improvement and safe manufacture and supply every year while Metropolitan city mayors, provincial governors and city mayors, county heads

and district heads shall make and execute a detailed plan to secure safety of agricultural and marine products manufactured and distributed in their jurisdiction. Safety inspection of agricultural and marine products manufactured and stored according to Article 61 of the 「Act on Quality Control of Agricultural and Marine Food Products」 and the Prime Minister Ordinance as well as farmlands, fish farms, water sources and materials is commissioned to the Ministry of Agriculture, Food and Rural Affairs and the Ministry of Oceans and Fisheries.

Therefore, the Ministry of Food and Drug Safety plays a role in the control tower overseeing all safety management issues of distribution, sale and consumption of agricultural and marine food products including production based on the Food Sanitation Act.

## 2. Major Results in 2012

### 1) Safety Management of Agricultural and Marine Food Products

600 safety inspections were conducted to detect pathogenic microorganism from farmlands and agricultural products from areas likely to be contaminated where leachate flowed around the sites of burial of animals due to FMD and AI. 62 out of 550 farmland sites and 15 agricultural products were found to have been affected by food poisoning and five were found to have coli form which were subject to delay of release or destruction.

At the same time, to strengthen safety management of agricultural products from areas around deserted mines which are a concern for continued environmental problems such as heavy metal, 2,958 inspections were conducted around the items subject to new standards(rice) and 61 heavy metal-found items(2%) were purchased by the government for destruction.

1,515 inspections for agricultural food were conforming(no detection of radiation) in the tests to find radiation affected agricultural and marine food products.

For safety control against heavy metals in marine food products, continued monitoring covers sharks as a deep-sea species(methyl mercury) against any excess. Global warming and abnormal temperature rise increased the contents of organic nutrients in the sea, leading to the ministerial efforts to stop distribution of marine food products containing paralytic shellfish-poison through intensive control.

\* Number of marine products exceeding the standards for shellfish-poison(2010) 516 → (2011) 189 → (2012) 324  
(Source : The 2013 Marine Product Safety Inspection Manual, National Fisheries Products Quality Administration Service)

At the same time, 3,493 cultured marine products were subject to a safety test. There were residual animal chemicals as trout contained malachite green and leg lobster had chloramphenicol. The relevant farms were subject to expanded a safety testing. Non-conforming marine products were destroyed or subject to delayed release, securing safety of marine products in the market.

The inspection of radioactive matter became stronger with an increase of national interest after a nuclear accident in Japan. For 16 major fish species in Korea, weekly radiation testing was planed and based on tests of 510 marine products from near and far seas such as squids, all samples were conforming. The test species included near-sea halibut, queen crab, herring, squid, tile fish, hairtail, mackerel, yellow, corvina, conch, laver, sea weed, kelp, far-sea pollack, tuna, shark and mackerel pike.

On the other hand, the Ministry selected agricultural and marine foodstuffs from hygienically vulnerable traditional market foods and wholesale markets, which are major trade-routes, based on a history of non-conformity and suspicious items and foods based on test results by overseas and domestic inspection agencies. Then, the Ministry examined a collection of 45,835 agricultural products and 4,750 marine products. As a result, 408 non-conforming agricultural products and 25 marine products were recalled or destroyed.

[ Table 4-1-1 ] Status of Culturing Environment for Agricultural Food and Safety Inspection at the Production Stage(Ministry for Food, Agriculture, Forestry and Fisheries)

(Unit : number, %, Source : Ministry of Agriculture, Food and Rural Affairs)

Year	Number of Tests	Non-conformity (%)	Major Non-conforming Issues	Non-conforming Items	Comment
2012	79,753	1,217(1.5%)	Residual Agricultural Chemicals (Endosulfan, etc.), Heavy Metal(Lead, etc.)	Sesame Leaves, Chives, Korean Chwinamul, etc.	

[ Table 4-1-2 ] Status of Collection and Inspection of Agricultural Products in Distribution(MFDS and Cities/Provinces)

(Unit : number, %, Source : Ministry of Agriculture, Food and Rural Affairs, Ministry of Food and Drug Safety /City, Province)

Year	Number of Tests	Non-conformity (%)	Major Non-conforming Issues	Non-conforming Items	Comment
2012	48,118	426(0.89)	Residual Agricultural Chemicals(Endosulfan, Chlorpyrifos, etc.), Heavy Metal(cadmium, lead, etc.), etc.	Lettuce, Sesame Leaves, etc.	

[ Table 4-1-3 ] Status of Safety Inspection at the Process of Production of Marine Products(The Ministry of Maritime Affairs and Fisheries and Local Governments)

(Unit : number, %, Source : General Food Management Division, Ministry of Oceans and Fisheries, Local governments)

Year	Number of Tests	Non-conformity (%)	Major Non-conforming Issues	Non-conforming Items	Comment
2012	8,372	371(4.4%)	Anti-biotic(Fefloxacin, etc.), Toxin (Paralytic Shellfish Toxin), Heavy Metals (Methylmercury)	Halibut, Eel, Mussel, Sharks	Shellfish Toxin Non-conformity 324(3.9%)

[ Table 4-1-4 ] Status of Collection and Inspection of Marine Products in Use(MFDS and Local Government)

(Unit : number, %, Source : General Food Management Division, Ministry of Oceans and Fisheries, Local governments)

Year	Number of Tests	Non-conformity (%)	Major Non-conforming Issues	Non-conforming Items	Comment
2012	4,878	25(0.5)	Heavy Metal(Methyl Mercury), Microorganism(Colon Bacillus Group, etc.)	Shark, Salmon (for Sushi), etc.	

## 2) External and Internal Conditions and Trends

As the new administration started, one of the nationally focused policies was ‘the fundamental prevention of adulterated food’ as one of the four biggest social vices. There shall be continued surveys and monitoring system to achieve this.

Continued news about unexpected food safety problems and accidents keep the nation anxious. Based on the consumer awareness survey, 33.4% were ill at ease(Statistics Korea, 2012).

\* Leakage of hydrofluoric acid in Gumi city(September 2012) and detection of arsenic from the US rice (September 2012)

Therefore, it will be necessary to arrange proactive responses to hazards and non-conformity as well as thorough safety control from manufacture to distribution, sale and consumption to reinforce consumer's reliability.

## 3. Major Plan in 2013

### 1) Proactive Safety Control for Agricultural and Marine Products

In order to arrange thorough, scientific and efficient safety management system from manufacture and storage to distribution and sale, the Ministry of Agriculture, Food and Rural Affairs(MAFRA), the Ministry of Oceans and Fisheries(MOF) and metropolitan cities and provinces have arranged close cooperation system. Based on close cooperation between agencies, safety control plans will be arranged with inspection of goods in distribution. There will be expanded inspection rates and subjects to strengthen inspection of non-conforming products as well as data about hazards. The non-conforming agricultural and marine products will appear on the 'Food Nara' on the website of the Ministry of Food and Drug Safety. As necessary, the data will be shared with consumers through press release, which will fundamentally suspend distribution and consumption.

## 2) Safety Management System and Guideline for Agricultural and Marine Products

The Ministry of Food and Drug Safety aims to establish and execute the 2013 Safety Survey Plan through collaboration with the MAFRA and the MOF to arrange the system to check safety and residual substances, to prepare for safe control guidelines to be reflected on the sites. It aims to provide education and promotion to manufacturers, distributors, sellers and consumers of agricultural and marine products, to expand HACCP to secure safety and improve hygiene of agricultural and marine products, to offer technological support, to strengthen cooperation to eliminate defective or adulterated products in cooperation with the National Agricultural Cooperative Federation and the National Federation of Fisheries Cooperatives based on MOUs to arrange collaborative system covering manufacture, distribution and consumption.

## 3) Education and Promotion Related to Safety of Agricultural and Marine Food

The aim is to provide guidance and education to agricultural and fishery population about safe use of agricultural chemicals and antibiotics to raise consumer awareness of safety of agricultural and marine products. The guidance and education is provided in cooperation with the MAFRA, the MOF, cities and provinces, agricultural and marine cooperatives for safe distribution and sale of agricultural and marine products.

## 02

Expanded HACCP  
Application

### 1. Progress

The Republic of Korea introduced HACCP as a program to prevent hazardous elements for safe manufacture and distribution of livestock products in 1998 to slaughterhouses and processing plants, expanded to all food networks including farms, shops, etc. The country has arranged a system to apply HACCP from farm to table.

Feed mills were subject in March 2009. As of 2012, 97 out of 98 assorted feed mills(99%) are subject. At the manufacture(farm) stage, there has been expansion from pig farms in 2006 to cattle farms in 2007, chicken farms in 2008 and duck farms in 2009. 4,059 out of 19,080 farms(21.3%) are subject to the system.

Since the introduction in 1998, slaughterhouses became mandatory subjects in 2003. As of 2012, there are 141 certified ones.

As for processing plants, the certified number increases rapidly. HACCP takes up 88% in the total manufacture. On the other hand, it is slow at distribution stages with 0.8% for meat sale and 1.8% for keeping and transportation. However, large distribution networks may become far more facilitated.

### 1) HACCP at Manufacture Stage(Farms and Feeds Mills)

As for feed mills, between March 2009 and December 31, 2012, 97 out of 98 assorted feed plants(cumulative) were HACCP-certified. In March 2009, the Ministry of Food, Agriculture, Forestry and Fisheries became responsible to designate feed mills for HACCP and the Korea Livestock Products HACCP Accreditation Service was commissioned to implement this.

As the related law was revised in 2006 to apply HACCP at the breeding and rearing stages, by stage, HACCP was applied to farms, covering pigs in 2006, cattle in 2007, chicken in 2008 and duck in 2009. As of December 31, 2012, at the stage of breeding and rearing, by type of animal, 2,179 sites(cattle), 915 sites(pigs), 880 sites(chicken) and 85 sites(duck) were designated. There are guidelines and models to be applied by animal types.

### 2) HACCP Application to Slaughterhouses and Milk Collection Sites

With an aim to settle HACCP at slaughterhouses, mandatory application was arranged to be yearly from July 2000 to June 2003 according to the size of slaughter. From July 1, 2003, all slaughterhouses were subject to HACCP and the authorizing cities and provinces should check the application. So far, 86 cattle and swine slaughterhouses, 43 chicken slaughterhouses and 12 duck slaughterhouses apply HACCP. As for milk collection sites, it began on November 27, 2007 and 30 have been designated.

### 3) HACCP Application to Livestock Products Work Sites

At the processing stages, the designation covered 1,078 packaging companies, 359 meat processors, 75 dairy processors and 35 egg processors, totaling 1,547. At the distribution stage, the designation included 7 keeping companies, 32 transporters, 390 meat sellers and 26 edible egg collectors and sellers.

### 4) Livestock Product HACCP Designation and Follow-up Management

For effective implementation of HACCP, in 2006, the Korea Livestock Products HACCP Accreditation Service was established to for HACCP assessment. As for slaughterhouses as mandatory subjects, consumer groups shall objectively assess HACCP management capacity every year.

In 2007, the effective HACCP period(3 years) was introduced for stronger follow-up control of HACCP designated companies. In 2011, the regular review of HACCP designated companies by the Korea Livestock Products HACCP Accreditation Service was removed. Also, the follow-up management of the designated companies was transferred to Metropolitan cities and provinces. Individual cities and provinces shall manage and supervise hygiene control standards for slaughterhouses, livestock processing sites, milk collection sites, and meat packaging companies once a year.

The Ministry of Food and Drug Safety manages sets up the HACCP standards and verify propriety while the Korea Livestock Products HACCP Accreditation Service surveys and assesses transporters, keepers, sellers and farmers. The latter designates and review the extension of HACCP. This has enabled multi-dimensional management through the division of labor among the central government, local governments and accreditation services.

## 2. HACCP Performance for Livestock Products

As the HACCP application expanded from production to sale, including slaughterhouses, processing sites and farms, sanitation improved significantly. In a slaughterhouse where HACCP application is mandatory, it is possible to confirm the preventive effects such as a decrease in microorganism contamination and violation in terms of residual materials. The detection of microorganism in meat increased from  $10^5\sim 10^6/g$  in 1998 to  $10^2\sim 10^3/g$  in 2010. The violation of the standards for residual hazardous materials fell from 0.2% to 0.15% over the same period. Also, training for businesses and HACCP responsible staff, on-site technological guidance and seminars have gradually increased the HACCP capacity of designated companies.

On the other hand, HACCP is run spontaneously and based on some policy incentives but the motive for progress tends to be poor. HACCP certification does not lead to economic gains and the will of companies for hygiene is poor than that of advanced countries. As for supply to military bases and schools, the incentives for HACCP products are limited, indicating insufficient institutional inducement for small companies, farms and shops. As for edible meat, even if it was manufactured at an HACCP farm, it will be difficult to handle it at HACCP shops, rendering the motivation for participation of farms low. The expanded promotion and education about HACCP for consumers increased consumer awareness from 18.1% in 2008 to

26.5% and 59.8% in 2010 and 2012, respectively but the market tends to fall below the growth. This may be because the participation rate of large companies with higher sale ratios is low and there are not many chances for consumers to experience.

### 3. Expanded Application of Livestock Product Safety Control Standards(HACCP)

#### 1) HACCP as Duties for Vulnerable Areas Including Dairy Products Much Consumed by Children

Milk collection sites to produce crude milk as a raw material for milk, milk powders and ice cream much consumed by infants and children who are hygiene-vulnerable and milk-processing sites to directly produce milk-processed products require higher levels of hygiene. It is necessary to improve the hygiene levels. Therefore, the sites subject to mandatory application of ‘Independent Safety Control Certification Standards’ under Article 9 of the 「Livestock Products Sanitary Control Act」 will expand from the current slaughterhouses to milk collection sites and livestock processing(dairy processing) designated under the Ordinance of Prime Minister.

[ Table 4-2-1 ] Stages to Introduce Mandatory HACCP Application to Farms

Time Introduced	Milk Collection Site(Daily Average)	Dairy Processing Plants(Annual Sale and Employee)
January 2014	150 tons or more	
January 2015	75 tons or more and below 150 tons	2 billion won or more, 51 persons or more
January 2016	Below 75 tons	500 million won or more, 21 persons or more
January 2017		100 million won or more, 6 persons or more
January 2018		Below 100 million and five employees or below

#### 2) System Improvement to Reinforce Awareness, ‘HACCP=Safety Secured’

Hazard Analysis Critical Control Point(HACCP) seems difficult and professional. The term will be revised as ‘Safety Control Certification Standards’ to help consumers to understand the meaning as safely managed livestock products, which may increase awareness of HACCP, promote demand and facilitate HACCP.

Also, the livestock HACCP symbol is different from the food HACCP mark, confusing

companies and consumers. This will be revised for unification with changes to the related regulations(Hazard Analysis and Critical Control Point System).

### 3) Comprehensive HACCP Application to All Processes from Farming to Sale

HACCP may be applied to all sale or farming sites according to the Livestock Products Sanitary Control Act. However, it will be designated at each distribution stage, presenting a limit that the designation does not ensure integrity in connection. For example, edible meat will be distributed through various routes such as farms, slaughterhouses, packaging sites, transportation sites, keeping sites and sale shops. If one stage has not been designated, the levels of hygiene will differ, making the designation and application of HACCP at the remaining stages meaningless.

Therefore, the Livestock Products Sanitary Control Act shall arrange the Comprehensive Safety Control Certification System which will certify that livestock products have been in compliance with the standards for safety control certification at all stages. The livestock cooperatives, brand management entities and large distributors which can control HACCP at all livestock distribution stages will be able to be certified as companies validated through the comprehensive safety control. This is expected to promote national health through the expanded supply of safe and sanitary livestock products based on scientific analysis and control of hazardous materials at all stages.

# 03

## Safety of Imported Livestock and Marine Products

### 1. Safety of Imported Livestock Products

#### 1) Current Status

The increase of imported livestock products involve possibilities of accidents in safety. Overseas accidents related to livestock products continue every year, including mixture of noxious materials or environmentally hazardous materials in the processes of manufacture and distribution due to industrial development.

#### (1) Inspection of Imported Livestock Products

Inspection of imported livestock products shall cover the contents of raw materials, usability and standards of labeling to check if the related contents are appropriate based on the import declaration documents.

Hazard-concerned livestock products which are imported first, by an importer who has a previous non-conforming case or was subject to administrative measures due to false declaration and have the case of hazard occurrence domestically or overseas will be subject to detailed inspection(random sampling included), ensuring a thorough control at the stages of import and customs clearance.

## (2) Livestock Products Imported in 2012

Based on the status of import declaration for livestock products in 2012, there were 80,147 reports, 1,112 Metric tons and 3,927,870,000 USD, involving 52 countries including the USA and Australia.

By a type of inspection, there were 70,785 document and sensory reviews(88.3%), 1,920 laboratory test(2.4%) and 7,442 random sampling tests(9.3%). There were 9,362 laboratory test and random sampling tests(11.7%) for hazardous products such as first-imported livestock, non-conforming livestock and others.

## 2) Major Performance in 2012

Through only the livestock products produced from approved sites are allowed for import, safety is secured with that stronger proactive prevention of hazardous livestock products. 76 overseas sites were checked for hygiene in eight countries including Chile, Uruguay and the USA.

The information of detection of zilpatero(growth stimulator) from Mexican beef and pathogenic microorganism from Canadian beef processing plant led to our measures to suspend shipment for export from those countries. The information of detection of ractopamine from the US beef and nitrofurans(growth stimulator) from Chinese processed meat led to the decision to strengthen the laboratory test.

## 3) Major Plans in 2013

### (1) Strengthened Proactive Safety Control Prior to Import of Livestock Products

At the import stage, safety of imported livestock products will be secured through thorough document review, sensory test and system. As for likely hazardous livestock products, the rate of laboratory test will increase and the items of test will expand. Also, the data of non-conforming livestock products will appear on the website. If necessary, press release will be available to provide relevant information to consumers.

## (2) Establishment of the Control System for Overseas Livestock Processing Sites

There will be a system to assess the hygiene control system of exporting countries to control overseas processing sites thoroughly. Accordingly, in order to arrange the legal grounds to approve the site and assess hygiene of the importing country upon approval, the 「Livestock Products Sanitary Control Act」 will be revised. Also, the methods and standards for approval of overseas processing sites will be specified while the methods of inspection on the sites will be standardized and professionalized by strengthening expertise through the manual for overseas inspection reports and advance education for the inspection team.

## (3) Rapid Responses according to Information on Hygiene of Livestock Products

There is a plan to collect and analyze overseas hygiene information of livestock products, suspend shipping for export from the site, to expand the range of document review and sensory tests and other urgent responses such as strengthened, consecutive five laboratory test for each import.

## 2. Safety of Imported Marine Products

### 1) Safety Control before Import

#### (1) Current Status

There are six agreements(marine products and live fish for China) with five countries including Vietnam, China, Indonesia, Thailand and Russia. Registration of the processing facilities in exporting countries is mandatory, establishing dual inspection system upon export and import from the parties and suspending import from the facilities found to be non-conforming. Public agencies discuss processing facilities at the party countries and ensure mutual inspection on local sites. Poor areas and methods of improvement are exchanged for the cooperation in hygiene between the two countries.

#### (2) Results

In 2012, for efficient implementation of the marine product hygiene agreement, hygiene inspection was conducted at processing facilities of the parties to the agreement(48 sites, five

times), resulting in corrective measures and improvement on the sites.

### (3) Future Plan

In 2013, inspection of imported marine products was transferred to the Ministry of Food and Drug Safety. There will be a collaboration system as to the hygiene agreement of marine products which used to be controlled by the Ministry of Oceans and Fisheries for joint responses to any problems with exported or imported marine products. Especially, as the quantity of marine products imported from the five hygiene agreement parties takes up about 67% (as of 2012, Marine Product Inspection Data System), there is a plan to strength hygiene control of overseas local processing facilities and prevent introduction of poor products to Korea.

## 2) Safety Management at Importation

### (1) Current Status

Laboratory test is conducted to check if animal medicines remain in the products as they are applied in the fish farming and due to marine pollution and advanced culturing. With an aim to prevent the import of adulterated marine products, those found to be non-conforming frequently will be designated as those subject to intensive control. If there are any data of hazards domestically or overseas, fortified measures are taken, including prompt special inspection.

Document review is to decide conformity with a check of the import declaration documents, covering the products aimed at securing foreign currency, raw materials to manufacture own products, products for research and development, products imported by the governments, local governments or their agencies and others imported consecutively every year and found to have no non-conformity or hazard-related data upon five or more yearly laboratory test (including random sampling).

Sensory test is to decide conformity according to the test standards by summing up a product's properties, taste, smell, color, labeling, packaging status and history of laboratory test. This covers the marine products found to need sensory tests among those subject to document review, those seized and confiscated in bonded areas and others of the same origin, product name, exporter and packaging place.

Laboratory test takes place according to physical, chemical or microbiological methods and covers marine products imported for the first time, products with problems known to contain hazardous materials in Korea and abroad and those found to be non-conforming upon laboratory test and subject to re-import as the same food from the same manufacturer in addition to those whose sensory tests tell higher risks of hygienic problems.

Random sampling takes place according to physical, chemical and microbiological methods for marine products except for those subject to laboratory test. This includes the marine products found to be necessary to secure safety of imported items by the Minister of Food and Drug Safety among those subject to document review or sensory test as well as those of frequently non-conformity decisions due to excess of the results from laboratory test and standards.

## (2) Results

In 2012, special inspection was conducted for the quick check of contamination from hazardous materials as there occur domestic or overseas hazard-related data on those which are not allowed in food and there were 15 such substances including malachite green and nitrofurans. Those found non-conforming frequently such as carbon monoxide were designated as the subjects of intensive control(18 items from 10 countries in the first half of 2012 and 17 items from 10 countries in the latter half), leading to higher ratios of laboratory test and intensive control.

## (3) Future Plan

Marine products, even of similar species, differ in prices greatly and it is important to confirm the product name declared for import upon sensory testing. In 2013, the inspection of imported marine products was transferred to the Ministry of Food and Drug Safety. There will be exploration and dissemination of knowhow books on the techniques of sensory tests under the category of inspection of imported marine products, which will increase the capacity of inspectors and prevent the introduction of marine products with problems. If there are domestic or overseas hazard-related data, contamination issues shall be checked speedily. The items found non-conforming frequently will be subject to intensive management and strengthened laboratory test, ensuring stronger inspection at the import and customs clearance stages.

# 04

## Expansion in International Cooperation for Hygiene and Safety of Agricultural, Livestock and Marine Products

### 1. Background and Progress

While the Republic of Korea and the ASEAN\* negotiated Free Trade Agreement(FTA), the latter wanted the Republic of Korea to share experiences in communication relating to hygiene and safety. The suggestion led to the reflection of the range, implementation and detailed cooperation in the area of Sanitary and Phytosanitary Measures(SPS measures) in the Korea-ASEAN FTA.

With this aim, the(Previously) National Veterinary Research and Quarantine Service(currently, Animal and Plant Quarantine Agency) under the(Previously) Ministry for Food, Agriculture, Forestry and Fisheries began hosting the 「Cooperation Project in the Area of Livestock Hygiene」 in 2008, making a breakthrough for cooperation between Korea and the ASEAN in the area of livestock safety.

The participating countries basically cover the ASEAN member states. They also may be other countries in cooperation with Korea through various routes such as those connected to the Agriculture Cooperation Committee and recipient countries from official development assistance(ODA) designated by the Development Assistance Committee(DAC) under the Organization for Economic Cooperation and Development(OECD). The recipient countries will be asked if they would like to take part in international cooperation projects and only those wishing to participate will be invited.

The (previously known as) National Veterinary Research and Quarantine Service is the host of the hygiene-area cooperation projects. The year of 2012 was the fifth occasion. The number of countries and participants increased little by little every year. In 2012, there were 26 participants from 14 countries.

## 2. Major Project Contents

Considering the limits of budget and human resources of the host, the fifth of 2012 livestock hygiene cooperation project was conducted for eight days, shorter than the previous occasions. The number of working days was five, which is relatively short. There were 19 participants from ASEAN member countries, two from the Azerbaijani Republic, one from Bangladesh, two from Bhutan and two from Sri Lanka. There were 18 males and eight females.

The project mainly consisted of the introduction to inspection and testing headquarters, visits to laboratories, visits to livestock manufacturers and private companies, on-site meetings, presentation of each country's livestock safety management system and participation in the autumn symposium of the Korean Society of Veterinary Science.

The participants were very interested in high-tech equipments and facilities when visiting testing rooms handling microorganism and residual substances and had good discussions with corporate participants when visiting dairy or meat processing plants. The participants from 14 countries presented their livestock safety control system such as status of livestock and regulations as well as livestock import procedure, securing a lot of attention and encouragement.

Meetings with dairy processing associations, meat processing associations and member companies from chicken export projects helped exporters to obtain information necessary for export from local managers or discussed their problems while questioning about unclear procedure upon customs clearance as well as import-related laws and regulations. They took advantage of the opportunity to learn about matters to be concerned and complied when exporting Korean livestock products to Asian countries.

The participants closely checked the raw meat management, temperature control and processing processes upon their visits to milk and meat processing facilities and found the hygienic working environment, microorganism and residual substance inspection system and employee safety awareness reliable.

Finishing the seminar, some countries wanted the cooperation project to cover wider areas. For example, Mongolia asked for the cooperation in relation to the laws of food safety and food inspection methods while Cambodia wanted tailor-made training where they could specifically acquire Korea's laws and systems related to hygiene. Sri Lanka and Bhutan mentioned their problems with lack of system and expertise and asked for cooperation to improve these problems.

### 3. Project Assessment

Based on results of a survey with the participants upon the closure of the 「2012 Asia Livestock Safety Management Seminar」, the level of satisfaction with the seminar preparation, presentation, program organization and management was high('Very Helpful' was 50~62%). The participants found that the seminar was very helpful for their works upon return to their countries.



[ Figure 4-4-1 ] Q&A in a Conference

However, 34% said that the seminar period was short and some wanted more participants. The locations and facilities for accommodation were satisfactory but 12% found food ordinary or unsatisfactory, necessitating more concern about these convenience issues.

To assess this cooperation project conducted mostly with seminars, various and comprehensive subjects were selected, placing a certain limit on more in-depth understanding. It may be necessary to select specific subjects to conduct intensive analyses and discussions, reinforcing substantial impacts of the cooperation projects.

### 4. Expected Effects

International food trades continuously increase with the establishment of the World Trade Organization(WTO) and Free Trade Agreements(FTA). Especially, as domestic food prices lose competitiveness, there are increasing trends to import food from East Asia as these countries provide products at lower prices.

The cooperation projects in the area of hygiene with Asian countries will promote our understanding the country's advance livestock hygiene and safety system. This will improve the hygiene system of relevant countries. It will ultimately increase safety of livestock imported from these countries.

At the same time, the data about the livestock hygiene management system and status of management of participating countries will be collected and shared with domestic exporters. There will be communication with private companies wishing to export livestock to Asian countries, removing barriers to Korea's livestock trade which is safe, hygienic and high in quality.

Hygiene experts from participating countries can check directly how hygiene management is conducted from the supply of raw materials to the manufacture of final products as they visit each country's excellent livestock manufacture facilities. This will strengthen the reliability of the countries' livestock safety.

It is also necessary to continue amicable relationships among livestock safety experts from Korea and the ASEAN by regularly providing Korea's current hygiene and safety issues as well as the changes, which is a follow-up measure and services for the seminar participants. Such efforts will maintain closer cooperation system in Asia in bilateral or multilateral international agreements in more diversifying and complex international dynamics. This is likely to contribute to a higher position and negotiating leverage of Korea.

Especially, human networks among countries will strengthen problem-adjusting and solving capacity upon accidents of hygiene and inspection which are likely to occur in increasing international trade, contributing to smooth and amicable problem solving. This will prevent accidents from developing into diplomatic conflicts.

## 5. Future Direction

On March 23, 2013, food safety control affairs were entrusted to the Ministry of Food and Drug Safety. As a result, it is necessary to expand hygiene and safety control seminars to marine products over a short period of time and cover agricultural products in the long term.

At the moment, there are many problems to be solved such as labor, budget and process. These can be overcome with a domestic general recognition to improve hygiene and safety of agricultural, livestock and marine areas in Pan-Asia.

While specific ways for realization shall be checked further for efficiency, seminars shall be conducted over a same period rather than divided periods. Considering specificities of each area such as the methods of precise inspection, standards setup and customs clearance, teams shall be set up by areas of agricultural, livestock and marine products. At the same time, to increase substantial effects of seminars and level of understanding, the period of time for the practice of inspection related to microorganism and residual materials shall be increased. Also considered is an increase of event periods with programs such as documentary reviews and visits to sites of precise inspection.

It is also necessary to expand communication and exchange with private companies to find ways to solve fundamental problems mutually by identifying real problems with export and import of agricultural, livestock and marine products so that seminars can provide substantial and visible effects rather than limited impacts such as governmental information exchange or human networking.

Also, despite improved hygienic system or inspection capacity through seminars, considering relatively poor economic conditions and limit to technological application, it may become necessary to combine the provision of high-tech inspection equipments, introduction of local inspection techniques and technological guidance. It is hoped that the Republic of Korea provides an ideal model for the currently promoted collaboration project.



2013 MFDS Report Ministry of Food and Drug Safety



# 05

## Drugs

01. Support of Safe and Appropriate Drug Uses
02. Rapid Support on Commercialization of Drugs
03. Quality Management Base Establishment for the Safe and Good Drug Provision
04. International Cooperation in Pharmaceutical Sector



## 01

**Support of Safe and  
Appropriate  
Drug Uses****1. Establishment of the Korean Institute of Drug Safety(KIDS) and Systematic Analysis and Management of Adverse Effects**

The major change in the field of drugs was the establishment of the Korean Institute of Drug Safety(KIDS) in 2012. This transition was significant in that the domestic market started to systematically and scientifically analyze the safety problems of adverse effects of drugs. The Korean Institute of Drug Safety was established to provide safety information about adverse effects and to clarify the reasons of pharmaceutical accidents in accordance with Clause 3 and 4 of Article 68 of the 'Pharmaceutical Act' on April 17th, 2012. Dr. Park Byung Joo(Preventive Medicine) was appointed as the first president and 35 people in 5 teams(Safety Information 1, Safety Information 2, Dynamic drug, DUR information and Management team) are currently at work.

The reported adverse effects of drugs have rapidly increased due to the continuing educational and promotional effects of medical and pharmaceutical experts and consumers, with 92,615 cases reported and 296,000 cases accumulated. The 'Regional Drug Safety Center' accounts for the largest proportion of the reported adverse effects, which amounts to 70% of the total reported cases. Consumer reporting accounts for 0.2%, which increased at large compared to 0.05% in 2011. The report materials of adverse effect are acculturated and managed by the Korea Adverse Effect Reporting System(KAERS) of KIDS and the reporting

frequency between specific medications and adverse effects is analyzed through the system.

[ Table 5-1-1 ] The Adverse-effect Reporting Status of Domestic Drugs

Year	1989~2006	2007	2008	2009	2010	2011	2012
Reported number	9,939	14,453	12,796	27,010	64,143	74,657	92,615

(Unit : case)

The adverse effect reporting from pharmaceutical companies and wholesalers, medical institutions and pharmacies became mandatory to the amendment of the 'Pharmaceutical Act' on June 7th, 2011(established as Clause 8 of Article 68) and a fine of less than 1 million won was imposed upon violation of the Act. In particular, the cases of serious adverse effects causing death, malformation and significant or continuous deterioration should be reported within 15 days from the reported date to KIDS.

In addition, the adverse effect reporting center(T.1644-6223) was installed in the KIDS for safer drug sales and reporting adverse effects at convenience stores.

The Local Drug Safety Center was introduced in 2006 in order to raise the awareness of adverse effect, expanding increasingly from 3 in 2006 to 20 in 2012. The center is distributed across the nation, 11 in the capital area(Seoul, Incheon and Kyunggi), 2 in each Daejeon and Chungcheong, Daegu and Gyeongbuk, Busan and Gyeongnam, Gwangju and Jeolla and 1 in Gangwon, mostly operated within advanced hospitals. In the future, the Local Drug Safety Center will be expanded even to the Pharmaceutical association, Consumer groups, inducing and enlarging the adverse effect reporting of pharmacies and consumers. The Local Drug Safety Center educates local hospitals, pharmacies and consumers to the truth of adverse effects and counsels them.

The KIDS performs analysis and evaluation of the accumulated reporting data on adverse effects in two steps. In the first phase, the combination of medicine and harmful case of the highest reporting frequency(Signal) are extracted from the data analysis of KAEFS. And in the second phase, the extracted 'Signal' is assessed by a literature review, an overseas status analysis, and an expert. In 2012, approximately 125,000 cases were analyzed and assessed. Meanwhile, two components of contrast medium(Iopromid, iohexol) and one component of antibiotics(Ceftriaxone) were instructed to add new information on abnormal effects to the precautions(September 18th, 2012).

In addition, overseas safety information is collected and identified in real time, resulting in appropriate safety measures through self review and the advice from the Central Pharmacist

Committee(Sales stops, restoration, disposal or instruction on permission changes).

In the last three years, the status of safety measures following the model of overseas information is estimated to be 82 cases including sales stops on 144 cases of 'sibutramine', 53 cases of 'Ceratiopeptidase' in 2011 and permission changes on 82 cases of 'Thalidomide'.

[ Table 5-1-2 ] Drug Safety Information Processing Performance in 2012

(Unit : case)

Classification	Total	Status of Measurement			
		Sales Stop	Safety Notice	Permission Change	No Specific Measure
Cases	5,150	-	15	67	5,068

The Ministry of Food and Drug Safety is planning to respond to safety matters about adverse drug reactions actively, improving the existing system and pursuing a new direction in 2013. First of all, the 'Drug safety information management regulations'(the Ministry of Food and Drug Safety) will be amended quarterly to promote regular reporting of pharmaceutical companies. In addition, the Korea Pharmaceutical Association will be appointed to the local pharmacy safety center so that the adverse effect reporting system of pharmacies can be activated. In addition, the development of safety information utilizing the adverse effect reporting data will be constantly expanded. Drug prescription, insurance benefits materials, distribution and supply performance, national health examination data, national statistics on disease and death will be integrated and analyzed so that the adverse effect will be detected in earlier stages for high level safety assessment.

## 2. Provision of Appropriate Drug Use Information

In 2012, the DUR information team in charge of the development of appropriate information for drug use was newly established in the Korea Pharmaceutical Safety Institute, so that the efficient information system was built. 104 cases of medication contraindicated for pregnant women that were announced in 2008 were updated, developed and provided with the latest information as well as diabetes, antidepressant medicines. 102 cases of antihypertensive and lipid lowering drug efficacy were developed and provided in order to provide a wider variety of safety drug use information.

In the future, the Ministry of Food and Drug Safety is planning to promote efficacy through the education and promotion for medical professionals and the general public by enlarging the

development and utilization of drug safety information such as drug dosing and allergies.

Thus, the safe and appropriate drug use and prescription will be promoted to make a healthy society.

[ Table 5-1-3 ] Drug Designation and Administrative Status of 'Combination Taboo', 'Age Taboo' and 'Pregnancy Taboo'

(Unit : number)

Year	2004~2008	2009	2010	2011	2012	Total
Incompatibility	308	48	117	139	-	612
Age Restriction	44	58	6	19	-	127
Contraindication in Pregnancy	314	-	-	-	1041)	418
Subtotal	666	106	123	158	104	1,157

### 3. Negative and Bad Drug Distribution Block and Network Activation

Negative and bad drug means ① a drug not authorized under the legislation of pharmacist, ② a less effective drug from the licensed content, ③ and a counterfeited or tampered drug.

Since 2000, a variety of social environmental changes including medical reform, flooding information and communication technologies presented by the Internet have diversified illegal distribution channels. Also, it has broken down the boundaries among countries. As a result, the circulation and diffusion of unauthorized drugs have been widely available.

In response to this, the Ministry of Food and Drug Safety and the local government have established an integrated management system monitoring illegitimate act to promptly crack down on unlawful distribution of medicines. The association of internet companies and their members signed a memorandum of understanding to perform cyber monitoring so that illegal drug sale websites or postings are deleted and blocked.

The Ministry of Food and Drug Safety will take full advantage of the authority to investigate with the central investigation association ① by emphasizing that drugs distributed on the internet are negative and bad products, ② by raising awareness of the illegality of Internet sales and its purchase, ③ by promoting the damages of prohibited drug sales on the internet as well as guiding the limit of right of consumers on the drug purchase on the internet, so that forbidden drug sale on the internet is ceased. On the one hand, the cooperation system along with foreign countries is reinforced through the 'IMPACT'(International Medical Products Anti-Counterfeiting Task force), the World Health Organization(WHO) and participation in

the illegal drug co-response project(Pangea VI) organized by INTERPOL.

#### 4. Establishment of a Management System for the Prevention of Drug Abuse

##### 1) Reinforce the Safety Management of Narcotics and Drug and Strengthen the Inspection System with Relevant Agencies

To crack down on the use of illegal narcotics and drugs, the Attorney General's Office, the Police Department and other related agencies periodically conduct joint inspections regarding the psychotropic appetite suppressant, propofol, which has become a social issue.

In particular, as drug abuse of propofol occurred continuously, the Attorney General's Office, the Police Department and other related agencies established a joint inspection system inspecting 140 hospitals handling propofol and prosecuted 74 violating businesses.

In the event of theft or loss of drugs, law enforcement agencies make thorough investigations by taking administrative actions on the spot after finding violating cases in accordance with the relevant laws and regulations. In addition, if necessary, the commands on changes and on-site training are conducted in parallel.

Meanwhile, continuous monitoring is carried out throughout the year to block on-line distribution of illegal drugs on the internet. Now the illegal cases requested to be investigated by police(strong crime investigation department) and the Korea Communications Standards Commission or portals have been significantly cracked down.

##### 2) The Efficient Follow-up for the Prevention of Narcotic Raw Materials(Precursor)

The term narcotic raw materials(Precursor) signifies materials can be used under the process of manufacturing narcotics or psychotropic substances among the nondrug type of materials. 30 substances are defined in the 'Act on the Control of Narcotics' in accordance with a Presidential Decree. In particular, group 1 of raw materials, which includes ephedrine and 22 other substances, is likely to be used in the manufacture of illegal drugs, and their import and export require approval of the Ministry of Food and Drug Safety. In addition, the records of manufacture and transaction of raw materials in both group 1 and group 2 should be retained for 2 years. In cases of transactions that are likely to be theft and illegal trade are obliged to report to the Minister of Justice.

In particular, to reinforce the follow-up on the compliance with the enforcement of the permit system on import and export for suppliers and manufacturers of group 1 of raw materials(June 8th, 2012), 118 companies were inspected on the appropriate handling of raw materials.

In addition, not only cooperative system with domestic relevant institution such as the Attorney General's Office, but also raw material trading status reporting(INCB), Project Cohesion, Project Prism and the DICE program strives to prevent illegal drug manufacturing, importing, sharing of raw materials of illegal drugs.

### 3) Support for Korean Anti-drug Campaign Center for the Fight against Illegal Drugs

The Ministry of Drug and Food Safety proceeds the business of promotion, education, and rehabilitation of addicts to prevent illegal drug damages through the Korean Anti-drug Campaign Center. The Korean Anti-drug Campaign Center was established from the Korea Pharmaceutical Association as a foundation by civil code in 1992 and is currently the statutory organization by the Act on the Control of Narcotics in 2002.

The Korean Anti-drug Campaign Center has fought against illegal drugs actively through 12 branches including Seoul, Busan, Daegu, Incheon. World Drug Day celebrations, combating drug symposium, anti-drug posters and flash animation competition, illegal drug eradication campaigns were held and advertising activities on combating illegal drugs are widely spread through various media such as TV, radio, cable, subway, city bus, newspaper, billboard, while the website provides information of the dangers of illegal drugs.

In order to increase the effectiveness of preventive education, more than 390,000 people were educated over 4,900 times in 2012 for elementary, middle and high school students. In addition, group counseling programs, peer education programs to train youth as leaders, as well as the program for local residents and parents are held. As a result, more people are aware of drug problems and their interest in combating drugs and training opportunities such as workshops and seminars for professionals in the community is increasing.

## 02

**Rapid Support on  
Commercialization of  
Drugs****1. Deregulation and System Improvement for Promoting Global Competitiveness**

The Ministry of Food and Drug Safety has reduced unnecessary procedures by reducing developing costs and facilitating rapid market entry cost of new drugs through various civil associations and meetings such as the 'Food and drug regulatory committee', 'Drug development association', 'Drug safety policy meeting' and 'Public meeting'. Thus it promoted the self-improvement system based on the submitted civil complaints to the Ministry of Food and Drug Safety. Additionally, in 2012, the screening system was advanced to support the pharmaceutical industry in accordance with the Korea-U.S., Korea-EU FTA. The feedback collection system and civil associations to improve systems are to be proceeded.

To strengthen the competitive power of pharmaceutical industry, the developing cost needed to be lowered to quicken market entry of newly developed drugs. In 2008, the quick screening system for newly developed medicines was introduced, and the drug commercialization support center was operated to support technical consultation from the early stage of R&D. In addition, drug research developers could obtain authorization of item without the approval of manufacturers. Thus, the commission of manufacturing as a whole was made possible due to the separated drug manufacturing system. To maintain the standard and consistency in handling of complaints regarding medicines, the 'Drug approval(Report) community' was established and operated. In addition, in 2011, introduction of the zero-phase clinical trials was

settled to improve the successful rate of drug development following the model of zero-phase clinical trials from the U.S., Europe and Japan. Toxicity tests such as incurable cancer drug based on the submitted data were exempted. The manufacturing safety standards for generic medicines of high frequency, safety and validation were expanded and the screening for safety and validation and pre-screening GMP validation data submission were exempted.

Improvement for the GMP system was demanded because of drug supply disruptions due to plant relocations, which caused shipment delays due to quality inspections of the finished products. Also, the international harmonization of the Korean GMP system was needed to enhance international competitiveness for the domestic pharmaceutical industry to enter into the global market.

For this, simultaneous validation during revalidation was permitted and the inspection on finished products which are completed by validated test was exempted. Also, data submission regarding the final packaging process in the pre-screening GMP evaluation was exempted to avoid re-packaging. In addition, drug handling period was shortened by unifying the GMP(raw material, finished product) and simplifying the GMP evaluation and document submission procedures. When it comes to the establishment of a new working place within a drug manufacturing place, GMP evaluation was replaced by a transitional management. The manufacturing and quality management was reasonably arranged by maintaining the finished test samples and one manufacturing unit. Furthermore, for international cooperation, a new system that approves large amounts of liquid medicines before the result of sterility test based on the manufacturing process management data was introduced, so that productivity was heightened by shortening waiting time for the sterility test. For cephalosporin antibiotics and cell toxic anticancer drugs, the facility standard was strengthened to separate the manufacturing facilities from manufacturing facilities of other drugs.

To support exports, the approval time was shortened by exempting the pre-screening GMP evaluation data submission and audit fees. In addition, the approval handling period was shortened from 70 to 25 days since drugs for export undergo separate approval processes. The pre-screening inspection for companies was conducted to prepare them for the requirements of exporting countries. The export support public-private partnerships and Drug Promotion Team were configured and to support foreign registration, which provided comprehensive information such as foreign drug registration(approval) processes and market conditions.

To reduce costs for pharmaceutical manufacturing, import and approval, the scope of cross-

examination was expanded. When it comes to mass change of items, deviation tests were to be made for only one test. In cases where the same material is used for the manufacturing of both drugs and medical devices, it was improved so that the facilities and equipment for drugs could be used for medical devices as well.

For the enlargement of patient treatment opportunities, the portability of psychotropic drugs for self-treatment during travel was allowed. To reduce the burden for patients with rare diseases, 6 new elements of rare drugs, such as 'caffeine citrate' for premature infant apnea, were added to support the rapid treatment of patients in 2010. In addition, in 2011, as regulations regarding rare drug designation were revised, drugs with urgent need of introduction were additionally designated(nine elements) and a total of 138 rare drug ingredients were specified. In addition, in 2012, the 'Rare drug development and supply support measures' are to be planned to contribute to the opportunities of rare disease treatment.

The small packing unit provision system, which is more than 10% of supply has been introduced for the settlement of safety problem and the disposal of distributed drugs since 2006. The low cost drugs were exempted from the applicable targets on August 1, 2008 and the burden of suppliers was reduced as the supplying inventory included the small package stocks. On July 3, 2009, the small packaging items were applied differently, less than 10% of supply, in the Korea Pharmaceutical Manufacturers Association as well as a committee of the Pharmaceutical Association.

When it comes to 175 items on June 4, 2010 and 810 items on March 11, 2011, they were differently applied for the approved items in the committees. In addition, the 'Drug supply information system of small packaging unit' was established so that the small package providers of pharmaceutical companies and consumers of the Pharmaceutical Association could cooperate.

For the competitive enhancement of the pharmaceutical industry due to the Korea-U.S. Korea-E. U. FTA, the 'Authorization advancement of examination system' and 'Competitive improvement of the pharmaceutical industry through the administrative procedure regulation' were planned in 2012. Moreover, 'the Drug development council' which has been operated since 2008 is to be enlarged so the in-depth discussions for the practical complaints and policy alternatives can be provided continuously.

## 2. Trusted Drug Approval

The Ministry of Food and Drug Safety has continuously supported the predictable approval screening, professionalism of auditors, improvement of screening criteria and international cooperation. Starting from the Preliminary Examination, drug item presentation and exposure of drug screening results of 2009, the annual permit report publication, new approval casebook publication and disclosure of parenteral drug product ingredient were activated in 2011 for the enhancement of the domestic development of generic drugs. In 2012, the 'General Guidelines for Drug Approval' was prepared for the quick approval of general drugs in accordance with policy changes regarding drug sales in pharmacy and reclassification of drugs. And, 'Korean Pharmacopoeia' and 'Other drugs pharmacopoeia standards in the Republic of Korea' were revised for the advancement of safety standard criteria.

### 1) The Status of Drug Approval(Report) in 2012

According to the result of the analysis of the Drug Approval(report) in 2012, the approved (reported) number of items was 4,733, and as the following: ▲ 1,002 prescription drugs ▲ 406 generic drugs ▲ 110 raw materials drugs ▲ 3,215 pharmaceutical raw herbs. In particular, generic drugs are increasing; 344 in 2010, 349 in 2011, and 406 in 2012. The results of the analysis according to ailment are as follows: ▲ the nervous system drugs 'Antipyretic, analgesic, anti-inflammatory drugs'(269, 19%) ▲ "Osteoporosis Metabolic Drugs(200, 14%) ▲ Circulatory system drugs such as 'Hypertension'(162, 11%). With institutional support such as increased investment of domestic pharmaceutical companies, the government drug development R&D and pre-review system operations, the development of domestic pharmaceutical drugs has grown in quantity rather than in qualitative aspects, so 3 new testaments, 6 IMD, 2 cell treatments were approved.

[ Table 5-2-1 ] Drug Approval and Reporting Status in 2012

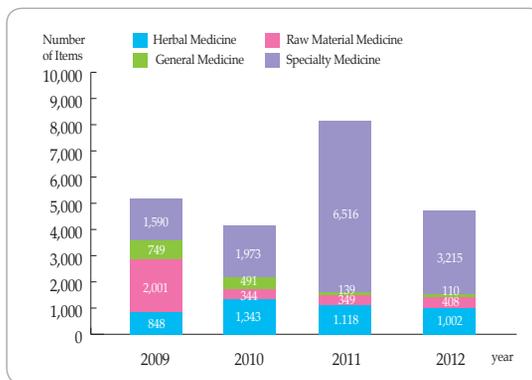
(Unit : number)

Total	Specialty	Generic	Raw Material	Raw Herbs	Remarks
4,733	1,002	406	110	3,215	New Drug 17 New Natural Material 2 IMD 6 Rare Drug 27

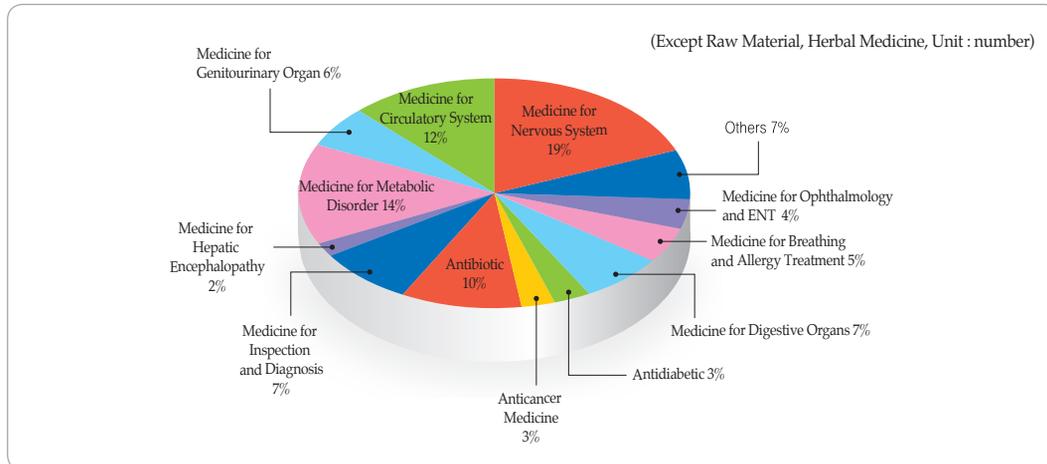
[ Table 5-2-2 ] The Drug Approval and Reporting Status in 2012 Compared to 2009~2011

(Unit : number)

Year	Specialty	Generic	Raw Material	Raw Herb
2009	848	2001 <sup>2)</sup>	749 <sup>3)</sup>	1590
2010	1343 <sup>1)</sup>	344	491 <sup>3)</sup>	1973
2011	1118	349	139	6516 <sup>4)</sup>
2012	1002	406	110	3215



- 1) Specialty Prescription drugs : Permission is increased due to the expiration of re-examination period or patent
- 2) Generic drugs : Permission is rapidly increased of pre-GMP is made mandatory(pharmaceutical manufacturing and quality control standards) by item in June 2009
- 3) Raw material drugs : Permission application is increased due to the authorization of item approval for imported raw materials in December 2009 and pre-GMP Mandatory in January 2010
- 4) Herbal medicines : The application item of manufactory is rapidly increased in accordance with the amendment of regulation on herbal medicines(herbal medicine supply and distribution management regulation; Health and Human Services Notice) from October 1, 2011



[ Figure 5-2-1 ] Approval(Report) Status of Major Remedial Effect Species in 2012

[ Table 5-2-3 ] The Approval Status of Domestic Developed New Drug, IMD, Cell Treatment Drug in 2012

No.	Name of Product	Major Ingredient	Name of Company	Remarks	Date of Approval
1	Supect Caps 100 milligram	Radotinib Hydrochloride	Ilyang Pharmaceutical Co. Ltd	New Domestic Developed Drug	Jan. 5, 2012

No.	Name of Product	Major Ingredient	Name of Company	Remarks	Date of Approval
2	Supect Caps 200 milligram	Radotinib Hydrochloride	Ilyang Pharmaceutical Co. Ltd	New Domestic Developed Drug	Jan. 5, 2012
3	Zemiglo Tab 50mg	Gemigliptin Tartaric Acid 1.5 Hydrate	LG Life Sciences Ltd.	New Domestic Developed Drug	Jun. 27, 2012
4	Apetrol ES Oral Suspension	Megestrol Acetate	LG Life Sciences Ltd.	IMD	Mar. 27, 2012
5	Ridonel D Tab	Risedronate Sodium 2.5hydrate / Cholecalciferol	Hanmi Pharm. Co., Ltd	IMD	Apr. 3, 2012
6	Risenex M Tab	Risedronate Sodium 2.5hydrate / Cholecalciferol	Hanlim Pharm. co. Ltd	IMD	Apr. 3, 2012
7	Letopra Tab 20mg	S-pantoprazole Sodium Trihydrate	AHNGOOK Pharm. Co., Ltd	IMD	Jun. 18, 2012
8	Nasaflex Nasal spray	Mometasone Furoate / Azelastine Hydrochloride	Hanlim Pharm. co. Ltd	IMD	Nov. 16, 2012
9	Motesone Plus Nasal Spray	Mometasone Furoate / Azelastine Hydrochloride	Hanmi Pharm. Co., Ltd	IMD	Nov. 16, 2012
10	Cartistem	Mesenchymal Stem Cell derived from Allogenic Umbilical Cord Blood(Treatment for Osteoarthritic Knee Cartilage Defect)	Medipost Co., Ltd	Cell Treatment Drug	Jan. 18, 2012
11	Cupistem	Mesenchymal Stem Cell Derived from Adipose Tissue (Crohn's Disease Fistula)	Anterogen Co., Ltd	Cell Treatment Drug	Jan. 18, 2012

# 03

## Quality Management Base Establishment for the Safe and Good Drug Provision

### 1. Introduction and Settlement of Good Manufacturing Quality Control Standards at the Level of Advanced Countries(GMP)

#### 1) Introduction of a New GMP

The quality of drugs can be secured only through the systematic management of all of the stages, from the shipment of raw materials to shipment of finished products. The GMP is the regulation to achieve this purpose and it is the necessary standard to ensure the quality of drugs.

In Korea, the new GMP system(post → pre, by formulation → by items, validation implementation, etc.) has been introduced and implemented from January 2008 under the goal of establishing the quality endurance system for the qualitative growth and consumer-oriented quality.

#### 2) Background of System Introduction

In the case of international organizations and foreign countries, the GMP standard has been steadily revised, but the technology management part of the KGMP has not been revised except for some administrative aspects since its announcement in 1977. This is the reason why

KGMP did not keep up with other nations in international harmony.

Since the GMP enforcement for raw drug materials in 2002, the drug quality has significantly been improved. However, the quality validation for 1 item is uncertain as the GMP specified 7 formulation groups. Furthermore, advanced countries already conduct validation which is the key element of GMP. Meanwhile, Korea did not introduce validation, but now realizes the necessity of revision in the GMP standard.

The Korean GMP standard didn't harmonize with international standards and this caused a gap in quality level among domestic companies and difficulties of export and mutual authentication amongst them(MRA).

Accordingly, the efforts of overall quality endurance ranging from raw materials to finished products and competitiveness enhancement of advanced foreign pharmaceutical companies have led to the introduction of a new GMP system.

In the meantime, the Ministry of Food and Drug Safety has upgraded the contents of KGMP to harmonize with international organizations or advanced countries. Creating drafts by choosing the amendment research project for the advancement of KGMP in 2003, the KGMP amendment research team has finally determined international harmony at the presidential advisory committee as well as the advanced medical industry promotion committee. Finally, pharmaceutical law enforcement rules were amended and GMP pre-assessment became mandatory.

[ Table 5-3-1 ] The Main Comparison of Country-specific Pharmaceutical GMP Standard

Standard	WHO	PIC/S	US	EU	Japan	India	Singapore	Korea	
								Before the Amendment	After the Amendment
Pre- GMP Assessment	○	○	○	○	○	○	○	×	○
Validation	○	○	○	○	○	○	○	×	○
Automation Device Management	○	○	○	○	○	○	○	×	○
Deviation Survey	○	○	○	○	○	○	○	×	○
Qualification Assessment	○	○	○	○	○	○	○	×	○
Change Management	○	○	○	○	○	○	○	×	○
Self Due Diligence	○	○	×	○	○	○	○	×	○

Standard	WHO	PIC/S	US	EU	Japan	India	Singapore	Korea	
								Before the Amendment	After the Amendment
Annual Quality Assessment	○	○	○	○	○	×	○	×	○
Safety Testing	○	○	○	○	○	○	○	×	○
Workplace Cleanliness Management	○	○	○	○	○	○	○	○	○

[ Table 5-3-2 ] New GMP Introduction Result

Standard		Jan. 15, 2008	Jul. 1, 2008	Jul. 1, 2009	Jan. 1, 2010
pre-GMP Assessment		New Medicine	Specialty	General	Raw Material and Quasi
Validation	Process	New Medicine	Specialty	General	Raw Material and Quasi
	The Others	-	-	-	○
Change Management		-	-	-	○
Suitability Testing		-	-	-	○
Annual Quality Assessment		-	-	-	○
Deviation Survey		-	-	-	○
Main Raw Material Manufacturers Assessment		-	-	-	○
The Middle Review of Testing Record		-	-	-	○

\*\* The quasi(solidity, liquid)

### 3) The Key Policies for a New System Settlement(2008-2012)

#### (1) Maintenance and Regulations of the GMP Management System

- Revision of Pharmaceutical Affairs Law Enforcement Rules(Jan. 15, 2008)
  - Pre-GMP assessment for each item and validation system introduction
- Implementation of the validation rules on drugs(The Ministry of Food and Drug Safety Notification) (Jan. 16, 2008)
- Establishment of 11 kinds of instruction such as pre-GMP operation instruction for the finished drug items
- Releasing the regulation on GMP standard
  - Shortening pre-GMP evaluation period(120 days → 90 days)
  - Harmonization of the GMP evaluation process and simplification of document

submission (30 → 11 species)

- Improvement of the GMP rating system in manufacture(7 formulation → sterile, non-sterile)
- Improvement of operation guidelines related to the change of management of the GMP facility

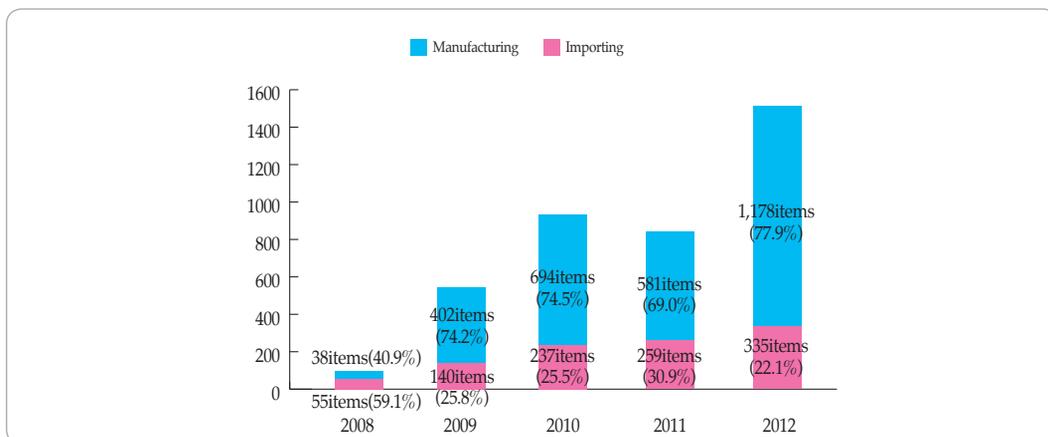
## (2) The Expansion of Good Drug Manufacturing Base by the Active GMP Policy Support

- The GMP system policy briefing and meetings : 20 times
- Validation fieldwork education : a total of 74 times, 1,395 people completed
- The prior practice diligence(Good Visiting Program) for Exporting vendors : 23 times
- Publishing of the GMP system commentary and guidelines : 16 commentaries on the new GMP system
- Providing the guidebook of the GMP standard

### 4) The Introduction of a New GMP(pre-GMP Evaluation for Items)

After the new GMP enforcement, for the last 5 years(2008 ~ December 2012), 115 new testament items, 3,346 specialty pharmaceuticals, 263 generic drugs, 197 pharmaceutical raw materials, a total of 3,921 items were applied. The application items are increasing since the enforcement of system in 2012, the application of domestic manufacturing item increased due to the change of drug regime.

3,073 items for application were completely evaluated. While 224 items were evaluated



[ Figure 5-3-1 ] The Number of Items for Application by Annual GMP Assessment

to be suitable, 2,624 items were suitable after supplementation and 30 items were not suitable. Besides, 195 items were requested to withdraw or voluntarily withdraw. While supplementations were pointed out over all sectors in manufacturing and quality management, the unsuitable reasons were fraudulent documents, lack of manufacturing facilities and non-compliant supplementations.

The GMP assessments regulate on-spot investigation in principle and the due diligence period is exempted for companies that already perform due diligence. Due diligence was conducted in 832 items out of 1,422 items in domestic manufacturing facilities and 590 items in 32 overseas manufacturing facilities such as in Germany, USA, Japan and India .

Meanwhile, domestic pharmaceutical companies have promoted the improvement of the GMP level through the establishment of new facilities by means of the new GMP enforcement. The Ministry of Food and Drug Safety has supported effective GMP policies such as pre-GMP for items and due diligence for exporting companies through various guideline punishments. Thanks to enhancing responsiveness to GMP inspections conducted by international pharmaceutical regulatory agencies, the drug export could be increased according to the improvement of overall drug quality management of the domestic pharmaceutical drugs.

### 5) The Registration Promotion to Pharmaceutical Inspection Cooperative Organization(PIC/S)

The Pharmaceutical Inspection Cooperative Scheme(PIC/S) was established for the international coordination of the GMP and quality improvement of the GMP system to minimize the difficulties arising from different GMP regulation systems among countries. It is a huge international council currently joined by 41 countries in July 2013 in the pharmaceutical sector.

In 2011, the Ministry of Food and Drug Safety and domestic and foreign experts established the foundation for the PIC/S registration by deriving the difference between PIC/S regulations. In April 2012, the Ministry of Food and Drug Safety submitted a PIC/S membership application and in the same year, in May, the rapporteur consisting of four countries including Austria(AGES) was specified at the PIC/S Regular Board meeting.

PIC/S takes 4-5 years to join from application to registration, and the registration approval is completed upon an on-site inspection and document review. If the registration period takes

more than six years, the respective country has to apply again.

In the future, the Ministry of Food and Drug Safety will make internal and external efforts for early registration to the PIC/S and the maintenance of GMP system that is in harmony with PIC/S, as well as proactive responses to the PIC/S evaluation system.

## 6) Future Plans

The Ministry of Food and Drug Safety is planning to support the globalization of pharmaceutical industry through the PIC/S registration and effective consumer-driven GMP policy, so that the GMP management capabilities of pharmaceutical companies can be improved.

At first, the GMP standard for clinical trial, raw material drug, radiopharmaceuticals, medical high-pressure gas are to be provided for system maintenance regarding manufacturing and quality control, which is required for PIC/S registration.

Also, the on-going stability test and validation on herbal materials rather than non-sterile materials will be introduced by complementing the GMP standard. The GMP application will be expanded so that the GMP evaluation is performed upon previously exempted rare drugs, manufacturing standard drugs and export drugs in the approval phase.

## 2. The International Harmonization for the Advanced Drug Safety Standard

'Pharmacopoeia of the Republic of Korea' and 'Quasi-drug pharmacopoeia standards of the Republic of Korea' were revised(December 2012) for the advancement of safety regulation standard and the 'Validation guideline of drug testing method' and 'Commentary'(September 2012) were amended.

The 10th amendment of 'Pharmacopoeia of the Republic of Korea' was amended from the 9th version in 2007, amending a total of 1,559 monograph and axiom items, general testing method and general materials including new 68 items. The monograph of drugs was divided into 2 parts; the first part includes 1,259 frequently used raw material drugs and basic materials; the second part includes other 400 items(179 Pharmacognosy and medicinal herbs, 46 biological, 19 mixed formulation, 140 additives, and 16 non-medical drugs).

In particular, 'Pharmacopoeia of the Republic of Korea' amended the material regulation

including the addition of new material, and breaking down the existing formulation and sterile microbial limit test method to respond the new domestic formulation development for international harmony. And in accordance with the International Union of Pure and Applied Chemistry(IUPAC), the Chemical Abstracts Service(CAS) Registry Number was newly amended so that the confusion coming from difference in names between countries was eliminated and enhanced the convenience of standard search.

'The other pharmacopoeia standards of the Republic of Korea' specify the registry regulation of the drugs commonly used in Korea which are not listed in 'Pharmacopoeia in the Republic of Korea', which was amended as the fourth edition on December 31, 2012 by arranging the items and standard regulation in consideration of domestic drug development, approval, usage status and science technology development. The fourth amendment listed a total of 1,027 items including raw material drug commonly used in the domestic market and 22 items of materials and the general testing method and rules described by monograph were integrated. Part 1 of the monograph listed the commonly used drugs, Part 2 listed the radiopharmaceuticals, Part 3 listed the vitro diagnostic drugs and Part 4 listed additives. The fourth amendment actively converged practitioners' opinions including pharmaceutical industries and testing analysis institutions and reflected the result of research business, so that standard regulations such as the endotoxin establishment and dose method improvement were modernized.

# 04

## International Cooperation in Pharmaceutical Sector

### 1. Globalization of the Pharmaceutical Sector

The WTO made it necessary to have mutually beneficial relationships within the international community to maintain national security and survive in the age of unlimited competition. International harmonization and research collaboration in the pharmaceutical sector have been the essential part through the ICH(Drug international coordination meeting) and the APEC.

### 2. International Cooperation and Trade Work Status

#### 1) Status

The international cooperation and trade work in the Ministry of Food and Drug Safety is responsible by the International Cooperation Office within the Planning and Coordination Bureau. However, the actual analysis, strategy establishment, consultation and implementation of major trade and international cooperation such as the FTA in pharmaceutical sector are mostly done by the ' Pharmaceutical Policy Division' in the Pharmaceutical Safety Bureau. The 'Drug Approval and Patent Linkage Operation TF team'(since March 2012) has been formed and operated in accordance with the Korea-U.S. FTA enforcement.

## 2) The Field of International Cooperation

### (1) Business Support for Public Aid in Medical Drug Sector

Korea is a member of the OECD Development Assistance Committee(DAC) as a country with a 20,000 dollar national income, which started from being a recipient country of development cooperation with a 67 dollar national income. Korea is now a country with the obligation of contributing to international community.

The Ministry of Food and Drug Safety proceeded the ODA invitation training based on drug safety management expertise with the Korea International Cooperation Agency in May 2012. A total of 15 drug regulatory officials from 8 countries of Vietnam, Laos, Cambodia, Myanmar, Indonesia, Bangladesh, Pakistan, Ethiopia participated for 20 days at the headquarter of the Ministry of Food and Drug Safety. In May 2013, those target countries for the invitation training were extended to African countries, and 13 drug regulatory officials from Ghana, Egypt, Kenya, Algeria, Nigeria, Uganda, Senegal participated for 20 days in the second training course. The Ministry of Food and Drug Safety is planning to expand the ODA training courses to twice a year.

### (2) ICH GCG

Korea participates in the ICH-International Cooperation Committee meetings(ICH-GCG) as a member country and joins in professional alliance(EWG, IWG) that develops the ICH guideline such as S10(Optical safety assessment), S1(Drug carcinogenic testing) and Q3D(Mixed metals management). Since November 2013, Korea was appointed as the chair of the representative meeting of drug regulatory authorities among non-member countries such as China, Australia, Russia, Brazil, Singapore and India, and is planning to actively participate in international cooperation with member countries for opinion exchanges.

### (3) Korea, China and Japan Leadership Meeting of Pharmaceutical Sector

The first Korea, China and Japan leadership meeting in pharmaceutical sector was held in Japan(Tokyo) in April 2008, following the agreement on global drug development cooperation such as clinical trials promotion of East Asia in the Health Ministers' Meeting in April 2007. The Joint Research Project on Ethnic Factors in Clinical Data, Information Exchange Scheme, collaborative research projects and the information exchange were agreed upon.

The second meeting was held in December 2009 in Beijing, China. Korea, China and Japan agreed to specific measures for promoting joint research on ethnic factors on clinical data (operating rules, ToR). Japan agreed to coordinate the research project and Korea agreed to coordinate the exchange of information amongst the three countries.

The third leadership meeting was held in Seoul in September 2010. The regulation of working group operation in Korea, China and Japan was determined. In addition, the operating provisions of the scientific research group(Research Group, RG) in the working group were prepared. In the field of information exchange on clinical trials, Korea agreed to create a concept paper based on the results of comparative table of the overview on clinical trials in Korea, China and Japan.

The 4th leadership meeting was held in Tokyo in October 2011. In this meeting, the ongoing researches on national element and project comparisons on clinical trials in Korea, China and Japan were shared and the clinical guidelines(draft) for three countries suggested by China were reviewed.

#### (4) The Operation on Pharmaceutical Sector Councils and Korea-China MOU

Based on the 'Cooperation agreement on food, pharmaceutical, cosmetics, medical devices of the Republic of Korea Food and Drug Administration and the People's Republic of China' in April 2009, the council will support the senior council in each area of expertise including medicines(including herbal), cosmetics and medical device.

Korea held the second Korea-China leadership meeting and working group council on drugs in Seoul on July 26, 2010.

In this meeting, 'Korea-China Symposium on Drug screening assessment', 'Korea-China medicine quality standards meeting' and 'Korea-China medicine authorization auditors meeting' were agreed upon.

The third Korea-China high-level meeting between drug regulatory authorities was held in Beijing in May 2011. In this meeting, the existing MOU signed in 2009 was amended and sectoral cooperation mechanism was newly established in order to promote cooperation across drugs, cosmetics, medical devices, health food that require approval and authorization.

#### (5) APEC Regulatory Coordination Center

Korean 'Harmony initiative' was set as the official agenda for LSIF meeting in February 2008

(Senior Officials Meeting(SOM) I , II discussion(February 5, 2008). The Korean Government announced the supporting plans and future operating plans of The Ministry of Food and Drug Safety at SOM at the third APEC Senior Officials' Meeting(SOMIII) on August 15, 2008 and it was approved at the APEC Summit Meeting in November 2008. After discussions, APEC Regulatory harmonization center guidelines were determined and symposium and workshops for local clinical trial activation, drug supply chain management along with opening ceremony were held in June 2009.

### 3) The Field of International Commerce

#### (1) Korea-US FTA

##### A. The Progress of of the Korea-U.S. FTA

The Korea-U.S. FTA began to be discussed as the Korean government started to promote the FTA with the U.S. at 'FTA Roadmap' in 2003. A total of 8 official meetings were made from June 2006 to March 2007. Since Korea and the U.S. signed on agreement on June 30, 2007, President Obama signed on the Korea-U.S. FTA on October 21, 2011. The FTA was passed through legislation and President Lee signed the Korea-U.S. implementation legislation on November 29, 2011 and it became effective on March 15, 2012.

##### B. The Results of Negotiation

The U.S. demanded that the protection of safety and efficacy submitted by an initial drug developer be kept for 5 years and we accepted the request by considering that our data was equally protected for 6 years through the reexamination system introduced in 1995.

As for the drug approval and patent linkage as well as the preventive measure for legal action, we prepared an implementation law by considering the negative effect of the patent protection principle and permit-patent linkage system on domestic companies.

We also requested cooperative measures between Korea and the U.S. for the mutual recognition of drug GMP, GLP and generic drug approval and the U.S. agreed to cooperate for the mutual recognition of the GMP, the GLP and the generic drug approval(MRA) of medicines.

## (2) Korea-EU FTA

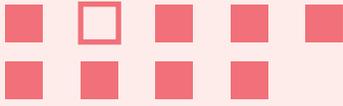
### A. Progress

The first negotiation of the Korea-EU FTA started on May 6, 2007. The actual meetings(8th), period negotiations(two times), ministerial meetings(11 times), chief meetings(13 times) were held(from May 2007). The negotiation was completed by the declaration of the minister of Sweden and then the legislation review process on agreement was followed.

### B. Highlights on Negotiated Settlement

As for the regulatory cooperation(Annex Article 5), international provisions for medicines, practices and guidelines were adequately considered and manufacturing and quality control standards conformity assessment(GMP) and non-clinical trial management standards (GLP) were processed. When it comes to the identified practices of both countries, one party requests the assessment to be accepted by the other party. And, the working group for mutual understanding of pharmaceutical and medical devices was initiated and the committee agreed to hold at least one meeting every year.

As for the drug patent, the data which meet the Article 39 of TRIPS agreement, regarding safety and effectiveness of drugs that were firstly submitted to get sales permission, is regulated at least 5 years from the first sales authorization date.



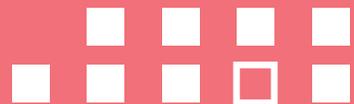
2013 MFDS Report Ministry of Food and Drug Safety



# 06

## Biopharmaceutics and Herbal Medicines

01. Thorough Safety Management of Biopharmaceutics and Herbal Medicines
02. Establishment of Safety Management System of Human Tissue
03. Sound Support for State-of-the-art Bio-pharmaceutical Industry Development
04. Supply of Safe and High-quality Herbal Medicine
05. Establishment of Safety Management System of Cosmetics, Quasi-drugs



## 01

**Thorough Safety  
Management of  
Biopharmaceutics and  
Herbal Medicines****1. Safety Management Policy Directions and Challenges**

Biological products such as vaccines are widely used for vulnerable groups such as children. Unlike generic drugs, they are derived from living organisms, which makes it hard to evaluate their safety with just physical and chemical tests.

The Ministry of Food and Drug Safety established a quality assurance system of the processed biological products in the market for the safe distribution of biological products. According to the amendment of the Pharmaceutical Affairs Law in June 2011, the 'Release approval system' in advanced countries was introduced. The national factory management system focuses on finished products applied to biologics, so that the manufacturing and quality management data of finished products are comprehensively reviewed prior to approval. Also, according to hazard analysis, the rational differential management on national factory approval drugs(test items, cycle, etc.) is planning to be provided. The comprehensive plan for international harmonization of manufacturing and quality control standards(GMP) was established in May 2013, the design -based quality assurance system(QbD) will be introduced and guidelines of manufacturing bio-pharmaceutical raw materials, and quality management standard(GMP) are planning to be arranged in October 2013.

In addition, the current biopharmaceutics safety information is managed in the same manner as other drugs. However, due to the lack of reporting of adverse events, the safety measures

are limited. Accordingly, the safety information management system has been promoted with regards to the characteristics of the vaccines. The council for the improved management on harmful cases of vaccines as configured in January 2013 is planning to manage the integrated hazard case information of vaccines collected to the Ministry of Food and Drug Safety(Bio-pharmaceutical Safety Institute) and the Center for Disease Control and Prevention in December of the same year. The improvement measures are also planned through the enlargement of re- examination cases.

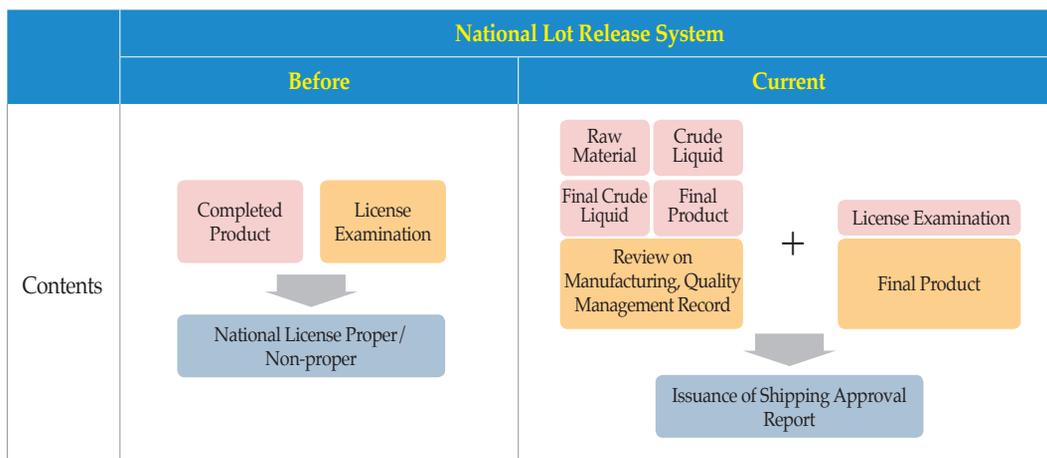
In addition, in order to enhance the safety management of plasma fraction drug such as albumin, which is of high social concern, the revision of the Pharmaceutical Affairs Law Enforcement Rule was proceeded for the unification of imported plasma management standards through the Plasma Master File(PMF) management system and the providence of legal basis of processing procedure.

In addition, the selective manufactory periodic inspection system based on the degree of harmfulness was introduced and implemented(Feb. 2013) and the advancement of manufacturing and evaluation system of quality control standards(GMP) along with PIC/S registration are currently in progress so that the construction project of manufactory management system can be carried out.

## 2. National Quality Assurance and Management(National Lot Release System)

### 1) Major Outcomes

The previous system issued either a pass or fail status by testing finished products, while the current system issues approval document by reviewing product information per manufacturing lot, a summary of technologies used in main manufacturing processes, materials used in manufacturing, bulk, final bulk and Summary Protocol of finished products.



[ Figure 6-1-1 ] Comparison of the Current and Previous System Change

## 2) Plan

In the long term, an efficient national quality assurance system based on hazard analysis will be established while improving release approval operation, including deriving variables and quality check periods by comprehending formulation characteristics such as production management history(Production history), national lot release test results, manufacturing and quality control standards(GMP) inspection data and violation on quality assurance of commercial distribution.

## 3. Strengthening the Sovereignty of Vaccines

Vaccines mean the biopharmaceutical medicines that contain antigens that give immunity or eliminate pathogenicity by processing toxins released from metabolic processes or the pathogen itself or some pathogens in order to prevent or treat diseases caused by human and animal pathogens.

In the past, vaccine was mostly referred to the single vaccine for rubella, smallpox, polio and hepatitis, but currently vaccine is gradually broadening its scope to those targeting multiple pathogens or multivalent vaccines targeting more than two peptides in a single pathogen. Also, innovative product research and development is increasing, such as cancer vaccine, HIV vaccine, bird flu vaccine, or anthrax vaccine.

Companies broadly expand their business areas and develop new concepts of vaccines that combine state-of-the-art biotechnology. In addition to existing vaccines, the vaccines for fatal diseases such as AIDS, malaria or anthrax are in progress as well as the development of therapeutic vaccines targeting cancer, Alzheimer, high blood pressure, diabetes, asthma and atherosclerosis. Promising vaccines for HIV, SARS and anthrax are expected to launch within the next three years.

For self-sufficiency of vaccines, an information and technical support center is planned to be established; early industrialization of vaccine through vaccine trial production, safety and toxicity assessment, non-clinical and clinical trial support, global license registration support and the participation of small and mid-sized biotechnology ventures are encouraged.

The Ministry of Food and Drug Safety is operating channels for communication between the biopharmaceutics industry and the Ministry of Food and Drug Safety, in order to secure the transparency, consistency and reliability of civil service and problem solving through various public and private communication channels, including Bio-CEO meetings, public and private councils for support of practical use of vaccine and TF support for new manufactory.

#### 4. Safety Management of Plasma Fraction Formulation

Since plasma fraction formulation is manufactured with raw materials from human blood, it always has the possibility of virus contamination. Therefore, strategies and principles are required to increase safety assurance through various steps, beginning with the collection of blood or plasma up until its use.

For domestic donation of plasma, the nucleic acid amplification test for HIV and HCV(NAT) is mandatory since February 1, 2005. When it comes to imported plasma, the NAT for HIV and HCV is mandatory since June 19, 2009, and 'Import plasma control standard' was amended to enable inspections on a regular basis.

Recently, the Pharmaceutical Affairs Law Enforcement Rule was amended to strengthen the safety of plasma used for the plasma fraction formulation on June 15, 2012, has been implemented since December 16, 2012. The rule is to clarify the management standard and to expand the target range of management of raw plasma material.

## 5. Future Plans and Prospects

To establish a national safety management system and high-quality supply base for quality assurance of biological products, a long-term plan and two-way communication between the public and private sector will be prepared. Thus, the foundation for public health will be laid by establishing a distinguished safety management system for biological products.

## 02

**Establishment of  
Safety Management  
System of Human  
Tissue****1. Summary**

Human tissue intended for transplant refers to parts of the human body such as bone, cartilage, ligament, tendon, skin, blood vessels, heart valves, amnia, and fascia that have been donated by brain-death, deceased, or living donors. Human tissue has the features of decreased graft rejection, a longer storage time(3 to 5 years) and the capability of transplanting to hundreds of patients compared to human organs(liver, kidney, etc.).

Donors infected with HIV, hepatitis B, C, syphilis and other infectious diseases may transmit them to multiple transplant recipients, which makes the safe management of human tissues an imperative matter. Thus, since the 1970's, relevant laws and regulations as well as organizations have been in place for the safe supply of human tissues.

The first human tissue(bone) was transplanted in Korea in 1972 at the Catholic University Hospital in treating a tumor patient. Then, in the early 2000's, approximately 40 university hospitals collected and transplanted human tissue, including bone. However, social controversy arose when safety issues were raised along with the spread of infectious diseases from transplantation, supply problems related to tissue donation, and excessive commercialism and ethical problems regarding human resources.

Under these circumstances, the MFDS implemented 'Human Tissue Safety Management Recommendations and Guides' on February 27, 2003 to better manage human tissue

for transplant. On January 20, 2004 and January 1, 2005, the ‘Human Tissue Safety and Management Act’ was institutionalized and enacted, which indeed laid the legal foundation for ethical use and safety of human tissue.

After the aforementioned act was implemented, the number of tissue banks increased from 72 in 2005 to 158 in 2012, and the use of human tissues has continued to rise as well from 55,1512 in 2005 to 271,707 in 2011. The rapid aging trend is expected to raise the demand of human tissues at medical institutes, however, due to a shortage of domestic donation, import of human tissues is expected to rise continuously.

[ Table 6-2-1 ] Tissue Production and Import Status from 2007 to 2011

(Dec. 31, 2012, Unit : number, Source : Biopharmaceutical Quality Management Division)

Classification	Bone	Tendon	Cartil Age	Liga Ment	Skin	Amnion	Fascia	Valves	Blood Vessel	Total	
Production	2007	24,168	289	224	2	13,031	2,239	28	155	249	40,385
	2008	67,250	431	160	8	19,819	1,572	55	151	358	89,804
	2009	110,672	1,164	485	0	23,390	1,868	695	82	383	138,739
	2010	143,535	978	272	0	25,117	1,878	931	72	326	173,109
	2011	128,061	1,456	524	8	21,004	16,840	1,499	64	527	169,983
Imported	2007	83,359	9,907	786	181	5,354	0	426	0	0	100,013
	2008	92,871	11,124	1,365	75	7,667	558	487	0	0	114,147
	2009	63,772	10,289	1,727	27	7,766	313	525	0	0	84,419
	2010	56,981	12,345	2,449	2	12,103	110	970	0	0	84,960
	2011	70,757	12,739	2,444	0	14,166	159	1,459	0	0	101,724

## 2. Modification of Laws and Regulations Related to Human Tissue

The implementation of the ‘Safety and Management Act on Human Tissue’ in January 2005 and the proper supply of human tissue demonstrates that the relevant rules and regulations for the safer management of human tissue have been introduced successfully.

The Ministry of Food and Drug Safety has been striving to further improve human tissue safety mechanism by managing human tissue donors, implementing the GTP(Good Tissue Practice), organizing human tissue and tissue banks electronically, enhancing imported human tissue review and evaluation rules/regulations, and creating and distributing quality human tissue management criteria guidelines.

There has been an increase in public demand for managing human tissues more safely due to increasing imported human tissues; thus, the MFDS has been conducting inspection

on overseas tissue banks since 2011. However, there are still shortfalls in the current systems which include difficulties in testing for transplantability with just documents submitted by tissue banks, lack of a mechanism that enables management of important tissue bank details in advance, and overseeing quality tissue.

The lack of a standardized display mechanism poses problems of inefficient trace-back of human tissue origin.

The MFDS will strengthen monitoring of imported human tissue and build a tracking management mechanism for it. It will also implement and modify relevant laws and regulations.

[ Table 6-2-2 ] Human Tissue-related Legislation History

Date	Legislation
Feb. 27, 2003	Safety recommendations and operating instructions on tissue grafts was provided
Jan. 20, 2004	The 'Human Tissue Safety and Management Act' was enacted
Dec. 30, 2004	The 'Safety and Management Act on Human Tissue' was announced
Dec. 31, 2004	The 'Safety and Management Act on Human Tissue' enforcement regulations were promulgated
Jan. 1, 2005	The 'Safety and Management Act on Human Tissue' was conducted
Mar. 23, 2005	'Details such as tissue banks operating permit regulations'(notice of the Ministry of Food and Drug Safety) was enacted

### 3. Post-approval Management of Tissue Banks

In Korea, 158 tissue banks are currently licensed, of which 29 tissue banks operate overseas and their human tissue products are imported to Korea(December 2012).

[ Table 6-2-3 ] Tissue Banks in Korea

(Dec. 31, 2012, Unit : places, Source : Biopharmaceutical Policy Division)

Organ Type	Medical Institution	Non Profit Organization	Processor and Handler	Importing Company	Total
Number of Tissue Banks (ratio)	57 [36.0%]	3 [2.0%]	6* [3.8%]	92 [58.2%]	158(153) [100.0%]

\* 5 processor/handlers have acquired tissue bank approval as well

[ Table 6-2-4 ] Tissue Importers' Overseas Tissue Banks

(Dec. 31, 2012, Unit : places, Source : Biopharmaceutical Policy Division)

Country	US	Germany	Belgium	France	Bulgaria	Netherlands	Czech Republic	Mexico	Total
Number of Tissue Banks	21	2	1	1	1	1	1	1	29

The Ministry of Food and Drug Safety conducts inspections for above tissue banks and monitors facilities and quality management mechanisms. In 2012, 53 tissue banks were inspected based on the efficient regular inspection mechanism and risk types. Also, 5 overseas tissue banks were inspected according to import history and tissue products types.

In addition, since the tissue of a single donor may be transplanted to multiple recipients, it is important to oversee the collection, preservation, handling, storage and distribution processes of human tissue, along with its management. Even with the aforementioned processes, surveillance and management is still limited, leading to the introduction of a quality human tissue management standard.

The nationally integrated network will be established 1) to enhance the expediency, convenience and efficiency of data reports of tissue banks, including the information of future donation, management, and transplantation of tissues, 2) to systematically manage tissue bank inspection results and tissue approval as well as import information, which in turn will improve the expediency and efficiency of human tissue trace-back and management, eventually leading to the arrangement of an information-sharing mechanism that will enhance the ethicality and transparency of appropriate human tissue supply and utilization.

## 03

**Sound Support  
for State-of-the-art  
Biopharmaceutical  
Industry Development****1. The Policy Direction and Challenges on State-of-the-art Biopharmaceutical Industry**

High-tech biopharmaceuticals such as recombinant DNA biotechnology drug, cell therapy, and gene therapy is considered a high value-added industry and the key area in personalized healthcare, supported by major countries such as the U.S., Japan and Europe.

As the patent of blockbuster-level biopharmaceuticals is about to expire, the Ministry of Food and Drug Safety prepared the second worldwide approval regulation on biosimilar in 2009, following the model of the EU. As a preemptive system, it also prepared the foundation and submission requirements of improved biological drug(bio- better) for global competitiveness.

In the meantime, the biotechnology(BT) community and processing center was reorganized and the commercialized support center was established in March 2009 to relieve the burden of bio ventures such as bio-industry cluster and biotechnology researchers in the early stage of development.

In addition, the project manager(PM) system for the adjustment of civil services and the legislative preliminary review was introduced in 2012 with the aims of providing intensive support from the beginning of development.

A variety of policies are implemented and enacted to enhance the entry of superior products, international competitiveness, and the treatment of patients with refractory disease through

professional review and effective management on state-of-the-art biopharmaceutics.

## 2. The Institutional Framework Establishment of Biopharmaceutics Evaluation

### 1) High-tech Biopharmaceutics Evaluation System Improvement

Nowadays, many biopharmaceutical drugs have been developed due to the involvement of major developed countries such as the United States, Europe, Japan in the biopharmaceutical industry(State-of-the-art biotech drugs). However, information regarding drug approval data for examination was insufficient because most developers in the biopharmaceutical industry were venture researchers.

Hence, the Ministry of Food and Drug Safety established evaluation guidelines since 2005: 7 kinds in 2005, 7 kinds in 2006, 13 kinds in 2007, 16 kinds in 2008, 9 kinds in 2009, 15 kinds in 2010, 5 kinds in 2011 and 4 kinds in 2012. These efforts contributed to the shortening the period of commercialization down to 5 years. 10 kinds of guidelines are to be published in 2013.

### 2) Establishment of Biosimilar(Biosimilar Product) Clearance Examination Standard

Biosimilar(biosimilar product) is a drug that is manufactured after the patent period of the original drug has expired, and is equal in quality, safety and effectiveness with the original pharmaceutical drug.

Biopharmaceutics including gene-recombinant pharmaceutical drug are impossible to replicate because it has a larger and more complex structure compared to chemical pharmaceutical drugs. As such, there is no concept of a biopharmaceutical generic drug and its authorization and management is different for each country.

However, as the market of biological products expands and the patent of main gene-recombinant pharmaceutical drug expires, second-tier companies are rapidly growing to develop products equivalent to the major existing blockbuster recombinant products. Currently, Europe has authorized 13 items based on the biosimilar product regulation enacted in 2007, and Japan has authorized 2 items.

In order to actively support domestic biosimilar development, the Ministry of Food and Drug Safety operated the 'Civil and governmental biosimilar council' concerning all steps from

the initial development to item authorization; and by 2011, it conducted 21 council meetings for 20 biosimilar items of 11 companies. In addition, in order to enhance the predictability and transparency of authorization and screening work, 5 Korean standard regulations of the international level were prepared. Thanks to these efforts, the number of approved cases of biosimilar products amount to 2 cases in 2009, 3 cases in 2010, 7 cases in 2011 and 6 cases in 2012.

Support for biosimilar development will persist by providing standardized biosimilar screening standards: The evaluation guideline for clinical and non-clinical biosimilars of recombinant granulocyte colony-stimulating factor(G-CSF) was prepared in 2012 and guideline for clinical and non-clinical biosimilars for monoclonal antibodies was prepared in 2013.

### 3) Reasonable Screening Criteria Establishment Considering Characteristics of Cell Therapy

Cell therapy, considered to be a key factor in the era of 'Personalized Medicine', is rapidly growing. The Ministry of Food and Drug Safety strives to modify the standards for authorization and screening of cell therapy in order to suggest a more reasonable screening standard and to provide better guideline to developers.

In 2012, the Ministry of Food and Drug Safety amended the 'Authorization and screening regulation on biological products' by improving the screening standard in quality sector and by simplifying the data requirements for non-clinical tests.

Likewise, the efforts for making reasonable systems are maintaining data requirement for clearer guidelines and preparing screening standards that are appropriate to international standards in improving authorization clinical test procedures.

### 3. Mission Empowerment

In order to dominate the world market, authorization and GMP evaluation should be elevated to the level of advanced countries.

In 2012, the Biopharmaceuticals and Herbal Medicines Bureau strengthened GMP validation capacity in bio-herbal agents, cosmetics and quasi-drug sector. In 2013, career, sectoral-specific

education program was operated, including various training seminars and foreign expert invitations. In addition, personnel exchange with the U.S. FDA will be actively promoted to construct a quality information sharing system with advanced regulatory institutions.

#### 4. Strengthening International Cooperation

The Ministry of Food and Drug Safety has taken a variety of international cooperation activities to advance its position as an advanced regulatory institution.

International forums regarding vaccine, biosimilar and cell therapy were held more than three times in 2011, 2012 and 2013. During this forum, the opportunity for education regarding the safety management policy and policy issue and directions were shared.

In October 2011, 'Special advisory group of the latest biopharmaceutics' in the 'Ministry of Food and Drug Safety' consisting of 13 scholars around the world was launched for an advanced scientific technology consulting in the field of stem cell treatment. As a result, international forums such as 'The challenges and opportunities of biopharmaceutics drug' in March 2012 and 'Bio- pharmaceutical regulatory science and development strategy' in May 2013 were held.

The Ministry of Food and Drug Safety was appointed as the Global Learning Opportunities(GLO) program by the WHO and has conducted educational training for 77 people from Philippines, Thailand, Iran, Turkey and 19 other countries.

The 'Biotherapeutic Products Roadmap' for regulatory harmonization in biopharmaceutics was created and submitted, based on a long-term plan as a championship nation in the biopharmaceutics sector in September 2011 as a result of the APEC senior official meeting. The detailed long-term plan following the roadmap is to be implemented.

#### 5. Future Plans and Prospects

In the future, three projects including the complete prevention through the improvement of authorization and screening system, prompt response through the safety management system, and optimal support for global competitiveness will be actualized through continuous effort for rational safety management that meet the characteristics of the latest biopharmaceutics.

In addition, the support for the CMO(Contract Manufacturing Organization) will be

strengthened to lower burdens and manufacturing cost of new ventures and existing companies, so that international cooperation of advanced regulatory institutions be reinforced with the US FDA, CBER, MOU and MRA.

## 04

**Supply of  
Safe and High-quality  
Herbal Medicine****1. Establishing Manufacturing Supply Base for Quality Assurance of Herbal Medicine****1) Introduction of Manufacturing and Quality Control Standard of Herbal Medicine(Good Manufacturing Practice, GMP)**

The trend of an aging population leads to an increase in the interest of herbal medicines and social demand for the improvement of the quality of herbal medicines.

Accordingly, in order to improve manufacturing quality management of herbal medicine, research on operation system of manufacturing quality management of herbal medicines was made in 2010. From December 2009 to May 2010, 11 herbal manufacturing companies conducted pilot projects regarding this. In June 2012, through the revision of the Pharmaceutical Act, herbal medicine standards were introduced and the commentary for herbal medicine and quality management standard were distributed for the early settlement of herbal medicines manufacturing and quality management standard.

In 2013, basic education and one-by-one specific practical training were provided for the understanding of the regulations. Also the local tour policy briefing and guidelines for GMP manufacturing and quality control standards are scheduled to be prepared.

## 2) The Advancement of Natural Product Regulation Standard

'Pharmacopoeia of Republic of Korea' in 1958, 'Other herbal pharmacopoeia of Republic of Korea' in 1984 and the integrated notice of 'The standard and testing method of the herbal pollutants' in June 2009 were enacted. In addition, in August 2011, the heavy metal(cadmium) standard was revised based on scientific basis in August 2011. 'Pharmacopoeia of Republic of Korea'(the 10th revision), 'Other herbal pharmacopoeia of Republic of Korea'(the 4th revision) and 'The standard and testing method of the herbal pollutants' were integrated.

In 2013, 'Other Herbal Pharmacopoeia of Republic of Korea' will be revised to enhance scientific quality control and distribution of new items.

## 2. Strengthening Competitiveness through the Authorization Maintenance System of Natural Medicine

### 1) Maintenance of the Authorization Management System of Herbal Pharmaceuticals

Even though the herbal pharmaceutical market is expanding every year, the size of herbal pharmaceuticals and health insurance application of herbal pharmaceuticals are reducing.

This is because the authorization requirements of Herbal Pharmaceutical is demanding, submission requirements are not clearly defined, and the authorization of pharmaceutical does not separate herbal medicine, so the controversy of prescription right occurs.

On May 22, 2012, the 'Regulation on approval and reporting of herbal medicine' was revised on the reflection of each characteristic of herbal medicines by clarifying the requirements of data submission.

In addition, the definitions of 'Indicator element', 'Standard amount of medicine' were established, the scope of data submission was itemized and data submission requirements of herbal pharmaceutical were newly established.

In 2013, a maintenance draft for terms not indicated in the Pharmaceutical act and 'Regulations on approval and reporting of herbal pharmaceutical' is scheduled to be revised.

### 2) Strengthening Raw Material Quality Management, Expanding Registration of Drug Substance

Improvement in quality management is required as the demand for quality control of natural medicine increases.

Accordingly, in June 2002, the 'Reporting instruction on raw material pharmaceutical' was enacted to improve the quality of raw material pharmaceuticals, so that raw materials of new medicine applied for approval since July 2002 would be notified after DMF registration.

In 2013, to expand drug registration, 'Regulation on the raw material pharmaceutical registration' will be revised and data submission for ingredients profiles will be mandatory.

### 3. Strengthening Harmful Element Monitoring

#### 1) Strengthening Follow-up Management on Natural Pharmaceuticals Focusing on Harmful Elements

With the development of science, new hazardous substances (Benzopyrene, etc.) that were not previously reviewed through item authorization process have been identified, but follow-up management at overseas manufacturing businesses is not in action.

As a result, in 2013, on-site inspection on manufacturing and quality management focusing on harmful substances monitoring, and monitoring of poor-quality herbal medicines will be reinforced from once to twice a year.

#### 2) Management Method by Herbal Medicine Rating

185 items out of 535 items of herbal medicines can also be used as food. However, some herbal materials such as 'Busa' are designated as items that need attention(toxic herbs), but there is insufficient handling limitations. Thus, safety management according to different levels, from items that need attention to edible items is required.

In 2012, research on 'Differential grading management measures for the safe use of herbal medicine' was conducted by separating domestic and overseas cases and items that need careful attention.

In the future, by promoting management methods for herbal medicine, preparing drafts and maintaining regulations, safety management on herbal medicines will be reinforced.

# 05

## Establishment of Safety Management System of Cosmetics, Quasi-drugs

### 1. Composition of Safety Management System of Cosmetics, Quasi-drugs

#### 1) Conducting Insecticides Review

As science technology develops, new harmful issues have come forth. In 2011, controversy regarding the safety of 'Insecticide containing Chlorpyrifos' became visible and the necessity of safety review on Chlorpyrifos was materialized at the United States Environmental Protection Agency(US EPA). Thus, the safety review on insecticides has been conducted since 2012.

#### 2) Establishing Regulations on Cosmetic Safety Standards

As 'Cosmetics Acts' were amended(Enforcement on Feb. 5, 2012), the 'Negative list method' listing prohibited ingredients for cosmetics was introduced to activate the cosmetic industry and raise its level to an international level. The government guaranteed a faster market entry of products by focusing on the supervision on the distributed products in the market and follow-up management.

As a result, cosmetics containing harmful ingredients were prohibited and standards for ingredients such as sterilization, preservatives and sunscreen were established. Standards and testing methods for unintentionally-created harmful substance and microbiological limits were

also suggested so that the quality of cosmetics can be ensured.

## 2. Reinforcing Industrial Competitiveness through Productive Safety Management

### 1) Strengthening Management on Harmful Cosmetic Ingredients

The 9 raw materials including lead, arsenic, mercury, antimony, cadmium, dioxane, methanol, formaldehyde and phthalate are prohibited for cosmetics, but they can be found in a variety of forms in cosmetics by the presence of impurities in raw materials or packaging materials during manufacturing or storage process. Therefore, an unintentional detection tolerance limit was set within the tolerance limit to the human body by assessing harmful degrees and considering the technology of level reduction, monitoring results, and harmonization with foreign regulations.

### 2) Preparing Commentary of Excellent Cosmetic Manufacturing and Quality Control Standards(CGMP)

In accordance with Article 5-2 of the 'Cosmetic Act'(Manufacturing vendor obligations), Article 12-2 of the same act enforcement regulations(Compliance of manufacturer) the Minister of Food and Drug Safety regulates to recommend the compliance of excellent cosmetics manufacturing management to manufacturers.

Accordingly, the Quality control standards excellent cosmetic manufacturing(CGMP) commentary was prepared for consumer protection, public health improvements and productivity improvements through the implementation of CGMP.

## 3. Strengthening Safety Management of Retail Cosmetics, Quasi-drugs

### 1) Monitoring Cosmetics, Quasi-drugs

The 'Manufacturing and Distribution Management Plan' was established by arranging annual monitoring directions for the foundation of safe manufacturing and distribution management of cosmetics and quasi-drugs. Local governments of the Food and Drug Division in each province perform follow-up management for such purposes. The monitoring of

cosmetics and quasi-drugs can be divided largely into 'Occasional monitoring' by accusation, reporting, 'Regular monitoring' by the self-planning of administrative institutions and 'Planned cooperative monitoring' by the cooperation of the Ministry of Food and Drug Safety, local administrative governments.

## 2) Inspection on Advertising and Labeling

In accordance with the announcement of the 'Special maintenance plan for local administrative organization' and its confirmation as a government policy (Organized by the Ministry of Security and Public Administration) in the regional development policy report meeting in July 2008, inspection of advertising and labeling of cosmetics and quasi-drugs is performed by local governments.

The 'Guideline for cosmetic labeling and advertisement management' has been implemented since October 1, 2011 to clarify the detailed regulation standard for false and exaggerated advertisement specified in Cosmetic Act. Following this guideline, expressions regarding treatment or prevention of 'Atopy', 'Acne', 'Breast enlargement, hair growth' were banned because they may deceive consumers.

In addition, the 'Display and Advertising Substantiation Act' was introduced (February 4, 2012) to protect consumers by providing responsibility on display and advertising. And the 'Regulation on the substantiation of cosmetic display and advertising' containing subsequent detailed standards were established.

## 3) Collection and Inspection of Cosmetics and Quasi-drugs

In order to enhance the quality management of cosmetics and quasi-drugs, the Ministry of Food and Drug Safety established the 'Quality Check Plan' annually and promoted the quality inspections on the actual collection and inspection by local governments.

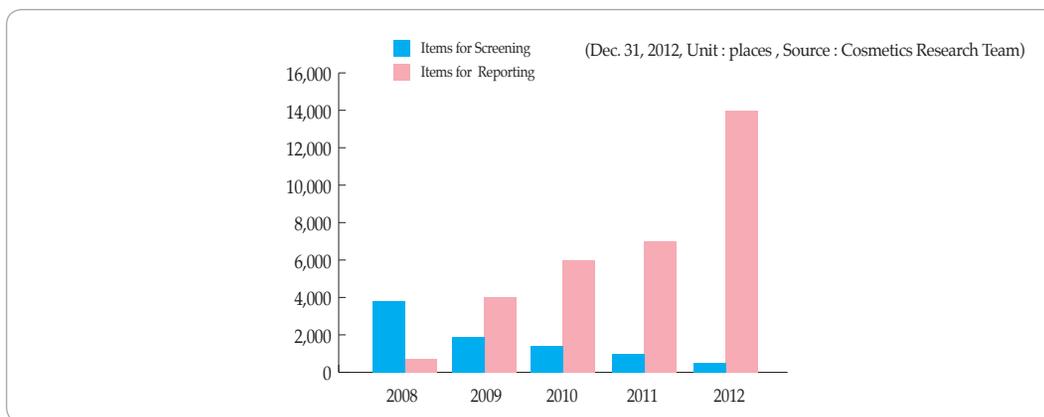
In 2013, the Local Ministry of Food and Drug Safety collects and inspects products of social concern, and local governments conduct quality inspections in accordance with the annual basic schedule.

## 4. Increasing Screening Transparency and Predictability

### 1) Activation of Swift Functional Cosmetics Review

The development for functional cosmetics is rapidly growing as the purpose of cosmetics changes from the simple correction of color to the active creation of beauty.

It is difficult to handle the screening of documents for this rapidly growing sector with limited personnel, so the screening system has been improved with the reporting e-document system.



[ Figure 6-5-1 ] Annual Examination / Reporting Status

### 2) The Credibility and Quality Assurance for Cosmetics and Quasi-drugs

In order to enhance authorization(screening), safety, efficacy and quality assurance system of cosmetics and quasi-drugs, regulations were amended and guidelines and instructions were provided. The main content includes 'Guideline for analysis of hazardous substances in cosmetics' and 'Effective mosquito repellents assessment guideline'.

### 3) The Advance of Screening of Quasi-drugs

Quasi-drugs contain many additive materials aside from the main ingredients compared to general drugs. 94 new items are listed in the 'Guideline for specifications and test methods'.

In 2011, the 'Guideline for measurement of lowering smoking appetite' for the analysis of harmful ingredients such as nicotine, carbon monoxide was provided. In 2012, the 'Tar' testing

method was added to the existing 'Carbon Monoxide' and 'Nicotine' testing method.

#### 4) Publication of Promotional Materials for Safe Use of Cosmetics and Quasi-drugs

Materials such as 'How to use menstrual hygiene products' for women, and 'The safe usage of mosquito repellents' was created and distributed.

In addition, 'Learn about hand sanitizers' for the purpose of prevention of infectious disease such as flu, 'The usage of sunscreen' for the proper use of sunscreen for the summer were created and distributed. 'Think about cosmetics' for the right information for cosmetics was also published.

### 5. Strengthening International Cooperation of Cosmetics

#### 1) The Korea-China Exchanges between Officials Related to Cosmetics

China was not only ranked as the second exporting country of cosmetics in 2012(19.6%) but also classified as the 10th in importing country of cosmetics in Korea(1.1%). Likewise, with trade volume increasing year by year, China is now one of the most important countries as a trading partner of Korean cosmetics. As a result, the Ministry of Food and Drug Safety signed the cosmetics industry cooperation agreement in 2009 with the Chinese Food and Drug Administration Agency(CFDA) by holding 'Korea-China Working Group Cosmetics' in Korea and China every year for mutual understanding and exchange of information. Regular meetings are to be held to solve bottleneck problems and further suggestions.



2013 MFDS Report Ministry of Food and Drug Safety



# 07

## Medical Devices

01. Scientific Development and Internationalized Standards for Medical Devices
02. Establishment of Internationally Harmonized Quality Control System
03. Customer-oriented Post-market Surveillance System



## 01

**Scientific  
Development and  
Internationalized  
Standards for Medical  
Devices****1. Overview**

Industrial development necessitates the standardization of products, technologies and institutions related to trade. The medical device industry requires internationalization in technical standards and regulatory systems including the standardization of product technologies and approval process.

The Ministry of Food and Drug Safety(MFDS) is an active participant of the International Medical Device Regulators Forum(IMDRF)<sup>1)</sup>, formerly known as the Global Harmonization Task Force(GHTF) to meet the flow of globalization of domestic medical appliance control systems, which was previously slow. In 2006, the Ministry held an Asian regional conference called Asian Harmonization Working Party(AHWP)<sup>2)</sup> as an attempt to take part in the international trends.

Also, the Ministry has strengthened the medical device's regulatory system to meet those in advanced countries by categorizing and reclassifying the items of medical devices in the

1) An international medical appliance regulation harmonization agency established in February 2011 for international standardization of medical appliances, which consists of USA, Japanese, EU, Canadian, Australian and Brazilian governments. Formerly, it was the Global Harmonization Task Force(GHTF), a conference for international standardization of medical appliances set up by the COMMISSION OF THE EUROPEAN COMMUNITIES.

2) An international organization set up in 2000 to discuss the systems and standardization of standards for medical appliances in Asian countries. Members include ten Asian countries such as Korea, China, Singapore and Thailand.

country, ensuring harmonization with international control standards.

Considering the impacts of safety and efficacy of medical devices, advancement of the standards is needed. Continued establishment and revision of domestic standards to reflect recent scientific advance and harmonization with international standards is an urgent matter, which will improve Korea's medical device industry's technological level and its global competitiveness.

## 2. Korea's Status on the International Standards for Medical Devices

The international standards for medical devices plays an important role not only as a technological assessment tool to ensure safety, but also as a guidance for quality control of medical devices from the perspectives of manufacturers and developers. Therefore, efforts towards international harmonization and reflection of up-to-date scientific development and international trends on technological standards are very important for the improvement of public health and medical device industry. Thanks to our efforts to continued researches and projects for ensuring incorporation of recent scientific development and internationalization of various standards, standards for 124 individual items and the three General Requirements applied for basic safety assessment of medical devices (General Requirements for Basic Safety of Medical Electrical and Mechanical equipments, General Requirements for Biological Safety, General Requirements for Electromagnetic Compatibility) have been established accordingly revised, and declared with notifications under the Ministry of Food and Drug Safety. Aside from the 127 standards for medical devices, the Republic of Korea recognizes and implements international standards, such as those set by the International Electrotechnical Commission (IEC)<sup>3)</sup> and the International Organization for Standardization (ISO)<sup>4)</sup>, along with the USA, Europe and Japan when the MFDS reviews and controls medical devices. However, in writing technical documents, data pertaining to international (national) standards such as IEC and ISO are not sufficiently available, making it difficult for applicants to search data independently. Thus, manufacturers request the MFDS to promptly provide standards and information relevant to approval application. The US Food and Drug Administration (FDA) provides data pertaining to the 'Recognized Consensus Standards' necessary for development

3) Oversees standards applicable to overall industries related to electricity.

4) Oversees the standards applicable to overall industries.

and approval of medical devices. In January 2011, the MFDS established its database system containing standards and began to provide information on the Ministry's website.

[ Table 7-1-1 ] Status of Standards Related to Medical Devices

Total	General Requirements for Basic Safety	Individual Standards	
		Standards for Medical Electrical-Mechanical Equipments	Standards for Medical Devices
132	3	66	63

[ Table 7-1-2 ] Standards for Electrical Medical Devices(66 Items)

Item(1-22)	Item(23-44)	Item(45-66)
Hearing Aid	Electroencephalograph	Hyperbaric Chamber
Radiation Shielding Apron	Laser Apparatus for Medical Use	Surgical Light System
Radiation Shielding Gloves	Stimulation System for Radiation Therapy	Bed for Medical Use
Film Viewing Devices for Diagnostic Imaging	Low-powered Defibrillator	Mercury Capillary Thermometer
X-ray Film Cassette	Transportable Infant Incubator, Mobile Infant Incubator	Electronically Powered Wheelchair and Automated Scooter for Disability
X-ray Grid	Haemodialysis System	MRI System
Radiation Shield Partition	Continuous Ventilator for Facility Use	External Lithotripter
Diagnostic X-ray System	Low-frequency Electric Stimulator for Medical Use	Hydrotherapy Massage Bath
Electrocardiographic Analyser	Electrosurgical System	Oxygen Concentrator
Open Infant Incubator	Electroconvulsive Therapy System	Automatic-inflation for Electronic Sphygmomanometer
Dental Unit	Invasive External Cardiac Pacemakers	Orthopedic Exerciser(Fixed, Top and Bottom Exercise Treatment Machine)
Dental Chair for Patient	Short-wave Diathermy Treatment System	Electrically-powered Orthopaedic Exerciser(Walking Training Machine)
Speculums for Medical Uses	Ultrasonic Diathermy Treatment System	Electrically-powered Medical Bed
Cooled Centrifuge for Medical Use	Patient Monitoring System Module(Blood Pressure, Noninvasive)	Electrically-powered Operation Table
Full-body CT System	Patient Monitoring System	Electronic Thermometer
Pulse Oximeter	Gas Anaesthesia System	Ear Infrared Electronic Thermometer
Fundus Camera	Slit Ophthalmic Light Microscope	Inhalator for Medical Use
Manual Ophthalmic Refractometer	Infrared Thermography System	Electromyograph and Evoked Response Equipment
Keratometer	Electrocardiograph Monitor	Large Moist Heat Sterilizer
Ultrasound Imaging System	Blood Flow Measurement Ultrasound System	Infant Heater
Teletherapy for Radiation Interstitial Therapy	Medical Heater	Overhead Blue Light Phototherapy Unit

Item(1-22)	Item(23-44)	Item(45-66)
Microwave Diathermy Treatment System	Retinoscope	Self-glucose Monitoring System and Strip for Self-testing

[ Table 7-1-3 ] Standards for Medical Devices(63 Items)

Item(1-21)	Item(22-42)	Item(43-63)
Gutta-percha	Intravascular Administration Set	Resin Composit Cement
Polymer-based Modeling Material	Blood Transfusion Set	Base Metal Alloy for Dental Casting(Cobalts)
Bone Cement	Sight Corrective Ophthalmiclens	Base Metal Alloy for Dental Casting(Nickels)
Enema Kit	Composite Filling Resin	Base Plate Wax
Orthodontic Bracket	Calcium Hydroxide / Zinc-oxide Eugenol Paste Endodontic Root Canal Filler and Sealer for Endodontic Root Canal	Zinc Phosphate / Zinc Polycarboxylate / Glass Polyalkenoatewater-based Cement
Silver Endodontic Point	Soft Reliner Denture	Mercury, Pure Metal
Paper Endodontic Point	Heat Curing Resin Denture	Hybrid Ionomer Cement(Non-composite)
Noble Metal Alloy for Soldering(at least 75wt.%, at least 25wt%), Base Metal Alloy for Soldering	Finger Cot	Hybrid Ionomer Cement(Composite)
Investment for Soldering, Gypsum Casting, Silicate Casting and Phosphate Casting	Intraocular Lens	Water-based Cement(Zinc Phosphate)
Laminaria Cervical Dilator	All-ceramic, Glass Ceramic, Injection Ceramic, Metal-ceramic Restorative System, Milling Ceramic, Ceramic Casting Powder / Paste / Blank	Alginate Impression Material
Resin Artificial Teeth	Self-curing Denture Resin, Chemical-curing Denture Resin	Agar Impression Material
Resin Pit and Fissure Sealant(External Energy-curing)	Syringe(Single-use)	Preformed Casting Wax
Resin Denture(Self-curing)	Hyaline Medication / Vaccine Injector	Crown and Bridge Resin
Noble Metal Alloy for Metal-ceramic Restorative Systems(at least 75wt.%, at least 25wt.% but less than 75wt.%), Base Metal Alloy for Metal-ceramic Restorative Systems	Syringe(Insulin Injection)	Catheter Guidewire
Single-use Acupuncture Needle	Single-use Aspiration / Injection Needle	Hpodermic Cartridge Syringe
Reusable Acupuncture Needle	Single-use Dental Syringe Needle	Contraceptive Male Condom
Non-implantable Haemodialysis Catheterization Kit	Reusable Aspiration / Injection Needle	Pessary

Item(1-21)	Item(22-42)	Item(43-63)
Nonabsorbable Surgical Suture	Medical gloves	Balloon Dilatation for Non-coronary Angioplasty Catheter
Gypsum Model	Compound Impression Material	Contraceptive Intrauterine Device
Ceramic Artificial Teeth	Dental Amalgam Alloy	Hard and Soft Contact Lens
Surgical Gloves	Noble Metal Alloy for Casting(at least 75wt.%)	Blood Collection Container

### 3. Progress

For the advance of domestic standards for medical devices, international standards have been integrated as shown in Tables 7-1-4 and 7-1-5 in addition to the reflection of opinions from related experts and stakeholders, resulting in the establishment and revision of standards.

[ Table 7-1-4 ] Establishment and Revision of Standards for Medical Devices in 2012

Classification	Amendments	Comment
International Harmonization and Advancement of Medical Appliances Standards	<ul style="list-style-type: none"> <li>Standards for 'Orthodontic bracket', 'Resin composit cement', 'Investment for soldering, Investment for gypsum casting, Investment for phosphate casting' were newly established.</li> <li>Physical and chemical testing methods and criteria of each standard shall be conform to the international standards.</li> </ul>	Standards for Medical Devices (No. 2012-96, August 30, 2012)
Unified Standards Applied to Dental Investments	<ul style="list-style-type: none"> <li>Standards for 'Investment for plaster casting' and 'Investment for phosphate casting' shall be abolished and standards for 'Investment for soldering, Plaster, Silicate casting and Phosphate casting' shall be Applied.</li> </ul>	
Implementation of the Amended 「Regulation on Medical Devices and Classification」	<ul style="list-style-type: none"> <li>Changes to the product code names and scope of application of 60 items such as 'Gutta-percha'</li> </ul>	

[ Table 7-1-5 ] Status of Establishment and Amendments of Standards for Medical Electronic Equipment

Classification	Amendments	Comment
International Harmonization and Advancement of Standards for Medical Appliances	<ul style="list-style-type: none"> <li>It is to ensure that the testing methods and standards for 'Safety and Performance testing' of nine individual medical electronic equipments such as 'Large moist heat sterilizer' conform to international standards</li> </ul>	Standards for Medical Electronic Equipments (No. 2012-117, Nov. 30, 2012)
Unification of Standards Applied to Diagnostic X-ray System	<ul style="list-style-type: none"> <li>This to remove three different individual standards (Photofluorographic x-ray system, Diagnostic x-ray system and Image intensifier fluoscopic x-ray system) and unify them to one 'Individual Standards for Diagnostic x-ray system' with an aim to prevent overlaps of application of the individual standards applied to Diagnostic x-ray system and confusion from different testing standards</li> </ul>	

Classification	Amendments	Comment
Implementation of the Amended 「Regulation on Medical Devices and Classification」	<ul style="list-style-type: none"> <li>• Reflection of the eight product code names and scope of application of the items of standards for individual medical electronic equipments, such as Diagnostic x-ray system (Stationary x-ray grid, ▶▶ Stationary radiation x-ray grid, Diagnostic x-ray system ▶▶ Diagnostic x-ray system, Hyperbaric chamber ▶▶ Hyperbaric chamber, Thermometer ▶▶ Mercury capillary thermometer, X-ray shielding partition ▶▶ Radiation shielding partition, Personal heater ▶▶ Heater system, Sphygmomanometer ▶ Automatic-inflation electronic sphygmomanometer, Electronic thermometer ▶▶ Electronic thermometer)</li> </ul>	

#### 4. Future Plan

The Ministry will continuously develop and implement standards for various medical devices while coming up with new assessment technologies for safety assessment of newly developed medical devices. Also, existing standards for each item will be revised and harmonized with international standards, contributing to the advance of medical device industry and public health in Korea.

# 02

## Establishment of Internationally Harmonized Quality Control System

### 1. Establishment of the Good Manufacturing Practice(GMP) of Medical Devices

#### 1) Meaning of GMP Introduction for Medical Devices

The GMP for medical devices aims to systemize the least level of standards for medical devices manufacturing process, which ensures that medical devices are manufactured consistently and controlled to quality standards appropriate to their safety effectiveness and intended use.

As its name, GMP refers to a system for manufacturing and quality control which describes systematic compliances and quality control, covering all processes from the organization, structure and facilities necessary for manufacture and quality control, design, to other processes including purchase of materials and components, packaging, installation and post-marketing measures.

Under the Pharmaceutical Affairs Act, in 1997, the 'Manufacturing and Quality Control Standards for Good-quality Medical Instrument' was introduced as the recommended guidance to manufacturing and control quality of medical devices. On May 30, 2004, the Medical Devices Act enacted the 'Manufacturing and Quality Control Standards for Medical Devices' based on 'ISO 13485' of the international standards for medical devices, which required manufacturers to comply with 'the Standards'. Currently, the Manufacture

and Quality Control Standards for medical devices are enforced under the 'Enforcement Regulations of the Medical Devices Act' and 'Manufacture and Quality Control Standards for Medical Devices(Notification by the Ministry of Food and Drug Safety)', requiring manufacturers and importers to obtain GMP certification through inspection if they wish to distribute medical devices in the Korean market.

Advanced countries like the USA(1978), Japan(1995) and Europe(1998) already operate 'Good Manufacturing Practice for medical devices'. The international trading environment is changing rapidly as can be seen from Mutual Recognition Arrangements(MRA) and Free Trade Agreements(FTA). The five countries(USA, EU, Japan, Australia and Canada) that take up 85% of the global medical device market set up the Global Harmonization Task Force(GHTF) in 1992, lead international harmonization on medical devices regulatory systems, including the Good Manufacturing Practice. Korea's implementation on mandatory GMP seems rather belated in comparison with the USA, Japan and Europe. However, it is based on the 'ISO 13485', meaning that the domestic standards are equivalent to the international level.



[ Figure 7-2-1 ] Good Manufacturing Practice by Country

The demands on medical devices in Korea are likely to keep increasing as the aging population and chronic diseases bring about changes in disease patterns. There are increasing demands for higher standards on safety and quality of medical devices from the public.

Accordingly, the domestic market size shows a dramatic growth. It is more than necessary to reinforce industrial competitiveness in the domestic medical device market, making it more important to regulate manufacturing and quality control standards.

## 2) Early Establishment and Facilitation of Good Manufacturing Practice

On May 30, 2004, 'the Medical Devices Act' was enacted, obligating manufactures to comply with GMP.

The registered manufacturers were given a grace period until May 30, 2007. For earlier establishment of GMP for medical devices, 'the Plan to Expand Participation in the Good Manufacturing Practice of medical devices' was executed on March 2006 with a focus on reasonable measures of addressing issues faced by participating companies and support measures for companies preparing GMP.

Based on the Plan, the companies certified for the Good Manufacturing Practice were exempted from periodic inspection as an incentive to earlier adoption. Nevertheless, applications for GMP inspection swamped in 2007, the final year of the grace period, resulting in a shortage of inspectors. As a result, in 2007, the number of companies that acquired GMP certification was three times higher than that in 2006.

In the same context, in 2009, the Ministry provided free technical support in relation to major issues such as risk management and validation if a manufacturer requested technical support regarding GMP. Also in 2012, the Medical Device Information & Technology Assistance Center(MDITAC) was established for free technical support tailored to individual manufacturers. In addition, there is a 'preliminary document review' which a manufacturer can consult with a designated third review party at an inexpensive cost regarding documentation before applying for GMP inspection. The Ministry of Food and Drug Safety has managed a section for 'the Good Manufacturing Practice(GMP) Data' on its website to provide various guidelines and related data.

In 2013, the Ministry is providing 'Good Manufacturing Practice(GMP) Class, region by region' to explain and provide information and guidelines regarding GMP policy directions to manufacturers in local provinces, excluding Seoul Metropolitan city and Gyeonggi Province. The website for 'GMP Talk! Talk! Talk!' has served as a place to provide and share information about GMP system, to approximately 1,200 members of the internet community. By 2012, there were 3,671 companies, 2,085 manufacturers and 1,586 importers that obtained GMP certification.

[ Table 7-2-1 ] Certification Status of GMP System on Medical Devices

(Dec. 31, 2012. Unit : number)

Classification	2007	2008	2009	2010	2011	2012
Total	2,471	2,721	3,022	3,291	3,551	3,671
Manufacture	1,312	1,460	1,637	1,838	1,983	2,085
Import	1,159	1,261	1,385	1,453	1,568	1,586

## 2. Improving GMP Operating System and Its International Standardization

### 1) Status of GMP Inspection Methods and Institutions

GMP conformity assessment of medical devices is conducted jointly by four 3rd party agencies designated by the Minister of Food and Drug Safety(Korea Testing Laboratory, Korea Testing Agency, Korea Testing & Research Institute and Korea Conformity Laboratories) and the Ministry of Food and Drug Safety(Headquarters and local Offices). The criteria for the operation system of GMP agencies are standardized according to the ISO/IEC Guide 62 and their operation status including their suitability to GMP inspection are annually assessed, recommended and supervised to improve the inspection system.

[ Table 7-2-2 ] Status of GMP Audit Institution on Medical Device

Audit Institution	Address	Date of Registration
Korea Testing Laboratory	Digital-ro 26 Gil, Guro-gu, Seoul, Korea	Nov. 24, 1999
Korea Testing Agency	Heunghangdaero 27 Gil 22, Gunpo-si, Gyeonggi-do, Korea	Dec. 10, 1999
Korea Testing & Research Institute	Beodunamuro 155, Youngdeungpo-gu, Seoul, Korea	Dec. 23, 1999
Korea Conformity Laboratories	Nambusunhwanro 319 Gil 7, Seocho-gu, Seoul, Korea	Nov. 8, 2000

The GMP types on medical devices are divided based on their condition on initial inspection, periodic inspection, additional inspection and inspection for changes.

[ Table 7-2-3 ] Types of GMP Inspections

(Apr. 8, 2012)

Type	Subject and Description
Initial Inspection	A medical device manufacturer requests a Good Manufacturing Practice inspection for the first time.
Periodic Inspection	A GMP certified company needs to take regular GMP inspection at least once in every 3 years(conformity check).
Additional Inspection	A GMP certified company is required inspection when it wishes to manufacture a medical device in different category from its original GMP certification.
Inspection for Changes	An inspection is required when a GMP certified manufacturer changes its manufacturing site.

When GMP application is received, MFDS conducts Quality Management System Inspection after having a Regulatory Audit in an opening meeting which coordinates GMP inspection

schedule with agencies. Inspection results are divided into Conforming, Deficiency, or Non-conforming.

## 2) Establishment of Various Guidelines to Apply GMPs of Medical Devices

The Ministry has established and distributed various manuals and guidelines explaining the GMPs of medical devices with aims to resolve issues faced by the medical devices industry in the process of GMP establishment, and to settle the GMP system in swift manner.



[ Figure 7-2-2 ] Overview of the Audit Procedure

### (1) Publication of Manuals for Good Manufacturing Practice of Medical Devices

With aims to raise the awareness of people related to medical devices manufacturing and Quality Control, and to assist with putting Quality Control in effect, MFDS has published, revised and distributed practical manuals based on ISO 13485, which explain criterion of GMP inspection in detail.

### (2) Publication of Various Guidelines on GMP of Medical Devices

The publication aims to help manufacturers by establishing guidelines by each area such as design control, packaging validation, sterilization validation, environmental control and risk management required for the application of the Good Manufacturing Practice of medical devices.



[ Figure 7-2-3 ] Guideline for Good Manufacturing Practice

### 3) Technical Support to Good Manufacturing Practice Including Risk Management

Risk management is a component of the advanced Good Manufacturing Practice to analyze and assess all risk factors that may occur throughout the total cycle of process of designing, manufacturing and use of medical devices, and to control and manage them within tolerable levels. Medical devices which are applied to human bodies must ensure their safety, and the level of risk management determines international competitiveness with regards to quality. Therefore, advanced countries operate GMP of medical devices with a focus on risk management and are obligated to submit risk analysis reports upon approval application, which makes it a requisite for Korean manufacturers to provide a risk analysis report when exporting medical devices to Europe or the USA.

In Korea, it is also mandatory to conduct risk management, sterilization process validation and software validation for Good Manufacturing Practice of medical devices. In relation to risk management, ISO 14971 shall be applied.

The Ministry has offered manufacturers customized technical supports from the approval application stage, such as providing one-on-one consulting and information on actual application of GMP, particularly regarding risk management and validation. They intend to have GMP swiftly incorporated in the regulatory system and enhance GMP operation up to level of advanced countries.

New manufacturers are eligible to receive technical support in all relevant areas, including risk management and validation, prior to a GMP inspection. If there are specific items requiring highly advanced professional technologies, the applicant is introduced to the 'Technical Experts Pool', comprised of relevant technical experts from academia, industry and institutions, with the goal of executing various types of technical support, such as on-site visits and letters since 2008.

On the other hand, in 2012, the 'Medical Device Information & Technology Assistance Center(MDITAC)' was established to carry out technical supports for Good Manufacturing Practice as a way of tailored technical supports for individual manufacturers.

#### (1) Publication and Distribution of Guidelines for Risk Management of Each Medical Appliance Item and Cases of Technical Advice

Various by-item guidelines of 47 items, which include syringes and artificial respirators,

have been published to raise awareness of risk management and to explain methods of application regarding GMP of medical devices through project commissions since 2008. As for medical devices with high level of risk and/or popularity, 'the Technical Expert Pool for Risk Management' was set up for technological advice. The expert opinions from technical and clinical perspectives were published in the Case Studies for Technical Advice on Risk Management to provide manufacturers practical assistance in risk management.



[ Figure 7-2-4 ] Case Study Publications

## (2) Publication of News Leaflets and Newsletters on GMP of Medical Devices

In order to introduce Good Manufacturing Practice System and provide information helpful to medical device manufacturers, importers, consumers and medical facility staffs, the Ministry has published and distributed 'Information on Good Manufacturing Practice of medical devices' and the 'Newsletter on Good Manufacturing Practice' since 2009.

## 4) Introduction of On-site Inspection Scheme for GMP Implementation in Foreign Manufacturers

Imported medical devices take up 65% of the Korean medical device market, of which a large percentage consists of medical devices with higher level of risk, Classes 3 and 4. However, confirmation of quality management was conducted indirectly through its GMP certificate by the country of origin without on-site inspection, whereas domestic manufacturers were subject to on-site inspections.



[ Figure 7-2-5 ] GMP Leaflets and Newsletters

Pilot projects and research projects were operated as a part of an effort to introduce on-site inspection schemes on foreign manufacturers under the Quality Control system from 2007, when the GMP System became mandatory on medical devices. As a result of such efforts, related regulations were amended to implement onsite inspections on foreign manufacturers starting from April 8th, 2012.

Consequently, the equal GMP Conformity assessment is applied to both domestic manufacturers and foreign manufactures, ensuring direct confirmation of actual Quality Control system for foreign manufacturing sites.

### 5) Strengthening the Good Manufacturing Practice Training

The GMP System of medical devices prioritizes training, as the stable and actual operation of GMP is only possible when all staff members in charge of product quality are fully aware of and implement the system.

Since 2005, the Ministry has devised support systems for such training when the mandatory GMP system was at its inception and has been providing practical training with essential information necessary for implementing stable GMP system through basic and professional courses.

The 'Korea Medical Devices Industry Association' had been designated as a Quality Control training provider, but since the second half of 2012, the 'Medical Device Information & Technology Assistance Center(MDITAC)' was chosen to provide training regarding the GMP system to staffs responsible for Quality Control from companies. The MDITAC is dedicated to improving industrial Quality Control by continuously expanding training infrastructure, increasing the base for on-site adaptation with practical training, and developing and distributing various contents including training for Quality Control managers.

Recently, many countries signed in the Mutual Recognition Arrangements(MRA) in the approval and evaluation of medical devices. The MFDS has made efforts to secure Korea's competitiveness by harmonizing the Quality Control system to current international trends, and maintaining training courses for advanced quality control methods, such as risk management, sterilization validation, and software validation. Along with this, Quality Control training courses with various training and educational contents have been developed and promoted.

### 6) International Harmonization of GMP Inspections through Differentiated Management by Classification

Until 2011, Good Manufacturing Practice inspections and conformity assessment were applied to all classes of medical devices, regardless of its level of potential risks. There were opinions that this caused difficulty in properly managing medical devices with high level of risk, while those that weren't of high risks were burdened with excessive control.

As the medical device approval and management regulatory system was revised in 2011, the GMP conformity assessment was no longer applied to the Class I medical devices with the introduction of a risk based differentiated control system. From April 8, 2012, Class I medical devices(excluding some items including sterilization) were exempted from GMP inspection, allowing manufacturers to perform voluntary Quality Control, thereby promoting international harmonization. At the same time, administrative efficiency was enhanced, allowing a more focused supervision on Class I·II medical devices, which have higher level of risks.



What is the Good Manufacturing Practice Mark System? The GMP Mark is a quality assurance system that enables consumers or users to easily identify GMP-certified medical devices. It was introduced in June 2007. A GMP Mark is labeled on a product by a GMP-certified manufacturer. Products without a GMP Mark are naturally driven out from the market, which would lead to enhanced quality of medical devices in distribution. Furthermore, it is expected to contribute to quality assurance of imported devices as on-site GMP Inspections on foreign manufactures and its GMP Mark gain recognition. The MFDS is also going to develop GMP system into an international quality assurance mark like Conformance European(CE) marks.

## 03

## Customer-oriented Post-market Surveillance System

### 1. Overview of Post-market Surveillance System of Medical Devices

On May 30, 2004, the Medical Devices Act was enforced. The growth of the medical device industry and explosive demands on home medical devices due to the 'wellness trend' have resulted in distribution of medical devices with poor quality or false efficacy and effectiveness. Against this backdrop, the Ministry of Food and Drug Safety in Korea is proactively engaging in supervising false or exaggerated advertisements of medical devices, cracking down on unapproved medical devices in markets, as well as inspecting and removing devices of poor quality. They are to prevent any industrial disturbance from illegal or poor medical devices and to secure public health. Also, adverse events reports and safety information on medical devices from home and abroad are collected for analysis and are distributed to the industry and users to prevent risk factors from possible reoccurrence and promote awareness for extra care.

[ Table 7-3-1 ] Basic Direction for Post-market Surveillance of Medical Devices

〈 Basic Direction for Post-market Surveillance of Medical Devices 〉

- ✓ Strengthened risk-oriented on-site guidance and inspection: Intensive control on companies with frequent regulatory violations, etc.
- ✓ Quality assurance of medical devices in distribution: Quarterly or irregular collection and inspection
- ✓ Termination of false or exaggerative advertisement: Strengthened monitoring of advertisements of

medical devices and special supervision on advertisements

- ✓ Re-confirmation on safety and effectiveness: Re-evaluation of medical devices
- ✓ Furtherance of safety information including Adverse Event Reports : Ten selected medical device Safety Information Monitoring Centers in operation
- ✓ Management of medical devices subject to tracking and control : Adjustment of designated medical devices subject to tracking and control

## 2. Medical Device Advertisement Management System to Protect Customers from False or Exaggerative Advertisement

### 1) Current Status and Prospects

Despite recent global economic slowdown, the medical devices industry in Korea has continued to grow due to Korea's entry into a super-aging society, 'wellness trends', modified lifestyles with increased incomes, and the advance of Information Technology, Biotechnology and Nano Technology.

Consequently, demands are surging for personal and home medical devices such as medical combinational stimulator and heating pads. As can be seen, false or exaggerated advertisements have become rampant to lure consumers into buying such products.

Medical device shops that particularly target the elderly with free trials, advertise home devices originally approved for its intended use of 'improvement of blood circulation or pain alleviation' as if their medical devices are effective for preventing or treating adult diseases such as hyperlipidemia, obesity, diabetes and lipid concentration, consequently causing more consumer harm.

Therefore, it is necessary to minimize damage to consumers by strengthening Prior Review of medical device advertisements, constantly monitoring the media outlets including the internet, newspapers and broadcasting outlets, frequently conducting joint-crackdown on shops offering free trials, as well as executing other various Post -Market Surveillance measures.

### 2) Achievements in 2012

#### (1) Prior Review System of Medical Device Advertisements

The Prior Review system of medical device advertisements was introduced in 2007 with purposes of preventing consumer damages from medical device advertisements, guiding appropriate use of medical devices, and preventing distributors from unintentionally breaking regulations and imposing penalties. Starting in 2007, there has been a continued increase; 1,489 cases in 2007, 1,231 cases in 2009 and 1,740 cases in 2011. In 2012 alone, 3,386 cases were reviewed through the Prior Review system, totaling 5,663 cases over the past six years. These numbers indicate that reasonable criterion and environment on prohibitive advertisements have been established under the Medical Devices Act, and hence, that the Prior Review system of medical device advertisements has settled to certain extent.

[ Table 7-3-2 ] Achievements by Prior Review System of Medical Device Advertisements in 2011

□ Status of Yearly Review of Advertisement Media Outlets

(Unit : number, %)

Media Types			2007	2008	2009	2010	2011	2012		Total (%)	
								Number	YoY		
Advertisement Media	Broadcasting Media	TV	148	123	98	84	90	88	97.8	453	
		Radio	11	3	7	9	13	20	153.8	30	
	Printing Media	Daily Newspaper	195	219	216	169	152	137	90.1	799	
		Weekly Newspaper	4	10	15	4	17	16	94.1	33	
		Magazine	117	117	83	77	60	94	156.7	394	
	Internet Media	Internet	1,011	668	755	1,393	1,220	2,734	224.1	3,827	
		Online Newspaper	3	2	2	3	75	5	6.7	10	
	Others	Others	-	-	55	62	113	274	242.5	117	
	Total(%)			1,489	1,142	1,231	1,801	1,740	3,368	193.6	5,663

□ Status by Review of Advertisements

(Unit : number, %)

Type	2007	2008	2009	2010	2011	2012	Total
Approved (%)	317 (21.3)	184 (16.1)	247 (20.1)	471 (26.2)	159 (9.1)	257 (7.6)	1,635 (15.2)
Conditionally Approved (%)	1,032 (69.3)	885 (77.5)	938 (76.2)	1,297 (72.0)	1,558 (89.5)	3,078 (91.4)	8,788 (81.6)
Not Approved (%)	140 (9.4)	73 (6.4)	46 (3.7)	33 (1.8)	23 (1.3)	33 (1.0)	348 (3.2)
Total (%)	1,489 (100.0)	1,142 (100.0)	1,231 (100.0)	1,801 (100.0)	1,740 (100.0)	3,368 (100.0)	10,771 (100.0)

## (2) Strengthened Post-management of False or Exaggerated Advertisements

In 2012, local offices of the Ministry of Food and Drug Safety and local governments inspected and issued recommendations to 1,003 retailer shops offering free trials with false or exaggerated advertisements targeting vulnerable classes, the elderly in particular. Through two inspections, 50 violations were revealed.

Also, eight full-time monitor personnel (two at the headquarters and six from the local Offices of MFDS) took charge of controlling false or exaggerated advertisements on influential popular media outlets, including the internet and newspapers. Each monitoring office is delegated to media outlets, making clearer responsibility on monitoring while avoiding overlapping redundancy.

Those in charge of each monitoring media and full-time monitor personnel were provided with SOP programs twice, respectively, to help in identifying false or exaggerated advertisements and reinforcing their individual capacity for monitoring against advertisements in violation of the Medical Devices Act.



[ Figure 7-3-1 ] Number of Illegal Advertisements Revealed During the Last Five Years

## 3) Future Plan

In 2013, medical devices for export and Class I devices with low levels of risk are going to be exempted from prior review of advertisements to improve efficiency of the Prior Review System of Medical Device Advertisements, whereas requirements for consumer protection will be further strengthened.

At the same time, case study publications which contain tips in identifying false or exaggerative advertisements and help reinforce public awareness will be handed out to medical device monitor personnel, medical device handlers, relevant organizations and consumers. Also, the Ministry plans to run consumer-oriented, tailored educational programs with consumers' groups while executing regular monitoring on retailers with free trials and

advertisement media outlets at all times.

### 3. Prevention of Risk Factors with Medical Device Reporting, Tracking and Control and Re-evaluation

#### 1) Current Status and Prospects

Thanks to technological advance of the infrastructure industry related to medical devices, gradual expansion of the use of medical devices with higher risks such as implantable prostheses in a human body, and raised awareness from the public regarding health and wellness, the use of medical devices has become more general. On the other hand, the public demand on safety is escalating.

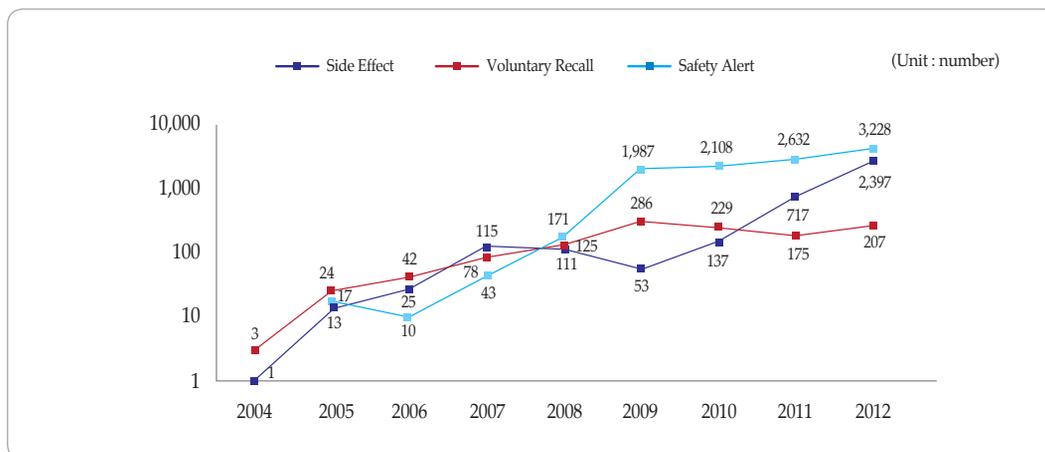
Since the implementation of the Medical Devices Act, the Ministry of Food and Drug Safety has continually developed overall circumstances for safety control of medical devices with the establishment of relevant systems and reinforcement of professional workforce, contributing to significant improvement in the foundation for control of safety and efficacy. In particular, the Post-market Surveillance tools such as Medical Device Reporting, designation of medical devices subject to control and tracking and Re-evaluation of medical devices have been institutionalized, which are expected to settle proactive and preventive control of medical devices in distribution and to further enhance the medical device industry in Korea.

#### 2) Performance and Progress in 2012

##### (1) Safety Information Including Adverse Events

Safety information reporting system such as the Adverse Event Reporting System is established to prevent repeating risk factors with dissemination of relevant information to the medical industry. If a problem of a medical device is found, medical device handlers are to report to the Ministry of Food and Drug Safety.

The Ministry established a more efficient online reporting system in the 「Comprehensive Food and Medicine Information Service」 to enhance convenience for the people. Also, in 2012, ten medical institutions in the country were designated as 「Medical Device Safety Information Monitoring Center」 to encourage medical facilities reporting events by medical



[ Figure 7-3-2 ] Status of Medical Device Reporting

devices, and the 「Regulations on Safety Information Management including Medical Device Reporting」 was amended to ensure better management of safety information by establishing and revising terminology, laying down grounds for publicizing the Safety Alert and Notice and establishing new evaluation criterion and methods. The 「Guideline for Medical Device Reporting(Breast Implants, Hip and Joint Prosthesis)」 was published to provide medical devices handlers and users information on reporting procedures and ways of preparing the MDR.

There have been continued efforts such as the publication of the 「Tip for Medical Device Reporting including Adverse Event」 for manufacturers, importers, medical facilities and consumers to encourage the Reporting system. Such efforts resulted in the augmentation of the MDR from 717 in 2010 to 2,397 in 2012, an increase by 234%.

## (2) Medical Devices Subject to Tracking and Control

The Medical Devices Act designates certain medical devices, those that may cause significant harm to the human body due to adverse effects or defects, subject to tracking and control and the Act requires manufacturers, importers, distributors and those who run medical facilities to make and maintain the records. The MFDS has designated 15 medical devices to be subjected to tracking and control. Medical devices which are subject to tracking and control are continuously adjusted through either addition or elimination for a more efficient and advanced tracking system.

※ Expanded Designation of Medical Appliances Subject to Tracking Management(August 24, 2012)

- Six items additionally designated : Artificial Temporomandibular Joint, Artificial Prosthesis for Lower Jaws, Artificial Lower Temporomandibular Joint, Vascular Stent, Implantable Electric Stimulator for Cerebellum, and Respiration Monitor

[ Table 7-3-3 ] Status of Designation of Medical Devices Subject to Tracking and Control in Korea

Number	Medical Devices Subject to Tracking and Control	Comment
1	Implantable Cardiac Pacemakers	Medical Devices Implanted and Remained in Human Bodies for at Least One Year
2	Electrodes for Implantable Cardiac Pacemakers	
3	Artificial Cardiac Valves	
4	Implantable Defibrillator	
5	Electrodes for Implantable Defibrillators	
6	Breast Implants(Applicable Only to Silicon Gel)	
7	Artificial Breasts(Limited to Those Containing Silicon Gel)	
8	Prosthetic Temporomandibular Joint(Including Biodegradable )	
9	Prosthesis for Lower Jaws(Including Biodegradable)	
10	Prosthetic Lower Temporomandibular Joint(Including Biodegradable)	
11	Vascular Stent(Applicable Only to Abdominal Aortic Aneurysm and Thoracic Aorta Stent Graft)	Life Supporting or Sustaining Devices for Home Use
12	Implantable Brain Electric Stimulator(for Psychological Therapy, Seizure Prevention, Oscillation, Pain Alleviation, Pain Removal)	
13	Continuous Ventilator	
14	Defibrillator	
15	Continuous Patient Respiratory Monitoring System	

In 2012, MFDS inspected manufacturers, importers and distributors in a total of 28 products and 30 facilities regarding their status of use and record-keeping of medical devices for home use(defibrillator, ventilator) and items with high numbers of AER(silicon gel-filled breast implants).

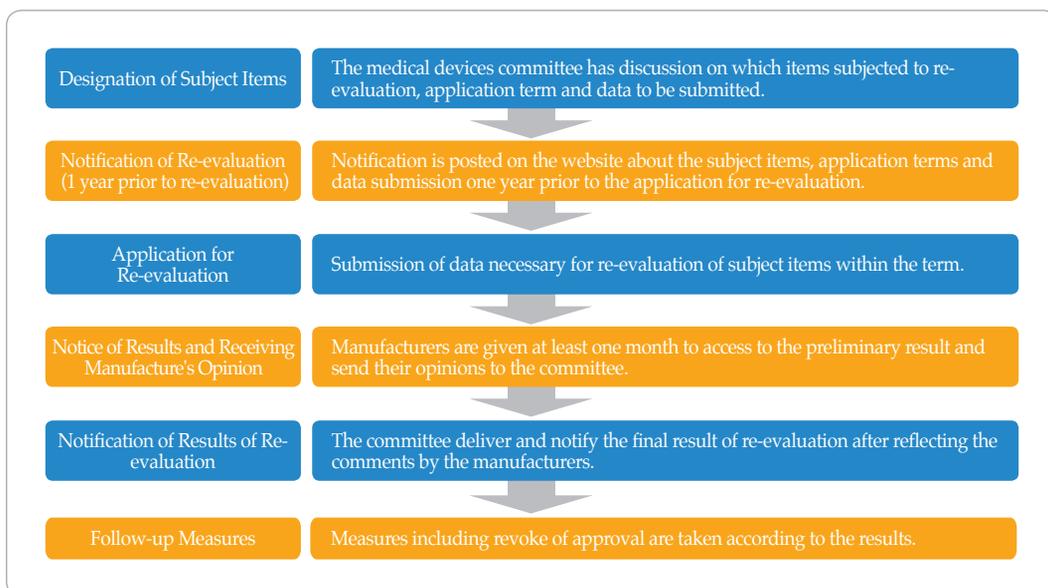
The results of the inspection demonstrate that regulatory requirements under the Medical Devices Act were kept in general, such as having a management system where related information about manufacturers to end-users is available at once. However, some companies were found to poorly maintain records such as manufacture serial numbers, and one company was penalized with a one-month suspension of sale of the item and another company was given a warning letter with administrative guidance. At the same time, leaflets were published and distributed to related companies and associations for the promotion of the record-keeping of medical devices and their management.

### (3) Re-evaluation of Medical Devices

Medical device re-evaluation is a system to re-verify the safety and efficacy of medical devices based on current scientific standards because time has passed since its approval and scientific standards used during the approval process may be outdated.

The re-evaluation system began in 2009 and medical devices approved prior to the establishment of 'the Basic Requirements' on Medical Devices(March 5, 2000) are subjected to scientific scrutiny with its test results and to verify its conformity with current Basic Requirements. From 2013, re-evaluation will cover all items(1,618), with approximately 220 items every seven years, as the Regulation is amended to reflect safety information and Medical Device Reports in the post-market approval on the re-evaluation process.

※ Notice on the 2013 Re-evaluation of medical devices(Sep. 28, 2012)



[ Figure 7-3-3 ] Flow of Reassessment of Medical Devices

### 3) Future Plan

Over the past three years, there were about 2,500 Medical Device Reports on a yearly average, including side effects in the country, which are far lower than the cases in the USA or Japan. It seems that this is due to medical device handlers who are not adequately aware of the relevant regulations are unsure if a certain adverse event requires reporting or not. Therefore,

instruction programs and promotions on Medical Devices Reporting will be actively provided to manufacturers, importers and those in medical circles to facilitate the Medical Device Reporting System and 'The Guidelines for Medical Device Reporting by Medical Device Items' will be produced for manufacturers, importers and medical facilities. Also, in 2013, twelve medical facilities will be designated as 'Medical Device Safety Information Monitoring Centers' to encourage in reporting Adverse Events.

Our 2012 survey of management of medical devices subject to tracking and control unveiled that medical facilities and handlers should be motivated to take more interests in devices subject to tracking and control. To this end, instruction programs on medical devices subject to tracking and control will be continued, while coordinating items subject to tracking and control with international trends in order to contribute fair business conditions for domestic manufacturers and enhance of the domestic medical device industry.

Also, in 2013, the Ministry of Food and Drug Safety is planning to overhaul methods of re-evaluation of medical devices so that comprehensive assessment on device safety and efficacy can be done based on various safety information, including domestic and overseas research papers, as well as adverse events and side effects submitted by manufactures and importers. The results will be reflected in the approval processes which look into the method of use and cautions in use, etc. If medical devices classified under re-evaluation fail to apply for re-evaluation or secure safety and/or efficacy requirements, will be met with administrative penalty. As Post-market Surveillance, various safety and side-effect information will be collected, assessed and reflected in approval status to enhance public health.

## 4. Collection and Inspection for Quality Assurance of Distributed Medical Devices

### 1) Current Status and Prospects

The Ministry of Food and Drug Safety has conducted inspection on medical devices in the market, ranging from devices for home use to human body implants. The quality assurance system is to verify conformity of distributed devices in terms of safety and efficacy after obtaining approval under the Medical Devices Act. If any non-conformity is revealed, administrative measures are taken and if necessary, recalls are ordered.

With the execution of the Good Manufacturing Practice on May 30, 2007, quality of medical

devices in the market are expected to be improved to a certain extent. Still, since medical devices can impose direct and enormous impact on public health by its nature, even more emphasis is given on the quality management and assurance. Therefore, medical devices that are highly likely to cause social problems in the future should be monitored more strictly, followed by intensive collection and inspection to induce voluntary quality management by manufacturers and importers. Overall, the Quality Control System should be continued and guaranteed so that only those medical devices with secure safety and efficacy are distributed in the market.

[ Table 7-3-4 ] Status of Collection and Inspections of Medical Appliances Over the Last Five Years

Year	Number of Items
2008	145
2009	289
2010	251
2011	322
2012	414

## 2) Performance in 2012

In 2012, 414 medical devices such as home heaters received quality inspection and resulted in findings of 57 products in non-conformity, some of which were ordered with administrative measures and some with recalls. At the same time, 「the Guideline for Recall and Disposal of Medical Devices」 was revised to specify the scope and the subject of recall, removal and disposal, procedures and standards, strengthening public safety in relation to medical devices.

[ Table 7-3-5 ] Results of the Collection and Inspection of Medical Appliances Over the Last Five Years

Year	Number of Items	Results of Inspection		
		Conforming	Non-conforming	Non-conformity Rate(%)
2008	145	137	8	5.5
2009	289	261	28	9.7
2010	251	189	62	24.7
2011	322	266	56	17.3
2012	414	357	57	13.7

### 3) Future Plan

In 2013, MFDS plans to designate products that received numerous complaints to the Korea Consumer Agency or other consumer organizations, medical devices for home use and implantable medical devices of which side effects or malfunctions may cause a wide range of damages to the public as subject to continued Post-market Vigilance.

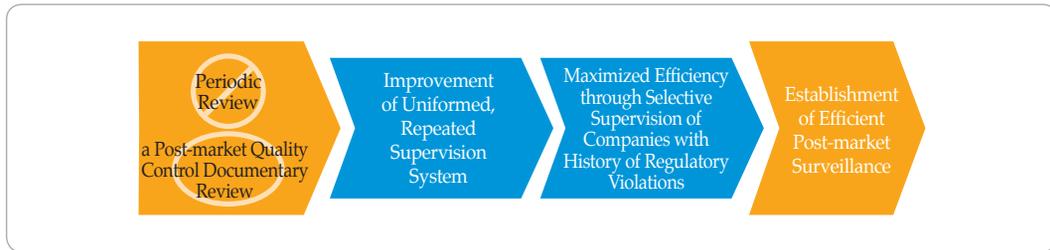
## 5. Changes to the Follow-up System for Medical Devices

### 1) Current Status and Prospects

In Korea, manufacturers and importers of medical devices have been able to increase their capacity for quality control thanks to the introduction of the certification of Good Manufacturing Practice equivalent to the international standards(ISO 13485). In line with this, there is rising awareness of the importance of quality and safety of medical devices in the market. Introduction of the certification system requires companies to pass the audit for regular renewal every three years. This resulted in the termination of 'periodic audit' conducted every two years in 2009. In its place, the 'Medical Device Status Assessment' was executed for companies to audit themselves as to their compliance with the Good Manufacturing Practice and submit the results. However, this system had its limits preventing Quality Control violations in advance or separating those companies in violation as this only involves document review without on-site inspection. Therefore, in 2012, the system was changed to apply to Class I medical devices. In order to strengthen monitoring regarding GMP compliance, the renewal audit and periodic audit were implemented in coordination. Companies with a history of regulatory violations were under intensive and pre-emptive risk based-quality management through irregular and planned on-site inspections.

### 2) Post-market Quality Control Documentary Review and Its Achievement

Every year a Post-market Quality Control Documentary Review was conducted on GMP certified device manufacturers and importers, and documents submitted by companies was reviewed according to the 'GMP System for Medical Device Manufacturer, Importers'.



[ Figure 7-3-4 ] Purpose of Self-audit

With the 2011 amendment of the Medical Devices Act and related regulations, 2012 has witnessed the establishment of efficient approval and review systems through selection and concentration and differentiated Post-market Surveillance System according to classification. Also, regular renewal audits and planned audits were coordinated in order to strengthen monitoring compliance with Good Manufacturing Practice. However, Class I devices, with the exception of some products, were exempted from GMP audit. Thus, it required companies that manufacture Class I devices to only undergo the regular monitoring system. Against this backdrop, companies manufacturing Class I devices only became subject to Post-market Quality Control Documentary Review .

[ Table 7-3-6 ] Participation Rate of Post-market Quality Control Documentary Review  
(Unit : number, %)

Classification	Total	Participating	Not Participating	Participating Rate, Compared with Previous Year	
				2011	2012
Manufacture	347	205	142	79.4%	59%( ↓ 20.4%)
Import	251	138	113	81.8%	55%( ↓ 26.8%)
Total	598	343	255		-

### 3) Irregular and Planned Inspections on Companies with History of Regulatory Violation

In 2012, the Ministry strengthened Safety and Quality Management Systems executing unanimous inspections prior to sales of second-hand medical devices, inspection on illegal use of investigational medical devices and regulatory compliance over companies with history of violations. In addition, prompt safety measures to medical devices with risk concerns have been carried out, such as inspections on distribution of dental implants suspected of possible

un-sterilization and execution of regulation to inspect sterilized devices.

< Major Crackdowns Over the Past Five Years >

- ✓ On a dental implant in distribution suspected of possible un-sterilization(November 2012)
- ✓ On quality control in relation to reverse flow of mother's milk in the use of breast pumps for babies and infants(May and June 2011)
- ✓ On illegal manufacturing or importing of medical scooters used by seniors and disabled people(December 2010)
- ✓ On any unapproved thermometer on sale in relation to Human influenza A(N1H1) (November 2009)

#### 4) Future Plan

In 2013, companies will be managed differently based on their history of regulatory violations. In this scheme, frequent violators will be subject to intensive inspection in line with stronger on-site guidance and audits. Frequent regulatory violators(three times or more) or companies that fail to acquire GMP certificate will be categorized as companies with deficiency and will be put under periodic inspection. Companies with a history of two or less violations will be categorized as those subject to intensive inspection. Companies handling sterilized devices will be subject to stronger control with a pre-emptive monitoring system for risk factors, as they have high potential to cause side effects.



2013 MFDS Report Ministry of Food and Drug Safety



# 08

## Food and Drug Safety Assessment

01. Expansion of Risk Assessment for Scientific Safety Management
02. Establishment of Drug Review System in Accordance with the International Level
03. Securing Global Competitiveness of Evaluation System on Biopharmaceuticals, Herbal Medicines and Cosmetics
04. Establishment of a Proactive Approval Review System of New Convergence Medical Device
05. Providing Scientific Basis for the Advance of Safety Management of Medical Products
06. Improving the Status as International Safety Evaluation Institution through the Advance of Safety Evaluation Technology
07. Strengthening National Lot Release System for Safe Use of Biologics
08. Promote R&D for Public Health



# 01

## Expansion of Risk Assessment for Scientific Safety Management

### 1. Summary

Risk assessment plays an important role as a means of communication to relieve peoples' anxiety against risk factors, and scientific evidence may be important in determining risk management policies.

The National Institute of Food and Drug Safety Evaluation will develop a safety standard on foods with harmful factors, a risk assessment base, and new evaluation techniques to reinforce pre-and post-management for the protection of public health.

### 2. Risk Assessment Principle

Risk assessment shall be carried out in accordance with four steps, which include hazard identification, hazard characterization, exposure assessment and risk determination; at first, risk assessment should use data to reflect domestic situation, but use data from international organizations or foreign materials in case of insufficient domestic data. Also, the analytical methods that are used throughout the steps covering supply and intake, including food manufacturing process, sampling, testing and exposure frequency should be considered.

Considering a variety of situations, risk assessment is written as realistic exposure scenarios. However, in case of sensitive groups to evaluation materials and high-risk groups, acute,

chronic, cumulative, complex effects should be considered, and for vulnerable groups such as pregnant women and children, a more careful analysis and information research is needed.

### 3. Outcomes

#### 1) Risk Assessment Results

The National Institute of Food and Drug Safety Evaluation carried out more than 100 cases every year regarding risk assessments of pesticide residues in food, animal medicines, pollutants, microorganisms and food additives, and packaging.

[ Table 8-1-1 ] Risk Assessment Result by Details

(Dec. 31, 2012, Unit : Case, Source : Food Safety Evaluation Department)

Field	Subjects	Substance	No. of Cases				
			2008	2009	2010	2011	2012
Residual Substance	Agriculture, Farm and Fishery Product	Glyphosate	153	174	122	119	91
Contaminant	Food	Ochratoxin A	11	34	14	12	15
Microorganism	Fishery Products	Staphylococcus Aureus	0	2	2	5	5
Food Additives, Food Packaging	Food, Migrants of Food Packaging	Tar Colors, Heavy Metals Etc.	7	9	16	22	41
General Component	Food	Glycidol	1	5	1	0	0
Total			172	224	155	158	152

#### 2) Establishing a Risk Assessment Base

In 2012, 110 test methods of newly registered pesticides, veterinary drugs, food additives, mycotoxins and heavy metals including 375 items were monitored.

[ Table 8-1-2 ] Test Method Development, Monitoring and Information Foundation Construction

(Dec. 31, 2012, Unit : Case, Source : Food Safety Evaluation Department)

Year	Test Method Development	Monitoring and Information Foundation Construction
2012	110	375
2011	41	32
2010	48	30
2009	42	39
2008	89	55
Total	384	300

The database website for pesticide residues and residual veterinary drugs, and the integrated website for contaminants were operated and updated findings of research. Also, a model for microbial growth prediction was developed and a management system for tracking causative agent of foodborne illness was built and operated.

The Monitoring Information Management System(MIMS) and Monitoring Database and Assessment Program(MAP) have been prepared, obtaining a total of 3,944,705 data for 488 kinds of harmful substances so far.

By providing 'risk communication' contents with various concepts to facilitate communication with people and understanding of scientific facts in Food Safety Management, the capacity for risk communication was reinforced and more tailored communication was supported.



[ Figure 8-1-1 ] Smartphone Apps and Animations for Pesticide Residues and Veterinary Drug Residues

### 3) Capacity-building Activities for Risk Assessment

For the sake of risk assessment method newly applied in Europe and America, policy-based researches including the development of education contents and training courses were carried out.

### 4) International Cooperation for Enhancing Risk Assessment

#### (1) Conclusion of a Memorandum with the Federal Institute for Assessment (BfR) in Germany

The actively cooperative activities such as joint research projects, eliciting information sharing and personnel exchanges and international symposium in the areas of food and

cosmetics assessment are carried out with the Federal Institute for Assessment in Germany.

## (2) International Cooperative Research for Standard Internationalization on OECD Endocrine Disrupter Search Method

The National Institute of Food and Drug Safety Evaluation has consistently participated in an international joint research for the establishment of testing method guidelines with OECD since 1999, and has proceeded the international validation study with the Chemicals Evaluation and Research Institute(CERI) and the National Institute of Health Science(NIHS) in 2012.

## 5) Evaluation Guidelines

The National Institute of Food and Drug Safety Evaluation has prepared risk assessment guidelines regarding residues, contaminants, food additives, migrants of food packaging and microbial every year.

[ Table 8-1-3 ] Risk Assessment Guideline Publishment Result

(Dec. 31, 2012, Unit : Case, Source : Food Safety Evaluation Department)

Year	Guideline Publishment for Evaluation
2012	3
2011	5
2010	2
2009	2
Total	9



[ Figure 8-1-2 ] Guideline for Evaluation, Analysis Guideline for Antibiotic-resistant Foodborne and Microbiological Risk Assessment Manual

## 4. Plan

### 1) Proposal of Scientific Risk Evaluation and Safety Standard

For setting reasonable standards and specifications, risk assessment regarding pesticide residue in all fields of products is performed, such as domestic and imported agriculture, farming and fishery product, veterinary drug residue, toxic substance of heavy metal, natural toxin of mycotoxin, dioxins, micro-organism, food additives, migrants of food packaging, drug and cosmetic. Especially, chemical supplies(detergents, wipes, etc.) will be assessed whether there is any hazardous materials, and science-based data for exposure assessment of the manufactured nanomaterial will be secured.

### 2) Expansion of Risk Assessment for Livestock and Marine Products and Food Risk Assessment Unification

In line with the appearance of the Ministry of Food and Drug Safety, the safety management division that belonged to the Ministry of Agriculture and Forestry was transferred to MFDS. Scientific standard and test method will be obtained.

### 3) Total Dietary Research with Regards to Actual Intake Patterns

Total dietary survey is scheduled to be performed considering actual intake patterns to find harmful substances in food. In particular, hazardous substances that are generated unintentionally in the manufacturing process will be investigated comprehensively.

### 4) Professional Education on Risk Assessment Domestic and Foreign Professional Network

To expand the domestic infrastructure for risk assessment, personalized professional training program is arranged. In addition, for advanced international exchanges and cooperation, symposium for the latest risk assessment technology will be held with the German Federal Agency. For the proposal of searching test methods of OECD medicine endocrine disrupter, the validation studies on transcriptional activity testing method of the androgen receptor of

human prostate cells will be proceeded with Japan's National Institute of Food Hygiene.

### 5) Information Providence for Practitioners and General Public for Risk Assessment Transparency

The National Institute of Food and Drug Safety Evaluation provides information about risk evaluation through the website for better understanding of procedure, evaluation and management. Furthermore, various workshops will be held regarding mobile app development, animation distribution for elementary school students, consumer PR content development for the prevention of food poisoning, executive meetings for packaging inspection, workshop for food additives test methods, mobile app development related to risk communication of climate change and food safety and reduction of estimated endocrine disruptors exposure.

## 02

**Establishment of Drug  
Review System in  
Accordance with the  
International Level****1. Operation of Good Review Practices(GRP)**

The Ministry of Food and Drug Safety has established and amended 'Good Review Practices' since 2004 to improve the consistency and fairness of drug review process so that reviewers and civil petitioners can utilize the GRP for their job. The area covered by the Good Review Practices is mainly as follows: 1) Transparency of review procedure through information disclosure about review process 2) Standardization of review procedure through the Good Review Practices-Standard Operating Procedure(GRP-SOP) 3) Enhancement of reviewers' expertise through systematic training programs.

In 2012, we released 118 cases on the 'review process of safety and efficacy' and the 'review process of specification and analytical procedure of drugs'. This includes clinical trial designs, selection criteria, the number of subjects and safety and efficacy endpoints as well as comprehensive opinion of reviewers, list of submission document related to review, regulations that should be applied. The disclosed review result was utilized as 'an indicator for transparency and fairness' when reviewing and 'reference' for pharmaceutical industry when developing similar products.

In particular, the 'Standard operating procedures for the Good Review Practices(GRP SOP)' is a manual that ensures consistency and predictability of safety and efficacy review on three key areas of the drug life cycle(during clinical trials, MFDS application review and postmarket

monitoring and analysis) and the first GRP-SOP was established in 2007. Currently, in 2012, a total of 31 guidelines are being operated. The SOP has enabled enhanced efficiency of review process, consistency of review process even when there is a change of reviewers and transparency of review process by publicizing the review principles.

## 2. Development of Guidelines through International Harmonization

By establishing guidelines and publicizing QnAs and Frequently Asked Questions raised by civil petitioners, the Ministry of Food and Drug Safety has enhanced mutual understanding among reviewers and civil petitioners, and expanded communication channel with pharmaceutical industry through the operation of working groups that include industry, civil presentations and discussion meeting.

For the advancement of safety specification standards, we have completely revised the 「Korea Pharmacopoeia」 and 「Korean Pharmacopoeia Codex」, (December 2012), as well as ‘the Guideline on Validation of Analytical procedure for drugs’ and ‘the Manual of Guideline on Validation of Analytical Procedure for Drugs’(September 2012) were revised to strengthen the efficacy of review on quality.

In order to ensure consistency and predictability through specific review criteria on safety and efficacy, we set two evaluation guidelines for non-clinical trials. In addition, we have also created and revised 8 evaluation guidelines on clinical study including ‘clinical trial evaluation guidelines for elderly people’ in order to provide information about selection criteria, study designs and clinical endpoints(See Homepage> Relevant Rules> guidelines and manual).

To promote consistency in the generic drug review process and provide more convenient services to civil petitioners, detailed standards about application test (pharmacokinetics/ pharmacodynamics/ comparative clinical trial) for 507 drug substances were established (September 2012). The standard will be reflected in the revision of the 「Designation of Drugs which require bioequivalence」 (MFDS’s Notification).

In addition, recommendations of bioequivalence test of 20 drug substances prepared based on the latest international trends(November 2012) and, accordingly, bioequivalence test data of 56 ingredients were provided.

In line with pursuing mandatory installment of the comparative dissolution testing machine control system by the government, ‘the management guideline of dissolution test’

was established(April 2012). This guidance includes the types of dissolution test facility, organization, equipment, reagents and to Standard Operating Procedure(SOP).

Also, in order to build a data management system that can be utilized in generic drug evaluation by comparing it with dissolution profiles to the reference drug, reference drug dissolution profile database was established in the MFDS's internal computer system through conducting research project(December 2012).

### 3. Effort for International Harmonization of Drug Review

Since Korea joined the ICH in the Global Cooperation Group(GCG) and the Regulators Forum from 2007, Korea has suggested the establishment of various collaborative working groups and participated in multi-facet activities enthusiastically.

In addition, Korea has actively taken its part in the guideline development by participating in the ICH Working Group since June 2011 and given many feedbacks regarding the development of four ICH guidelines that the MFDS has been participating as a member of the working groups. As a result, the 'Periodic Benefit-Risk Evaluation Report(PBRER)(E2C)', which Korea had participated in its development, reached step 4 in November 2011.

The APEC Harmonization Center(AHC) was established in the Ministry of Food and Drug Safety(MFDS) in June 15, 2009 to provide a platform on harmonization regarding review processes and management systems of pharmaceuticals and medical devices within APEC region and promotes active discussions on current issues and development of training programs.

It has conducted various works in a consistent way through network, publishing e-publication and operating web-site by sharing information actively with its member economies, conducting research on regulatory policies and requirements as well as offering training programs.

In particular, since its establishment, the AHC has organized 14 workshops that has offered training opportunities to a total of 5,300 domestic and international regulators and experts from industries.

In every workshop, the MFDS and Korean pharmaceutical industries gained opportunities to build wide networks with global experts and regulators from overseas.

Additionally, the AHC has invited trainees from developing countries in APEC region

and provided them training opportunities. By AHC programs, Korea has contributed to the development of APEC region such as strengthening human resources in health industry of developing countries and promoting regulatory harmonization in APEC region.

Also, by AHC, Korea has played a role as a communication bridge between developing and advanced countries that has enabled Korea to gain a favorable attention on its export goods from the related countries as well.

# 03

## Securing Global Competitiveness of Evaluation System on Biopharmaceuticals, Herbal Medicines and Cosmetics

### 1. Establish Future-oriented Biopharmaceutics Review System

As biomedicine, recombinant medicine and cell therapy have complex structures and their approving review systems should be different from synthetic drugs, considering a high risk of contamination.

Due to a variety of specificity of biomedicine, a separate operating regulation from synthetic drugs has been operated since 2003. In addition, annual guidelines were published each year for the adequacy of bio-medicine review process as well as for the standardization bio-ventures.

[ Table 8-3-1 ] Biopharmaceuticals' Guidelines Published in 2012

(Dec. 31, 2012, Source : Biologics Division)

No.	Title
1	Non-clinical and clinical evaluation of biological factor (G-CSF) biosimilar Guideline for Recombinant granulocyte colony-stimulating
2	Validation guideline for Mycoplasma detection method using nucleic acid amplification assay
3	Cell Culture Inactivated Influenza Vaccine Review Guideline
4	Approval and examination guideline for High-risk virus in vitro diagnostic rapid diagnostic drug

The open-examiner system and functional review system were introduced in order to strengthen expertise in biopharmaceutics review system, as well as long-term job opening for

enhancing regulator's capacity, which has contributed to rapid, safe and effective approval of biopharmaceutics and its domestic supply.

In the future, regulations that fit for international standards and guidelines for approval are to be established and amended, so that more rational screening criteria for high-tech products are to be proactively prepared. This will contribute to the international competitiveness and the facilitate of high-tech bio-medicine by improving the capacity of auditors to the level of international experts.

Also, the Ministry of Food and Drug Safety is going to sign a confidential agreement with advanced regulatory institutions such as the U.S. Food and Drug Administration(the Food and Drug Administration, FDA) and Germany Federal Republic of Biologics Evaluation(Paul Ehrlich Institut, PEI) to enhance the partnership with regulators. Also, the Ministry of Food and Drug Safety will join in the international standard preparation with World Health Organization(WHO), United States Pharmacopoeia (USP) and participate in WHO blood products regulators by leading role in contributing to international regulatory harmonization. These high-quality international activities will contribute to the international reliability in the field of bio-pharmaceutical regulations.

## 2. Support Global Competitiveness of Biosimilar

The Ministry of Food and Drug Safety has made efforts to support domestic market and Korea's global competitiveness in domestic biosimilar products. First, the relevant provisions were preemptively enacted to meet the international harmonization. Biosimilar was defined as 'biological products' and its permission and review standard was reflected in 'Biological products evaluation guideline' in July 2009. Second, communication channel between developers and regulators was provided through the 'Civil and official Biosimilar working council' so the process of clinical trials and commercialization could be rapidly processed. Third, the institutional foundation such as the introduction of the unit review system of quality and non-clinical test. As a result of these various supporting policies, the 'Remsima(Celltrion)', the world's first biosimilar monoclonal antibodies, was approved in July 2012, as well as marketing authorization from European Medicines Agency(EMA). This way, safe and effective biosimilar development is to be supported actively through the consistent cooperation with international organizations and internationalized standards.

### 3. Realization of People's Safety through the Self-sufficiency of Vaccine

The Ministry of Food and Drug Safety is supporting necessary skills for the establishment of vaccine manufactory by configuring the council with domestic pharmaceutical companies and by providing consulting service from the stage of vaccine development to its approval.

Currently, 28 kinds(15 kinds designated as NIP vaccines such as B Hepatitis vaccine, 9 kinds of non-NIP vaccines such as A hepatitis vaccine, 4 kinds of anti-terrorism such as anthrax or avian flu pandemic vaccine) are divided as major domestic vaccine. Among this, 7 kinds are domestic self-produced vaccine and only 24,300,000 dose(48.5%) out of 50,000,000 dose supplied in domestic market is produced in domestic market. Thus, the Ministry of Food and Drug Safety is going to increase its self-sufficiency ability of vaccine by expanding 22 kinds of domestic production per year. As a result, 7 kinds out of a total of 15 species are to be produced in domestic market, but it will be increased to 12 kinds in 2017 and 13 kinds in 2020. 9 kinds of other vaccines are not scheduled to be produced in domestic market, but it will be increased to 4 kinds in 2017 and 5 kinds in 2020. Currently 4 kinds of anti-terrorism vaccine is expected to be produced in domestic market.

### 4. Natural Drug Development and Global Market Support

#### 1) Improve Accessibility through Scientification and Standardization of Herbal Pharmaceutical Product

##### (1) Status and Outcomes in 2012

Currently, the Herbal Pharmaceutical product has the problem of poor accessibility and misunderstanding of consumers. This caused to have a variety of measures for the activation of the Herbal Pharmaceutical products by enhancing their accessibility.

- ✓ Preparing permit direction review(draft) on prescription of oriental medicine hospita
- ✓ Holding step-by-step policy roadmap briefing for the application of composition profile quality standard
- ✓ Conducting training of approval and reporting system for herbal medical hospital

##### (2) Plan in 2013

The approval and review method for the Herbal Pharmaceutical product will be provided

and the development of excellent herbal pharmaceutical product will be promoted as a guideline for ingredient profiles.

## 2) Natural Drug Development and its Global Market

### (1) Status and Outcomes in 2012

Recently, the natural medicine is emerging as new resources in pharmaceutical industries and foreign countries. In addition, as the overseas expansion of domestic natural new drugs is taken shape, guidelines were published to support the development of domestic natural medicines.

- ✓ Organizing and operating the 'Natural medicine industry development council' formulation branch(total 9)
- ✓ Publishing the 'International common technical document guideline for Herbal medicine formulation(quality)'
- ✓ Publishing the 'Regulation commentary on herbal medicine authorization and reporting'
- ✓ Discovering and implementing natural product drug globalization support
- ✓ Drawing approval and permit countermeasures against the Convention on Biological Diversity

### (2) Plan in 2013

Workshops inviting regulators of natural products for companies are to be held and data sheets for country-specific natural medicine approval system are scheduled to be published.

## 5. Improve the Examination System for Quasi-drugs and Cosmetics

The Ministry of Food and Drug Safety has prepared the approval management method to secure the safety of items that were questioned with safety problems such as humidifier sterilizer. In addition, some regulations were revised for the ease of purchase of safe items and the establishment of standard on additives and mosquito repellent contributed to activation of industry and transparency in evaluation process.

Meanwhile, the Ministry of Food and Drug Safety has introduced a new Cosmetic Act in order to improve our cosmetics to world-class products. For rapid adaptation for consumers and industry, hazardous material management plan and scientifically proven method for the display of content and advertising were presented. In the case of functional cosmetics,

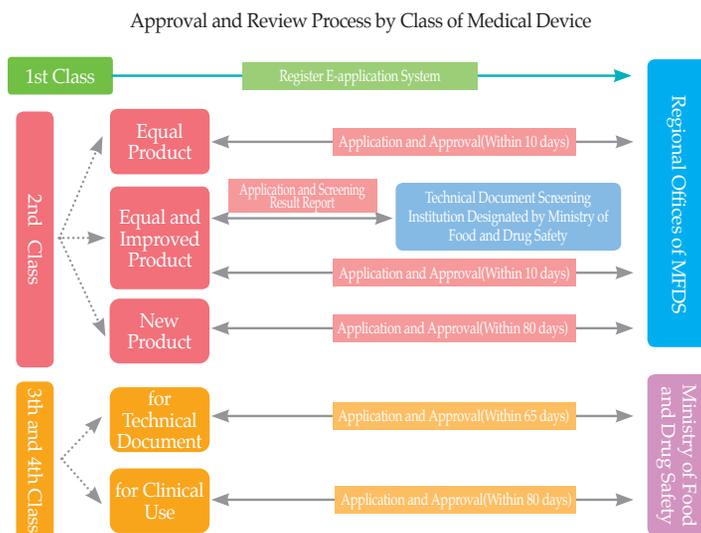
consumer choices were constantly reinforced by lowering the barriers of market entry. These efforts are expected to help our cosmetics to be world-class cosmetic products.

## 04

## Establishment of a Proactive Approval Review System of New Convergence Medical Device

### 1. Background

The government has strengthened the infrastructure of medical device industry under the vision of being the world's 7th in the medical equipment sector by 2020 through the strategy for the development of medical devices. The Ministry of Food and Drug Safety tried to ensure objectivity and transparency of review and approval process by strengthening the safety



[ Figure 8-4-1 ] Medical Device Approval and Review Process Diagram

management system.

While developing technology applied to medical device releases a variety of products, there is a difficulty of limited authorized screening personnel. However, the Ministry of Food and Drug Safety does its best to respond to the market environment quickly and positively under the goal of public health, safety and medical equipment improvement.

## 2. Promotion in 2012

The department of medical device evaluation strives to improve the approval and review system of medical device through the simplification of licensing procedures, selection and concentration of management efficiencies and transparency and objectivity of examination. In particular, the support of approval and review for a new convergence medical device is to be strengthened.

### 1) Support of Approval and Review

#### (1) Activate the Permit System Such as Newly Developed Medical Devices

In order to inspire the development of the domestic manufacturers and medical device industry, the approval, clinical trials, manufacturing and quality control standards(Good Manufacturing Practice, GMP) is supported with administration and technology from development to commercialization with the specified authorized representative of each sector as a helper. In addition, 'Core medical equipment project for commercialization' is also supported for the global competitiveness of domestic medical equipment. The business agreement with Korea Industrial Technology Evaluation and Korea Testing Laboratory has made it possible to approve the helper system with 12 developing products such as Laser Surgical equipment.

#### (2) Support the Approval and Review of State-of-the-art Convergence Medical Equipment

The newly developed state-of-the-art medical equipment and convergence medical equipment are supported with a quick and reasonable system. The 'Clinician cooperation program' is its first one. The clinician cooperation program appoints clinical experts in

domestic medical institutions by clinical disease. It is the program for a new clinical method for medical devices, safety and effectiveness of the evaluation and consultation from experts on the new feasibility. The second one is 'Review system with external experts'. As state-of-the-art medical equipments requires a wide range of knowledge, this program makes the rapid commercialization of products possible through the preemption of world market.

### (3) Revise the Excellent Medical Screening Guidelines

The policies and procedures for medical devices are managed by business unit standardizing legal background, roles and responsibilities of business practitioners and detailed procedures and operating instructions and 35 excellent screening instructions are operated. In order to reflect changing policy environment, 'excellent medical screening guidelines' are established and revised consistently.

## 2) Enhance Approval and Review Expertise

### (1) Establish the Commercialization of U-health Care Medical Device

The commercialization foundation for the activation of U-health care medical equipment industry was established. Thus a 'Professional council for U-health care medical equipment' was organized for the guidelines of itemized screening. Accordingly, the training and education for U-health care products developers and practitioners were carried out. The Ministry of Food and Drug Safety is going to strengthen its support for the 'Activation of U-health care medical equipment market' as the one of the 'Government 3.0 key promotion businesses'.

### (2) Strengthen Cooperation of Medical Device Clinical Statisticians

To ensure the reliability and objectivity of medical examination, 16 external experts of clinical statistics was utilized and the results of clinical reports and statistics were reviewed in the process. Professional meetings for the clinical and statistical review was conducted in more than twice a month.

### (3) Operate Partnership Program with Clinical Experts of Medical Device

The 'Partnership program with clinical experts of medical device' is going to be operated to

get advice from experts. Each clinical experts is expected to join in the program to offer advice on approval and screening. In 2011, there was 31 experts in 7 clinical sectors and 129 experts in 16 clinical sectors in 2012.

### 3. Future Plan

The government is going to strengthen auditors' professionalism by ensuring the objectivity and transparency of auditors for the development of the medical device industry. Considering the advent of an aging society and chronic diseases, the need for structural changes are inevitable due to the rapidly growing medical device industry. The approval and review system for the development of new convergence medical device will be continued preemptively.

# 05

## Providing Scientific Basis for the Advance of Safety Management of Medical Products

### 1. Research on Drug Safety Management

#### 1) Advancement on Standards, Specifications and Test Methods

Essential and frequently-used drugs are managed with respect to 'The Korean Pharmaceutical Codex' besides 'The Korean Pharmacopoeia'. In 2012, 85 items out of 116 items were revised and 61 green testing methods which replace the hazardous solvent with environmentally-friendly solvent were developed. A handbook for general test method of 'The Korean Pharmacopoeia' was published, as well as the DB(data base) of an official compendium was modified to provide information and educational materials for drug testing methods to the relevant research institutions.

#### 2) Standard Management

The reliability, consistency and suitability of the quality control on pharmaceutical standards are essential for the production of pharmaceuticals. The Ministry of Food and Drug Safety has distributed the standard products that were made from the raw material drugs. 176 kinds(14%) out of 1,243 kinds of standard products are retained as of March 2013 and products that have been distributed are on the rise from 1,322 in 2011 to 1,401 in 2012.

### 3) Provide Drug Safety Information for Underprivileged Level of People

In order to provide drug safety information for the underprivileged 'The information for using generic drugs that are commonly used' was published in braille with a voice recognition code and in multi-language. The book contains 10 kinds of drugs such as wound treatment, preventive medicine for travel sickness and so on.

## 2. Research on the Safety Management of Biopharmaceutical Products

### 1) Prepare the Foundation of Leading Evaluation for Biopharmaceutical Products

A variety of guidelines(draft) and test information booklets are developed and published each year for the evaluation of the high-tech bio-medicine and a rapid and scientific development. In addition, 3 cases including 'Validation guideline for Mycoplasma detection using nucleic acid amplification' for cell therapy in 2012 and 3 test information booklets have been prepared for the quality assessment of recombinant formulary of drugs such as biosimilar. Since 2010, MFDS has been trying to put the recombinant formulary of drugs on the Korean Pharmacopoeia's list. In 2012, standards for Somatropin and erythropoietin flood, human insulin and human insulin injection reference standards(draft) were established.

### 2) Standardization Research of the Assessment on the Biopharmaceutical Products

The Ministry of Food and Drug Safety launched the manufacturing and processing businesses for biopharmaceutics of national standard in 1998 and 40 items were manufactured and managed until June 2013. 150 cases were distributed to outside vendor in the year of 2012. In order to improve the reliability of national-standard quality, MFDS has been monitored for its safety in every year with separate storage rooms.

Through the research on the harmonization of test methods and development of national examination method such as vaccines, 55 evaluation test methods(37 enactments, 18 amendments) and 3 guidelines including 'Guideline for Influenza assessment for cell culture inactivation' were established.

### 3) Evaluation and Research on Drafting and Approval of Biopharmaceutical Products

The safety management was strengthened by conducting the evaluation research of four vaccines such as Hepatitis A vaccine. The evaluation was done by monitoring on clinical effect of vaccines that are distributed in domestic markets. In addition, educational programs and brochures were distributed for the safe use of insulin for diabetic patients.

## 3. Research on the Safety Management of Natural Products

### 1) Advancement on the Reference Standard of Natural Medicine

As the national quality management technique using natural medicines changes rapidly, Korea is setting test method by using standard herbal medicine for scientific and rational quality control. In order to design a standard contents from the active ingredients, scientific and evidentiary materials were gathered and element profile data of herbal medicine was consistently accumulated.

### 2) Management of National Medicinal Plants Resource Management Center

The National Institute of Food and Drug Safety Evaluation has managed 'Herbal resource center' in Chungbuk Okcheon, Gangwon-do Yanggu and Jeju to support development of natural products(medicine, herbal cosmetics and health food). Among the centers, Okcheon center holds about 1,000 species of medicinal plants.

The 'Herbal medicine resource center' was completely constructed in August 2010. The center exhibits about 3,000 samples including official and civil materials, which gives opportunity of field experience to students majoring in the Oriental Medicine and Pharmacy.

### 3) International Harmonization of Natural Product Drug

The Professional forum(FHH) was established with the purpose of unification of origin and size of oriental medicine among 7 countries in the World Health Organization(WHO) and the Western Pacific Regional Office(WPRO). Korea, Japan and China are the centers of this forum configuring 3 sub committees. Korea is in charge of the 2 subcommittee and conducts FHH website covering Good Manufacturing Practice(GMP) and Good Agriculture Practice(GAP).

Korea also emphasized the need of 'International herbal standard manufacturing guideline' in November 2012.

## 4. Safety Research on Cosmetics and Quasi-drugs

### 1) Prepare the Reference Standard(Draft) and Support Effective Permit Review

For the convenience of drug purchase, 48 items including digesting and invigoration medicine were switched to quasi-drugs in July 2011, which makes it possible to be sold outside pharmacy. Thus, for the active and efficient quality management of the quasi-drugs, notice for standard specifications for 26 raw materials(draft) was prepared, including pesticides as mosquito repellents. In addition, according to the revised Cosmetic Act(August 2011), the 'Notice for safety management standard of cosmetics(draft)' and the 'Efficacy Evaluation Guideline for elasticity, moisturizing and sebum control' was established.

### 2) Support Safety Management Based on Scientific Evaluation and Post-quality Management

As the standard of living becomes better, the interest in cosmetics increases. Accordingly, the safety problems regarding materials and contaminants are frequently issued. In 2012, a risk of benzene from eye cosmetic products was assessed. In addition, international workshops for risk assessment were held by inviting professionals from the US and Germany. Besides, a guideline(draft) for analysis method of steroids and related substances from colored cosmetics was prepared.

### 3) Provide Information for the Proper Use of Cosmetics

In order to provide the information for the correct use of cosmetics, 'Think cosmetics', a consumer education material with various information about functional cosmetics, was published and distributed for high school students, university students and housewives.

## 5. Research on the Safety Management for Medical Device

### 1) Advancement on the Reference Standard of Medical Equipment

The Ministry of Food and Drug Safety has set the latest scientific information as compared with domestic and international standards of various medical devices and has established the reference standard which ensures the safety of medical devices.

### 2) Build Evaluation Guidelines for Medical Equipment with New Technology and Radiation Safety

The domestic and international competitiveness of medical device was enhanced based on the improvement of screening standardization, internalization and civil convenience due to the guideline of test method of the latest medical device. In addition, for the reduction of X-ray radiation exposure for patients, guidelines for the recommendation of patient dose were published continuously as well as the annals of personal exposure dose for radiation workers.

### 3) Development of the Evaluation Technology of State-of-the-art Medical Equipment

The Ministry of Food and Drug Safety is trying to support rapid screening of the latest medical device reflected with state-of-the-art technology such as a blood-free glucose meter.

### 4) Medical Radiation Standard Maintenance and Supply

In December 2010, calibration facilities were installed in Chungbuk Osong and designated as new calibration institution by the Korea Laboratory Accreditation Scheme(KOLAS). And, quality system that meets KS Q ISO / IEC 17025 criteria was established so that radiation standards are provided through the calibration of 5 items in radiation field such as chamber-type dosimeter. In 2012, a total number of 170 calibration on radiation meter was conducted as well as 516 radiation standard survey were conducted using irradiation device.

### 5) Safety Management of Medical Radiation Generators

In 2012, 27,052 cases of diagnostic radiation generator test were conducted with 7,488 radiation defense tests. In addition, 766 device corresponding to 2.8% of all cases were unsuitable. Unsuitable for radiation defense was 2 cases which were equivalent to 0.03% of the whole. Unappropriated equipments and facilities were repaired and used after being retested.

### 6) Support on Medical Devices Quality Control Inspection and Institution

By June 2012, the advanced and scientific test methods for medical equipment made it possible to test 123 items including synthetic condom, thermometer by measuring safety and accurate performance of medical devices. In addition, technical supports and overall management supports were carried out for medical testing institutions that registered to the Ministry of Food and Drug Safety.

# 06

## Improving the Status as International Safety Evaluation Institution through the Advance of Safety Evaluation Technology

### 1. Development and Research on National Management of Toxic Materials and Nano-toxicity Technology

#### 1) National Management of Toxic Substances

In order to provide scientific information that can protect public health from hazardous substances, the National Toxicology Program in Korea(KNTP) has been promoted since 2002. Toxicity data for 41 kinds was produced and utilized as evidence for safety assessment.

#### 2) Technology Development for Nano-toxicity Assessment

In order to arrange safety assessment of nanotechnology-based products, the standardization for nanomaterials toxicity test methods are discussed through the participation of international validation study on toxicity testing of nanomaterials and nanotechnology standards organization members from the Organization for Economic Cooperation and Development(OECD) and the Working Party on Manufactured Nanomaterials(WPMN) and this effort is strengthening international cooperation.

### 3) Toxicity Information System

Since 2006, Toxicity information system(TOX-INFO) that includes addition information DB and product information DB has been operated with the purpose of giving quick toxicity information of hazardous substances and domestic addiction treatment. Until now, 1,182 Toxicity information, 340 addiction information and 17,499 product information was built. Upon the past accident of humidifiers and hydrofluoric acid, the number of use of visitors on the system is on the rise.

## 2. Build International Cooperation of Animal Alternative Test Methods and Infrastructure

Recently, the social needs for animal welfare are on the rise. The Ministry of Food and Drug Safety established the Korean Center for the Validation of Alternative Methods(KoCVAM) in order to support policy establishment for the development of alternative test method for test animals based on the international trend. Through this, Korea became the 5th country that signed the International Cooperation on Alternative Test Methods(ICATM) following European Union, USA, Japan and Canada and proactively respond to the international trend on animal alternative test method through validations. Furthermore, the latest information and training opportunities are constantly provided through website, symposia and workshops. Korea cosmetics animal alternative test method validation center distributed eight 'Animal toxicity testing guidelines for alternative method', as well as support for animal studies, development of alternative test methods and validation studies and professional evaluation.

## 3. Prediction Research of Drug Safety

### 1) Support for Technology Related to Drug Safety Management and Research Advancement

Recently, scientific evidence for policy decision such as feasibility studies on temporary drugs or growing domestic inflow of new similar drugs has been provided. In addition, for more rapid dependence evaluation, development of rapid assessment studies using state-of-the-art technology such as 'in vitro / in silico' are ongoing in parallel.

## 2) Research on Safety Pharmacology Studies

The mandatory testing of safety pharmacology including cardiovascular, respiratory and central nervous system was established in accordance with the international standard of 'The International Conference on Harmonization(ICH)' and its authorization and approval work has been supported constantly.

## 3) Drug Interaction and Metabolic Evaluation

A standardization of intestinal microbial enzyme mix was developed for the first time in Korea. After it was metabolites with using intestinal microbial metabolism enzyme mix and Korean fecal samples upon synthetic drugs, the metabolism was analyzed qualitatively and quantitatively. Consequently, the comparative research on the role of drug metabolism reaction system of oral administration drug has been conducted. In addition, research to establish evaluation and validation system of major cytochrome P450(Cytochrome P450) related to metabolism of drugs is on the progress.

## 4) Prediction of Dielectric Technology Applications Safety

The genome analysis of obtaining step-by-step genomic profiles by extracting mesenchymal stem cells from human bone marrow and umbilical cord blood is on the progress and research on ensuring genome profile by steps of which the mesenchymal stem cells are differentiated into cardiocytic cells and cartilage cells is also ongoing.

# 4. Research on Korean Clinical Trials and Drug Evaluation System

## 1) Provide Scientific Basis for Personalized Drugs Suitable for Korean

According to the paradigm shift of pharmaceutical use to personalized drug therapy, the number of drugs that contain the genetic information are increasing in advanced countries. The National Institute of Food and Drug Safety Evaluation has established the Korean Pharmacogenetic Information DB harboring 50,390 cases of pharmacogenetic information and 16 patents on Korean drug response prediction method to acquire Korean-specific

pharmacogenetic information. The NIFDS also developed drug response comparison booklets between ethnics / races according to genotype and methods for genotype analysis of 18 drug metabolizing enzymes. The NIFDS also released a draft guideline of drug labeling for pharmacogenetic information and provided draft drug label with pharmacogenetic information for 5 drugs including voriconazole. In addition, the NIFDS developed the pharmacogenetic diagnostic kit for that simultaneously analyze 141 genes / 392 genotype at single assay. Results on personalized drug were published in journals listed on Science Citation Index(SCI).

## 2) Advancement of Clinical Trials and Building System on Drug Benefit and Risk Assessment

In order to strengthen the international competitiveness of domestic clinical trials, we established two draft guidelines for cutting-edge clinical trials including adaptive clinical trial guideline and 71 draft guidances on clinical trial design and evaluation. The NIFDS released to public an updated version of Clinical trial Knowledge Based containing a total of 1,314 clinical trials data. To respond drug safety issues, drug benefit / risk balance assessment procedure(draft) was established and published a 'Comprehensive drug Information Booklet' for the appropriate drug use which harbored labeled information of 30,046 market authorized drugs.

## 5. Improve the Status as an International Testing Analysis and Research Institution

### 1) Establish an International Testing and Analysis System

Relevant documents are established and revised annually not only to ensure rapid and accurate results in testing and inspection analyses in an international level but also to build a reliability of scientific detecting techniques and/or inspection process. Contributing to the improvement of reliability of many inspection agencies which are managed by Ministry of Food and Drug Safety (MFDS), an internationally-competitive education system has been developed for food testing and inspection fields and a standard operating system model for pharmaceutical laboratories has been developed. Furthermore, we provide proficiency testing(PT) samples to 13 accredited overseas inspection agencies to improve reliability of food

and drug inspection agencies and manage the Advanced Core Laboratories.

## 2) Improvement and Development of Analysis Methods

As the unlawful adulterant of food and medicine gets diverse, 703 cases of illegally mixed compounds in food and medicine was analyzed in 2012. In addition, the world's first isolation and identification of 'Chlorosibutramine', which is the analogue of sibutramine (appetite suppressant) was carried out.

## 6. Laboratory Animal Resource Management and Research

### 1) Repository for Animal Model

The National Institute of Food and Drug Safety Evaluation, which was designated as the Bioresource Repository, is supporting drug efficacy evaluation and life science research. Model mice deposited from external research organization or internal one were preserved, cared or parceled out to external universities and research institutions. Total 12 mutant model animals were maintained and supplied 6 times to domestic researchers.

### 2) Scientific Support for Animal Experiments and Management of Animal Care and Use Program

The National Institute of Food and Drug Safety Evaluation completed the on-site assessment for certification from the Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC-I). In addition, the institutional animal care and the committee (IACUC) are organized in accordance with the law on experimental animal. It directs the deliberation and approval of animal use protocol, oversees the animal care and use program. Members from the NGOs, professional veterinarians or other external members are included in the committee. In order for the scientific and ethical use of laboratory animals, the animal experiments are to be conducted only for those who have completed education and training program. In accordance with the animal care and use program, a total of 30,668 out of 5 kinds of animals were supplied for national shipping approval testing and research tasks in 2012.

# 07

## Strengthening National Lot Release System for Safe Use of Biologics

### 1. Summary

In Korea, the national lot release system is implemented to check the quality of biologics such as vaccines and plasma derivatives once again before being distributed to markets. Its purpose is to check the assurance of quality and safety of biologics by lot numbers.

### 2. Achievements

#### 1) National Lot Release

The national quality management system of biologics such as vaccines and plasma derivatives in June 2012, changed into the 'National lot release system' that added the review on quality information from raw material to finished product based on the lot release test of finished product.

The biggest change in accordance with the implementation of the national lot release system is the mandatory submission of 'Summary Protocol(SP)'. So the national quality assurance level could be improved due to the quality control ranging from raw material to finished product.

In 2012, the National Center for Lot Release has conducted national lot release for a total of

2,049 lots increased by 194 lots compared to 2011, which shows the constant increase as 13% annual growth rate over the past three years.

[ Table 8-7-1 ] Annual Performance of National Lot Release

(Dec. 31, 2012, Unit : Lots, Source : National Center for Lot Release)

Classification \ Year	2010	2011	2012
Bacterial Vaccine	306	417	299
Viral Vaccine	562	574	600
Plasma Derivatives	659	772	989
Botulinum Toxoid	70	92	161
Total	1,597	1,855	2,049

## 2) Quality Control Laboratory Network(QC Lab-Net)

In order to promote the efficiency of quality control and international harmonization through the information exchange between manufacturing laboratories and national laboratories of biologics, the Quality Control Laboratory Network(QC Lab-Net) was organized in 2011.

And, the National Center for Lot Release has conducted international harmonization of quality management test method and standardization research, testing training and proficiency program through the QC Lab-Net and enhanced communication through annual workshops.

## 3) International Co-operation Activities in World Health Organization(WHO)

The National Center for Lot Release has conducted international cooperation actively such as the WHO Technical Service Agreement, Vaccine Hands-on Training program management and technical advisory on international guidelines of WHO.

### (1) WHO Technical Service Agreement(TSA)

The Ministry of Food and Drug Safety(The National Center for Lot Release) has conducted potency test and thermal stability test after signing a contract for Measles, Mumps, Rubella(MMR) in 2006 and sent its result to WHO. In 2012, Ministry of Food and Drug Safety was designated as contract testing laboratory for Japanese encephalitis vaccine and live attenuated Japanese encephalitis vaccine.

## (2) Vaccine Hands-on Training Program

In line with a cooperation project with the WHO Collaborating Center(CC), international education program for vaccine test has been developed for the officials in developing countries. In 2012, 6 people from 5 Asian countries including Vietnam were participated and learned the advanced National lot release system of Korea and the latest testing techniques.

## (3) Technical Advice on WHO International Guidelines and Participation in International Meetings

Active international cooperation projects such as giving technical advice on the establishment or amendment of guidelines for international standard organized by WHO, attending professional meetings are carried out.

## 4) Strengthening Quality Management in Testing Areas

The National Center for Lot Release has built a systematic quality management and quality assurance system in order to obtain international confidence and was accredited by the Korea Laboratory Accreditation Scheme(KOLAS) in accordance with the requirements of the International Organization for Standardization(ISO) in 2004.

The National Center for Lot Release has been confirmed for its reliability and fairness at field evaluation in September 2012 and recognized as an international accredited testing laboratory for 12 years in a row by the end of 2016.

## 5) Proficiency Testing Program

The international and domestic proficiency program has been operated continuously in order to ensure the objectivity and reliability of testing abilities.

## 3. Future Plans

In order to establish the National lot release system and advanced quality control system, QC Lab-Net communication is going to be expanded.

Also, regulation procedure for national lot release system is going to be improved such as

increasing exempted items in the national lot release process, extending deadline of submission of summary protocol and simplifying procedure for the same lot number.

In the near future, an advanced quality control system is going to be settled down through the effective national lot release system based on a risk analysis by preparing product-specific management method with comprehensive analysis.

In addition, the National Center for Lot Release keeps going to strengthen its status as an international accredited testing laboratory in the national test sector by performing QC Lab-Net, WHO international cooperation activities and international and domestic proficiency testing program.

## 08

**Promote R&D for  
Public Health**

As an aging society demands more welfare, national interest for the development of science and technology related to the 'Quality of life' such as health care is also increasing. In 2013, the R&D budget of the Ministry of Food and Drug Safety was 62.7 billion won, 0.4 percent of the R&D budget(17.1 trillion won) of the whole country, which enabled to proceed a variety of research for the scientific basis for safety management policy on food, medicine and medical devices.

**1. The Expansion of R&D Budget for Scientific Safety Control on Food and Drug**

In response to the rapid growth of food and drug safety management in scientific technology, the Ministry of Food and Drug Safety has expanded the R&D scale to establish a new policy and scientific basis. Major directions for R&D budget compilation are as follows: First, improve productivity by promoting R&D projects. Second, introduce a flexible response system to reflect the policy in demand. Third, improve the cohesiveness of research to establish an operating base for large-scale project. In addition, a scientific and integrated management for hazardous substances of food and medicine through the 'Safety Control on Risk Material' projects were established in 2010. In 2012, a regulation science foundation for food, medicine and medical devices was built through the 'Advancement of Safety Technology' business combination.

[ Table 8-8-1 ] R&amp;D Key Business Financial Management over the Past Five Years

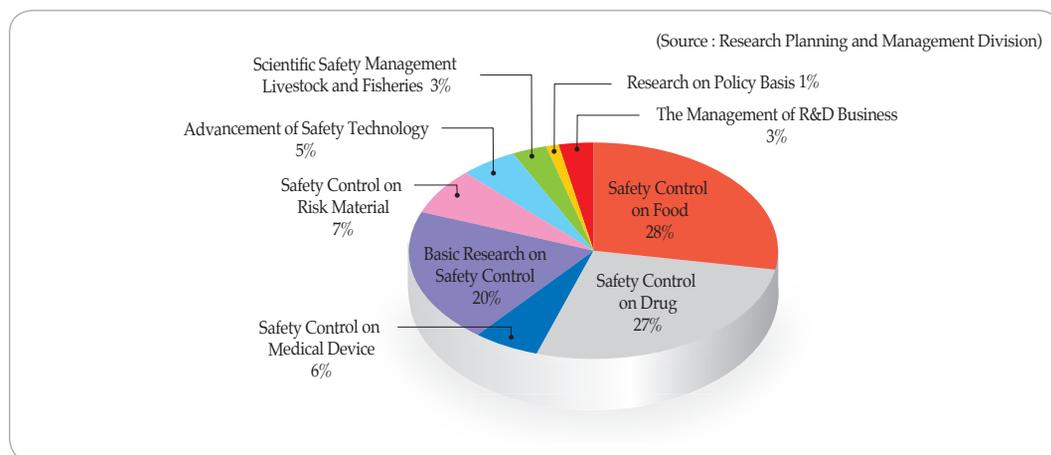
(Jan. 2013, Unit : Billion won, %, Source : Research Planning and Management Division)

Classification	2009 Budget	2010 Budget	2011 Budget	2012 Budget	2013 Budget	Annual Growth
Total	517.8	543.1	582.8	597.3	627.0	4.9%
<b>【Food and Drug Safety Research and Development】</b>						
·Safety Control on Food	173.4	175.1	185.5	185.0	177.4	0.6%
·Safety Control on Drug	103.3	155.1	183.3	168.1	172.6	13.7%
·Safety Control on Biological Drug <sup>1)</sup>	35.1	-	-	-	-	
·Safety Control on Medical Device	30.1	37.8	35.1	36.7	34.8	3.7%
·Basic Research on Safety Control	146.3	103.0	100.1	118.8	123.2	△4.2%
·Safety Control on Risk Material	-	49.5	49.5	51.8	47.2	△1.6%
·Advancement of Safety Technology	-			10.0	29.4	194.0%
·Scientific Safety Management Livestock and Fisheries <sup>2)</sup>	-	-	-	-	17.7	Transferred budget
·Research on International Cooperation Study <sup>3)</sup>	12.6	-	-	-	-	
·Research on Policy Basis	2.0	7.6	10.5	9.6	8.1	42.0%
·The Management of R&D Business	15.0	15.0	18.8	17.3	16.6	2.6%

1) Integrated to Safety management of Pharmaceuticals from 2010

2) Transferred from Ministry of Agriculture and Forestry from 2013

3) Finished Business in 2009

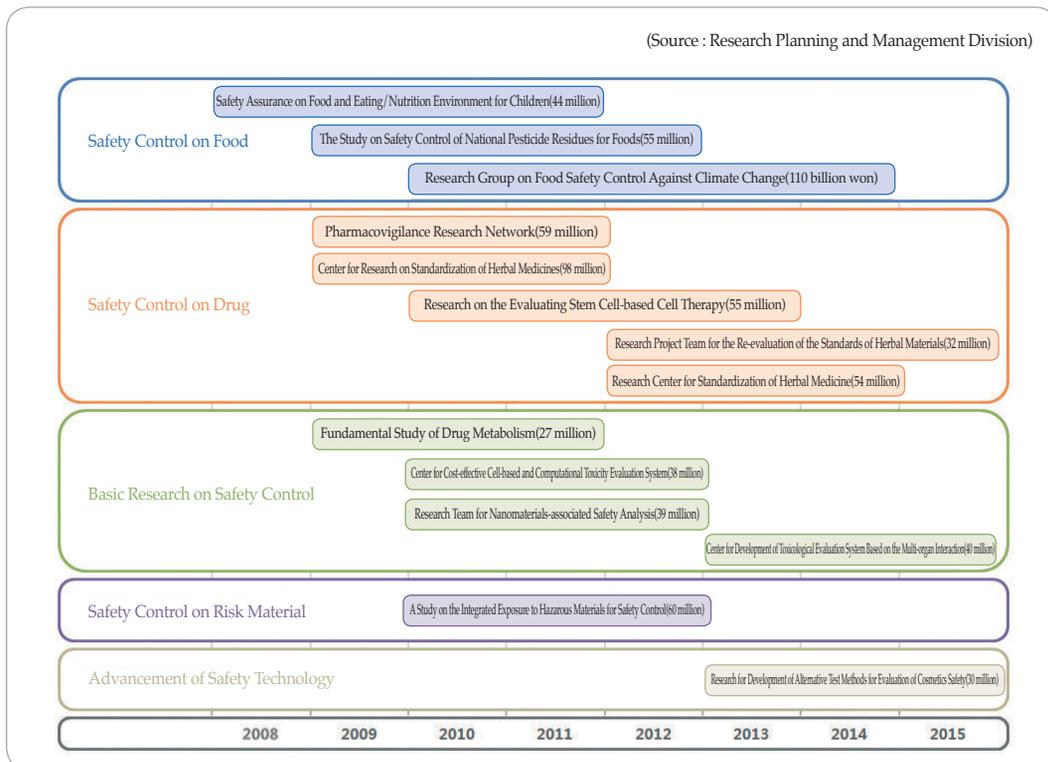


[ Figure 8-8-1 ] Distribution of R&amp;D Business Budget in 2013

## 2. Advanced Research and Development Project Planning and Efficient Management System

### 1) R&D Planning Groups of the Ministry of Food and Drug Safety

In order to set long-term direction and performance-based project planning, 'R&D Planning Group' participated by a variety of experts and policy makers from school, research institution and industry has been launched. It established a long-term promotion direction in preparation for environmental change and future needs, as well as R&D classification systems. In 2012, pre-planning was emphasized to complete the planning in the first half for strengthening the linkage between policy reflection and its budget. As the Ministry of Food and Drug Safety was promoted to the rank of the safety management control tower in 2013, the limit of the existing projects and development methods were discussed. In 2014, it is scheduled to introduce a variety of business method including projects focusing on technology development for the



[ Figure 8-8-2 ] Center for Research Status

active safety management on risk factors, as well as the pre-emptive research development for the prevention of risk factors.

## 2) Promote R&D Project Groups to Combine Projects

Along with burden reduction of R&D initial launch period, research cohesion and achievement was reinforced. And research business group in the form of long-term large-scale projects was introduced to ensure research continuity and autonomy by giving responsibility and authority to each researcher.

## 3. Services to Assist Understanding of Researchers

### 1) Publishing the Guidebook for R&D Projects and Research and Development Expense

In order to support the proper execution of research and development expense, 'Research and development service guide for researchers' and 'Research center guidebook' have been published. In these guidebooks, the purpose, direction and information of R&D projects are introduced to have researchers better understand of R&D business of the Ministry of Food and Drug Safety.

### 2) Consignment Calculation of R&D Projects

The Ministry of Food and Drug Safety started consignment calculation in order to improve the transparency of research and development expense. As a result, it has been possible to concentrate on the review of the service research and transparency of research and development expense has been improved.

## 4. Effective Performance Management for R&D Projects

The Ministry of Food and Drug Safety has reflected its R&D characteristics on performance indicator and utilizes it from the planning stage to tracking evaluation. The Ministry of Food and Drug Safety has conducted tracking evaluation annually and has participated in investigation and analysis of the Ministry of science, ICT and future planning.

## 1) R&D and its Performance Status

The Ministry of Food and Drug Safety has managed R&D performance with 4 performance indicators including proposal for the establishment and revision of standard and regulation, guideline suggestion and test method development, monitoring and information foundation business building and published journal papers and patents in accordance with R&D characteristics. And outputs of each performance indicator are on the rise every year.

[ Table 8-8-2 ] Performance Status over the Last 3 Years(2010~2012)

(Dec. 31, 2012, Unit : Case, Source : Research Planning and Management Division)

Performance Indicator	Year	2010	2011	2012	Total
Proposal for the Establishment and Revision of Standard and Regulation		452	448	481	1,381
Guidelines Suggestion and Test Method Development		251	284	410	945
Monitoring and Information Foundation Business Building		141	149	182	472
Published Journal Papers and Patents		50	137	191	378
Total		894	1,018	1,264	3,176

## 2) Tracking Evaluation

Tracking evaluation is conducted for R&D projects over 1 year from the end of the project. In 2012, a total of 327 projects were carried out and 18 projects with the results of below 'Insufficient' grade submitted backup plans, which will be re-evaluated in 2013.

## 3) Investigation and Analysis

Investigation and Analysis in 2012 was conducted for 6 detail businesses(refer to table 5, 582.8 million) in 2011.

## 4) Business Evaluation

The Ministry of Food and Drug Safety conducts business evaluation of each detail business every three years and the Ministry of Science, ICT and future planning reviews its adequacy. All results of the business evaluation are reflected in the budget next year.





2013 MFDS Report Ministry of Food and Drug Safety



# 09

## Policy Support

01. Regulatory Reform to Enhance the Public Assurance
02. International Trade and Cooperation in Food and Drug
03. Integrated Food and Drug Information Service
04. Civil Affairs Administration Service



# 01

## Regulatory Reform to Enhance the Public Assurance

### 1. Regulatory Reform Directions

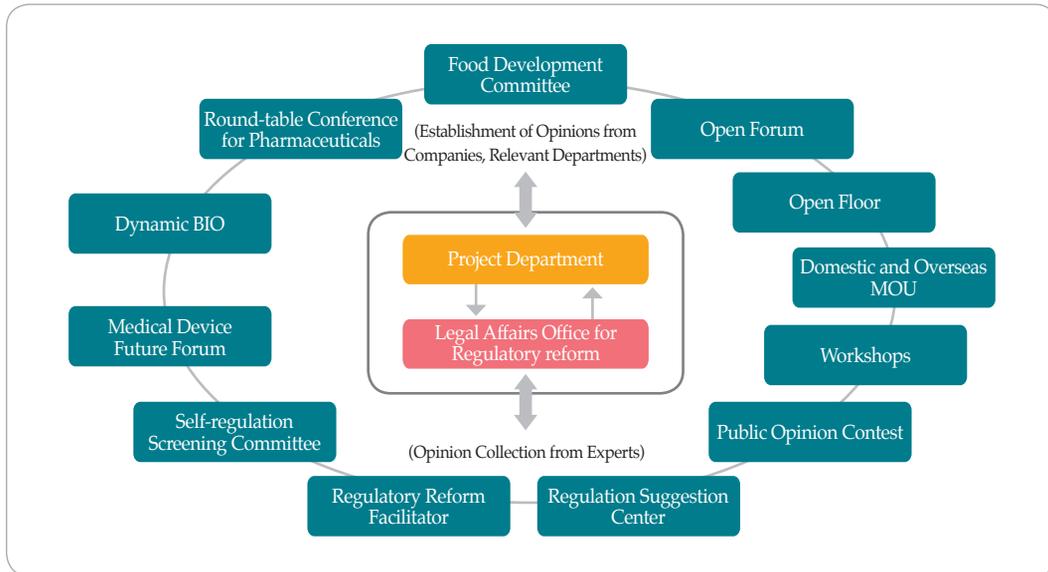
#### 1) Overview

In 2008 the administration has supported economic recovery by reducing the burdens of people and companies. In 2012, difficulties of small and medium-sized companies were expected to continue and as a result achievement and promotion efforts were strengthened by focusing on regulatory reform for a stable and active economy.

The Ministry of Food and Drug Safety has actively found the regulatory reform tasks with private sectors in order to eliminate rituals and conventional practices. Starting from 63 tasks in 2008, more than 400 tasks were found and improved over the past 5 years. Particularly, 108 tasks were found and 89 tasks were improved in 2012, which improves the performance of regulatory reform.

#### 2) Regulatory Reforms System

The Ministry of Food and Drug Safety has pursued consumer-oriented regulatory reform after listening to various opinions.



[ Figure 9-1-1 ] A System for Reforming Regulations

### (1) A Variety of Communication Channels for Regulatory Reform by Sector

The efficiency of the regulatory reform system has been improved by creating communication channels by sector, taking into account professional and various business areas of food and drug products.

As for the food sector, a food development council was organized along with roundtable conferences for the pharmaceutical sector, bio-pharmaceutical industry Dynamic Rio for the bio sector and medical device future forum for the medical device sector. Since 2010, 'Open floor', a conference consisting of presidents from 6 areas of food and drug association and CEOs has been held annually.

### (2) Public Suggestion Contests for Public Participation Administration

The public suggestion contest for the irrational regulations in food and drug sectors has been conducted since 2009 while promoting national participation and interest for regulatory reform.

Over the past 4 years, a total of 422 cases were received through the public suggestion contest, and a total of 32 cases were selected and awarded through the review committee. The selected tasks were included in regulatory reform tasks.

### (3) Regulatory Reform Proposal Center

The Ministry of Food and Drug Safety has operated a center for regulatory reform online through a site called 'National square' and managed it on a real-time basis as well as an offline channel in order to listen to the voice of the people.

### (4) Regulatory Reform Facilitator

The Ministry of Food and Drug Safety has secured private sponsors to support regulatory reform in order to improve inconvenient customs since 2008. The regulatory reform facilitators consist of a total of 20 people(4 from food, 12 from the pharmaceutical sector, 4 from medical devices) finding tasks for improvement and collecting responses from the general population.

## 2. Major Contents of Regulatory Reform

### 1) Creating a Consumer-friendly Regulatory Environment

A Life-friendly regulatory environment has been intended to be created by improving regulations closely related to people. Food additives manufacturers, distribution companies conducted their own hygiene check-ups and the range of advertising media for children's favorite food products were revised accordingly. In order to providing audio information of medicines for visually impaired people, smart phone applications(called 'Apps') were created and the Ministry of Food and Drug Safety recommended companies of standard guidelines for barcode location in products. In addition, generic drug permits with written instructions were established for consumer and patients to prevent drug abuse.

### 2) Stimulating the Economy

#### (1) Improvement of Business Environment by Reducing Administrative Data

In order to reduce burdensome administrative data for companies and people, 45 tasks for improvement were found through surveys.

Unnecessary documents such as a certificate of seal impression for reporting health food items(for authorized inspection agency -> agency or self report), reporting suspension of manufacturing production manager justification and reporting shutdown of manufacturers

were exempted from submission. In addition, application documents for applying Good Manufacturing Practice(GMP) were allowed to be submitted on a CD, so more than 45 tasks were found to be reformed.

## (2) Health Food Industry Support

The importance of the health food industry is gradually increasing due to the improvement of income levels, an increasing interest in self-health care and progress of an aging society. In addition, a demand for health food was intended to be increased through the improvement of regulations and investment on research development and quality control.

As the inspection costs and test periods for new nutrition substances were reduced due to the relieved health food labeling duties, 3,312 manufacturing and importing companies are expected to directly and indirectly benefit by 2 trillion and 807.3 billion won for the next 5 years.

For easier accessibility of accurate health food information, a web portal and webpage were linked and developed.

## (3) Support for Prompt Commercialization of Newly Developed Biomedical Drugs

In order to support prompt commercialization of 'Bio-Pharmaceutical Industry Competitiveness', a rapid screening system was built with a clarified item authorization process, so that environment for investment was created with time and cost reduction. The research clinics were divided into pure research purpose and therapy purpose and clarification of items for approving domestic gene therapy was performed for facilitating the research and development and improving patient access.

The product development period and cost for domestic cellular therapy were also reduced. The burden of patients was also relieved due to the cost cuts of the other drugs stemming from bio-similar drug authorization(67% reduction due to the authorization of Remsima Ing. on July 2012, the bio-similar of the rheumatoid arthritis drug Remicade). Therefore, future predictability was enhanced and treatment opportunities were expanded by designating orphan drugs from the initial development stage through comprehensive review on development plans, possibilities, and needs.

### 3) Rationalization of Standard and Procedure

Unreasonable standards and procedures have continued to improve. For the advancement of quality standards for drug safety, the Republic of Korea Pharmacopeia was revised so that drug quality management standard and testing method were improved. Furthermore, a bio-similar commentary guideline was also prepared for the activation of submission of the International Common Technical Document(CDT) for application for generic drug permission. This means that a foundation for approval from foreign countries with domestic documents is established. Moreover, international standardization document of medical devices(STEP) was introduced to the domestic market so that the screening period for authorization was shortened by more than 20 days, which has contributed to the activation of exporting of domestic medical devices.

## 3. Future Direction of Regulatory Reform

### 1) Assessment of Regulatory Reform

In order to encourage autonomous and proactive regulatory reform, the Prime Minister's Office is conducting an annual evaluation for the achievement of regulatory reforms of central administrative organizations. The evaluation focuses on the 'Improvement quality' rather than 'the number of improvement cases'.

The Ministry of Food and Drug Safety has found 87 tasks(87.9%) out of 99 tasks of registered regulations over the past 5 years(72.4% in 2009, 68.6% in 2009, 103% in 2010, 93.6% in 2011 and 99% in 2012).

### 2) Direction for 2013

Regulatory reform is going to be actively promoted, focusing on job creation and economic recovery in accordance with the direction of the Park Geun-Hye administration launched in 2013.

Accordingly, public anxiety about food safety will be relieved and unnecessary regulations will be improved so that the global competitiveness of the food industry will be promoted considering small domestic medical devices. In particular, the whole regulation process will be reviewed for relieving burdensome regulation.

# 02

## International Trade and Cooperation in Food and Drug

### 1. Outline

In the rapidly changing environment, food and drug safety management became one of most significant fields of government management that is directly related to the health of the nation. With the increase of import and export of food and medicine in the era of globalization, it is becoming essential that some degree of trade cooperation with international organizations and foreign governments must exist.

Trade cooperation with international counterparts are being made in two principal types; WTO(World Trade Organization) as multinational cooperation and FTA(Free Trade Agreement) as bilateral cooperation.

### 2. International Cooperation

#### 1) Task Cooperation

Continuous exchange and cooperation with all the countries of the world and international organizations is particularly prominent in the fields of foods, drugs, cosmetics and medical devices. The Ministry of Food and Drug Safety is putting effort into the protection and enhancement of the nation's health by reinforcing the cooperative partnership with

international organizations like the WTO and leading trade partners such as China, U.S. and EU.

Up until now, since the Ministry of Food and Drug Safety has signed the cooperation with the General Administration of Quality Supervision, Inspection and Quarantine(AQSIQ) of China on food safety cooperation in 2003, cooperation agreement with the United States and China Food and Drug Administration (CFDA<sup>1</sup>), Health Sciences Authority(HSA), World Health Organization Western Pacific Regional Office(WHO/WPRO) and Food Standards Australia New Zealand (FSANZ). For the current condition of cooperation by countries, a total of 18 cooperation agreements were signed with foreign organizations.

[ Table 9-2-1 ] Current Cooperation Agreement Status(Overseas)

□ Current Cooperation Agreement Status by Country

(Dec. 31, 2012, Unit : case, Source : International Cooperation Officer)

Country	WHO (WPRO)	EU	Germany	U.S.	Chile	Japan	China	Singapore	Vietnam	Australia	Indonesia	Total
Cases	1	1	1	5	1	1	4	1	1	1	1	18

□ Cooperation Agreement Status by Organization

(Dec. 31, 2012, Unit : case, Source : International Cooperation Officer)

Classification	Governmental Organization	International Organization	Academia	Non-profit Organization	Industry	Total
Cases	15	1	1	1	0	18

In 2013, MOUs for building cooperative systems with Poland Pharmaceuticals and Uganda medical device administration agencies and information exchange related to Good Manufacturing Practice(GMP) were signed respectively. In October, MOUs for the French pharmaceutical agency(Agence Nationale de Sécurité du Médicament et des produits de santé(ANSM)) regarding information exchange of drugs(including bio-pharmaceuticals), medical devices and cosmetics are going to be signed and the international cooperation with various countries such as Germany, Mexico has been promoted continuously.

Also, the Korea and China delegation conference is going to be held in November 2013 from 2009 in order for the amendment of agreements.

In addition, the Korea and Singapore delegation conference is also going to be held in October 2013 in accordance with mutual agreement with the Singapore Ministry of Health Science.

1) The organization was restructured from SFDA(State Food and Drug Administration, level of vice-minister) to CFDA(level of Minister).

A total of 111 cases of domestic service agreements were signed by 2012 with 8 cases with Ministry of Sciences, ICT and Future Planning and National Police Agency in 2013. In September 2013, agreement with Wando Fair organizers were also being promoted.

[ Table 9-2-2 ] Current Cooperation Agreement Status(Domestic)

(Dec. 31, 2012, Unit : case, Source : International Cooperation Officer)

Classification	Governmental Organization	International Organization	Academia	Non-profit Organization	Industry	Total
Cases	14	21	57	6	13	111

## 2) Reinforcement of Cooperation by Participating International Conferences

The Ministry of Food and Drug Safety has dispatched 2 food and drug safety officers to Beijing and Qingdao of China and 1 officer to Washington D.C in the U.S., as an effort to resolve the problems of entering the Chinese and U.S. market of foods, drugs, cosmetics and medical devices through site support. Also, officers were dispatched to the WHO and the CODEX Alimentarius to improve cooperation and raise Korea's status in international communities in regards to food and drug safety.

The Ministry of Food and Drug Safety is also actively conducting the international collaborations by attending international meetings and conducting on-site inspections of foreign manufacturers and companies. Accordingly, additional dispatch to Vietnam, Thailand, Indonesia, EU and Chile are in the process.

From 2008 to 2012, there were a total of 1,792 overseas trips recorded and 6% of these trips required pre-authorization.

[ Table 9-2-3 ] Overseas Business Travel Status

(Dec. 31, 2012, Unit : case, Source : International Cooperation Officer)

Year	Preliminary Examination Is Unnecessary					Preliminary Examination Is Necessary		Total
	International Meeting	Cooperation Meeting	On-site Inspection	Academic Meeting	Training	Daegu Office	Reward System, Encouragement	
2008	38	17	103	85	36	27	0	306
2009	36	43	126	32	22	33	1	293
2010	33	40	159	56	22	17	0	327
2011	61	32	196	51	29	15	0	384
2012	52	56	227	92	32	23	0	482
Total	220(12.3%)	188(10.5%)	811(45.3%)	316(17.6%)	141(7.9%)	115(6.4%)	1(0.0%)	1,792(100%)

The Ministry of Food and Drug Safety charged 71.3%(1,277 cases) of the overseas trips and the National Institute of Food and Drug Safety Evaluation charged 19.4%(347 cases). The Pharmaceutical Safety Bureau and Bio-pharmaceutical department charged 66.2% out of the entire overseas trips in the Ministry of Food and Drug Safety.

[ Table 9-2-4 ] Overseas Business Trips Status by Organization

(Dec. 31, 2012, Unit : case, Source : International Cooperation Officer)

Year	Head quarter	National Institute for Food and Drug Safety Evaluation	Seoul Office	Busan Office	Seoul-Incheon Office	Daegu Office	Gwangju Office	Daejeon Office	Others	Total
2008	211	55	3	15	12	3	4	3	0	306
2009	211	56	3	10	8	0	2	3	0	293
2010	236	66	2	3	7	3	3	5	2	327
2011	280	60	7	9	14	2	2	8	2	384
2012	339	110	6	11	6	2	5	3	0	482
Total	1,277 (71.3%)	347 (19.4%)	21 (1.2%)	48 (2.7%)	47 (2.6%)	10 (0.5%)	16 (0.9%)	22 (1.2%)	4 (0.2%)	1,792 (100%)

### 3. International Trade(Multilateral Negotiations and Bilateral Negotiations)

#### 1) Multilateral Negotiations : The World Trade Organization

In 1948, 'Agreement on Tariffs and Trade(General Agreement on Tariffs and Trade(GATT))' was launched with the aim of removing trade barriers, but it had problems of absence of legality and conflict resolution.

Uruguay Round(1986-1994), the Agreement on Tariffs and Trade system, added to the agreement of agricultural subsidy cuts and market access allowance, intellectual property service and SPS besides the industrial product. As a result, the World Trade Organization was launched by complementing tariffs and trade systems in 1995.

In 2001, Doha Development Agenda(DDA) was launched in order for the additional market opening. It also focused on economic development support for developing countries. The conflict between importing and exporting countries for agricultural products and conflict between developed and developing countries caused the poor state of negotiation. In July 2013, the 'Doha Development Agenda trade facilitation negotiation' is going to be held again.

The Ministry of Food and Drug Safety directly and indirectly participates in the 'Agreement on the Application of Sanitation and Phyto-sanitation(SPS)' and 'Technical Barriers to Trade(TBT)' of the WTO, actively responding to pending issues related to Korean safety policy on food, drug, cosmetics, medical devices and negotiating with members if required to protect the health of the Korean public. The Ministry of Food and Drug Safety also notifies newly established or amended regulations and policy related to SPS and TBT to members through the WTO secretariat in order to provide them a proper use of autonomy.

The World Trade Organization committees are discussing the application and negotiating issues with bilateral and multilateral trade issues. The Ministry of Food and Drug Safety is responding actively to the trade issues related to food and drug safety policy by participating technical committees regarding trade and WTO.

It is also providing responses to inquiries made by members while working as the inquiry point to analyze notifications. These are subsequently delivered to the related organizations and private associations(Table 9-2-5).

[ Table 9-2-5 ] The Number of Notifications to WTO for the Past 5 Years

(Dec. 31, 2012, Unit : case, Source : International Cooperation Officer)

Classification	2008	2009	2010	2011	2012
No. of Case	30	61	34	20	36

## 2) Bilateral Negotiations : Free Trade Agreement

While various trade issues are handled through the multinational mechanism of the WTO system, the necessity of bilateral cooperation also emerged as international trade increased. In January 2012, the bilateral or local negotiations registered to WTO were 511 cases activating 319 cases and more than 50% of all whole trades were done through free trade agreement.

The Free Trade Agreement, one of the most loose agreements and Regional Trade Agreement, refers to the agreement that provides exclusive trade favor to specific countries. It is spreading rapidly because of advantages of production improvement, economic growth through direct investment from foreigners and economic profits due to its prompt procedures.

Following the trend of international trade, the Korean government is discussing and responding to issues through Chile, Singapore, European Free Trade Association(EFTA), Association of South-East Asian Nations(ASEAN), India, EU, Peru and the U.S.

### 3) The Implementation of the Existing Free Trade Agreement

#### (1) Korea-US FTA

The U.S. is the largest market that charges 21.8% in the world market, accounting for 49.8 billion dollars of export and 40.4 billion dollars of import. Korea is in excess of 70% of dependence on foreign countries, so the Korea-U.S. Free trade agreement has a significant effect in terms of securing a stable market.

The Korea-U.S. free trade agreement was suspended after June 2007 and the additional negotiation came into force in December 2010.

##### A. Concession of Tariff

Even though two countries made an agreement on the high level of market opening that eliminates tariffs in a short period, the short-term elimination ratio of health care products is relatively small(79.5%). For 10 of the main items including cosmetics, electrocardiograph, MRI, Ultrasound diagnostic equipment, endoscopic, diagnostic X-ray, pharmaceuticals such as ethylene glycol and medical devices secured a 10-year period of tariff elimination.

##### B. Related Facts on Pharmaceutical/Medical Device

The committee for pharmaceuticals, medical devices for mutual cooperation was agreed to be set up so that the 1st(July 2012) and 2nd(November 2012) committees were held for mutual recognition of standards of bio-similar medicines, medical device manufacturing and quality control.

##### C. Pharmaceutical Intellectual Property Rights

The Korea-U.S. FTA mainly covers the intellectual property rights of pharmaceutical products, especially, in approval-patent schemes. If Korea permits the use of patent information by the generic medicine manufacturer, the MFDS is to notify the patent holder of such request if the patent period is still active. Also, the MFDS will prohibit sales of generics that did not gain the patent holder's permission(while patent period is still active). The infringement of a patent is currently determined after the sales of generic medicine. However, once this scheme is implemented, the infringement is determined during the generic medicine approval procedure.

## (2) Korea-EU FTA

The European Union is the biggest economic area in the world and the second biggest trading partner, the biggest investing partner for Korea, accounting for 49.2 billion dollars of export to Europe, 79.4 billion dollars of the total trade, which is bigger than the U.S. Accordingly, the Korean government selected the European Union as a long-term free trade partner along with the U.S. and China(August 2003) in the 'Roadmap for Free Trade Agreement' and confirmed the interests and expectations of the two sides through both of the preliminary rounds in 2006. After that, private sectors and relevant stakeholders had advisory conferences related to Korea-EU Free trade agreement.

The first round was held in May 2007 followed by the 8th round and the agreement entered into practice in July 2011.

### A. Concession of Tariff

Korea and EU made an agreement on the high level of market opening that eliminates tariff for all items including industrial products and forest products. In the case of medical device products, EU eliminated tariffs for all products and Korea secured a buffering device that relieves market shock from rapid elimination of tariffs by keeping 7 years for the competitively disadvantaged items.

### B. Related Facts on Pharmaceutical/Medical Device

At the request of one Party, the other Party agreed to consider mutual recognition of standards related to pharmaceuticals, medical devices. At the first Trade Commission(October 2011), the installment of a task force for the mutual recognition in the pharmaceutical, medical device manufacturing and quality control was agreed. And in April 2012, the first pharmaceutical and medical device task force for the mutual recognition of manufacturing and quality management standard is in progress.

## 4) Current Ongoing Free Trade Agreement Negotiations

### (1) Korea-China FTA

The Korea-China FTA is expected to create a relatively large ripple effect compared to

current FTAs in progress. China has the largest amount of food and drug imports and exports as Korea's first trade partner and recently showed continuous economic growth. Korea opened the industry-government-academia for joint research with China in March 2007 and both trade ministers signed the MOU to close the joint research during May 2010. Also, both countries held the first pre-intergovernmental consultation in September 2010. As the Korea-China FTA negotiation approaches, the MFDS is discovering and analyzing the medical issues and preparing relevant strategies.

### (2) Korea-Indonesia Comprehensive Economic Partnership Agreement(CEPA)

Indonesia is the 8th trade partner and 7th investing partner for Korea based on 2012 reports. The Korea-Indonesia Comprehensive Economic Partnership Agreement(CEPA) strengthened the economic relationship between two countries and it is expected to be one of the best practices of the free trade agreement with emerging countries. A joint study was conducted in 2011 and the Comprehensive Economic Partnership Agreement negotiations were initiated in March 2012 and currently the third negotiation(May 2013) is in progress.

### (3) Korea-China-Japan FTA

Korea-China-Japan FTA started as the summit of the three countries in 2009 from the first negotiation in Seoul in March 2013 to the second negotiation in China in July. It is expected to establish a stable relationship in political cooperation based on the comprehensive economic partnership by creating a large domestic market and strengthening economic cooperation among three countries.

## 5) Nagoya Protocol

At the United Nations Environment and Development conference held in Rio de Janeiro, Brazil in June 1992, the Convention of Biological Diversity(CBD) was adopted in accordance with the formation of international consensus on the need of the conservation of biological diversity. One of the main contents of the agreement is the purpose of fairly sharing profits from biological genes.

The countries containing biological resources has continuously demanded the selection of international standards ensuring a profit share for the use of generic resources based on

the Convention on Biological Diversity. As a result, the Nagoya Protocol regarding Access to Genetic Resources and Benefit Sharing (ABS) was adopted at the 10th meeting in October 2010. This adoption of the Nagoya Protocol has a significant meaning in that the principle for the access of genetic resources and benefit sharing is incorporated into the legal framework of international law.

The signature of the Nagoya Protocol was opened by February 1, 2012 and is going to be effective in 90 days after the approval is deposited to the Secretary-General of the United Nations. The Minister of Environment in Korea signed the Nagoya Protocol at UN headquarters in New York on September 20, 2011. In July 2013, 92 countries, including Korea, were currently signed and 18 countries including Gabon, Jordan, Mexico and India were ratified.

The positive side of this protocol is to improve transparency in procedure when using foreign genetic resources and the negative side is to cause additional burden due to the profit share.

In particular, the health industry sector such as medicine, cosmetics and functional food uses the most of raw materials from genetic resources, so it is expected to be influenced by the Nagoya Protocol significantly.

Therefore, the Ministry of Food and Drug Safety has installed the work force in cooperation with the Ministry of Health and Welfare since 2010 in response to the Nagoya Protocol. The Ministry of Food and Drug Safety has done research projects for database construction and the department of cosmetics and herbal medicine are operating databases. In addition, more support measures will be continuously discussed.

# 03

## Integrated Food and Drug Information Service

### 1. Background and Goal

As hazards in food and drug increase, single channel service was demanded by the public for the provision of relevant information. Therefore, the Ministry of Food and Drug Safety established a comprehensive information service channel in 2008. Based on this, the Ministry of Food and Drug Safety is planning to improve the convenience of online civil services, effectiveness of the administration, response capacity and information sharing with other organizations.



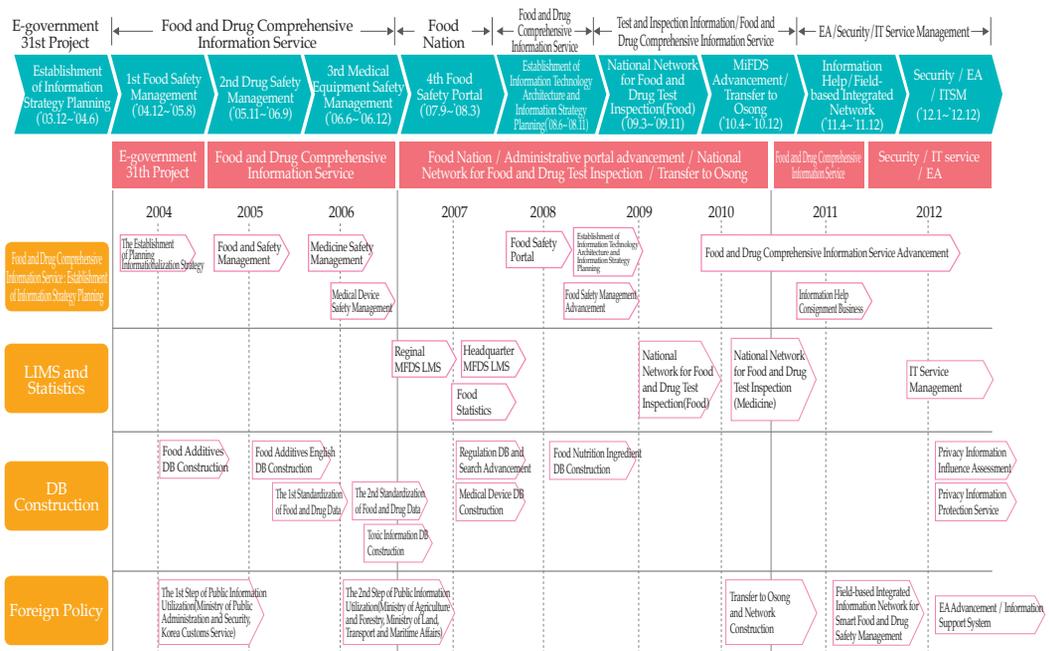
[ Figure 9-3-1 ] Objectives

## 2. Performance

Ministry of Food and Drug Safety promoted the projects based on ‘Information Strategic Planning(ISP)’ from December 2003 to June 2004. It covers 4 subjects: general service for food and drug, administration portal, information sharing and safety information service for food and agricultural, marine, livestock products. The Ministry of Food and Drug Safety also established the Food Safety Portal System as the last stage of Food Safety Comprehensive information service on food and safety in May 2008 based on the infrastructure.

The Ministry of Food and Drug Safety is planning to establish the customer-focused service application system and improve and advance the Food and Drug Safety Information Service.

In addition, projects for the ‘Foundation for Enterprise Architecture(EA) and information strategy planning’ were successfully promoted in order for future information from June 2008 to November 2008. Through consistent system improvement, the cases of handling civil affairs were rapidly increased in food(93.5%→98.7%), medicine(34.4%→90.3%), medical devices(46.6%→90.5%).



[ Figure 9-3-2 ] Current Status

[ Table 9-3-1 ] Acceptance Rate on the Internet

(Dec. 31, 2012, Unit : case, Source : International Cooperation Officer)

Classification		Whole(A+B)	Internet(A)	Visit(B)	Acceptance Rate on the Web(%)
Food	2007	292,037	273,165	18,872	93.5%
	2008	279,896	263,381	16,515	94.1%
	2009	290,976	276,416	14,560	95.0%
	2010	336,011	324,814	11,197	96.7%
	2011	348,698	344,152	4,546	98.7%
	2012	371,926	367,292	4,634	98.8%
Medicine	2007	53,614	18,454	35,160	34.4%
	2008	65,765	25,698	40,067	39.1%
	2009	51,589	40,396	11,193	78.3%
	2010	48,897	38,680	10,217	79.1%
	2011	55,123	48,731	6,392	88.4%
	2012	61,596	55,631	5,965	90.3%
Medical Device	2007	33,048	15,416	17,632	46.6%
	2008	30,098	17,912	12,186	59.5%
	2009	33,566	21,305	12,261	63.5%
	2010	35,851	24,812	11,039	69.2%
	2011	31,097	26,048	5,049	83.6%
	2012	39,850	36,046	3,804	90.5%

The main contents of the Comprehensive Food and Drug Information Service are as follows.

### 1) Comprehensive Food and Drug Information Service for Step 1- Enforcement of Food and Drug Information Service

The budget for the Food Safety Management Information System for step 1 was a total of 3.49 billion won from December 2004 to August 2005.

This system enables public inquiries through electronic authentication, signature, electronic payment, and security system. In addition, this system was implemented in order to provide convenience for the public through the linkage with civil innovative system(G4C) from the Ministry of Public Administration and Security and internal information system.

In particular, it improved the convenience for people significantly because it made the 3,000~4,000 won fee charge-free by switching the existing Electronic Data Interchange(EDI) based import food inspection system to an internet(web) based system.

## 2) Comprehensive Food and Drug Information Service for Step 2 - Enforcement of Food and Drug Information Service

The budget for Food Safety Management Information System for step 2 was a total of 5.6 billion won from November 2005 to September 2006.

This system includes the administrative system for civil affairs and joint use in the field of food while linking the Ministry of Agriculture and Forestry and Ministry of Maritime Affairs and Fisheries.

The administrative system for civil affairs handles the safety, standard and efficacy of medicine electrically including radiation safety management.

In addition, the efficiency of information collaborative usage was also enhanced by linking about 60 organizations including the Ministry of Agriculture and Forestry and Health Insurance Review & Assessment Service.

## 3) Comprehensive Food and Drug Information Service for Step 3 - Enforcement of Food and Drug Information Service

The budget for the Food Safety Management Information System for step 3 was a total of 2 billion won from July 2006 to December 2006 focusing on the follow-up management of medical devices.

The main contents of the safety management system include the 3 fields of the comprehensive information service in food, drug and medical devices.

## 4) Comprehensive Food and Drug Information Service for Step 4 - Enforcement of Food Safety Portal

The budget for the Food Safety Management Information System for step 4 was a total of 3.8 billion won from September 2007 to March 2008.

The main contents cover the integrated management system for food safety information by classifying food safety information with the collaboration with other institutions. Also, food risk management system including a warning system was established for the effective response and preventive measures against food safety accidents.

This enabled to provide a variety of customized food safety information in a single channel

so that a foundation for a healthy life for all citizens could be established.

### 5) Information Technology Architecture and Strategic Planning

The foundation for information technology architecture was built from the end of June in 2008 to November 2008, while covering strategic planning for an integrated information management system.

As a result, an integrated and comprehensive information management system was established systemically and strategically.

### 6) National Network for Food and Drug Test(Food Sector) for Sharing Information of Test Results

The budget for the national network project for food and drug test(food sector) was a total of 4.59 billion won from March 2009 to November 2009.

This enabled development and distribution of the laboratory management system for test information and basic data in order to enhance reliability for the Institute for Health and Environment Research and Institute for Food Sanitary Test. Also, management systems for standardization of testing information were integrated with the existing testing analysis system.

This project improved the reliability and productivity of testing institutions by simplifying the reporting process and utilizing food standard management information of the Laboratory Information Management System(LIMS). In addition, food products which have safety problems could be found early so that international reliability for the test result could be secured thanks to the national network for food safety.

### 7) National Network for Food and Drug Test(Food Sector) for Sharing Information of Test Results(Pharmaceutical and Other Fields)

The budget for the national network project for food and drug test (pharmaceutical sector) as an expanded business of national network for food and drug test(food sector) established in 2009 was a total of 0.66 billion won from April 2010 to December 2010.

This established the standardization of the test system and integration of test information for

pharmaceutical products, herbal medicine, cosmetics.

This project improved the productivity and reliability of test organizations by simplifying the reporting process and standardized test system.

In addition, foundation for enhancing capability of risk management was prepared with utilizing statistics through real-time research on testing information.

### 8) Information Communication Network and Information System Transfer to O-song

The budget for the national network project for the information communication network and information system transfer was a total of 1.55 billion won from June 2010 to October 2010. As a result, implementation projects for disposal and relocation planning, optimization, network design and implementation(O-song office), computational design(Osong office), step-by-step network construction, network equipment and infrastructure facilities were completed successfully, which contributed to the opening of a new era of O-song.

### 9) Consignment Operation for Information Help Service

In accordance with the increase in the use of information systems and internet users, the information help service has been established since September 2011. 5,910 cases of consumer complaints were handled compared to 2,190 cases handled in the previous month after the establishment of the information help service.

### 10) Field-based Integrated Network for Smart Food Safety Management Information

The integrated network for smart food safety management information has enabled the organized cooperative system between the central and local regions against food accidents. The introduction of a smart work system based on a mobile system resulted in advanced risk management by real-time monitoring and emergency management.

## 11) The Sophistication of Comprehensive Information Service of Food and Drug in 2012

The sophistication project of comprehensive information service of food and drug followed by the 1st, 2nd, 3rd and 4th project from 2008 to 2012 enabled the efficiency of work by supporting electric processing and stable service, so customer complaints were reduced and customer satisfaction was improved.

This covered the 5 food sectors, 4 pharmaceutical sectors, 6 medical device sectors while enhancing convenience for people by adding continuous amendments of laws and systems.

## 12) Information Technology(IT) Service Management System

Measurement index for achievement and management of Service Level Agreement(SLA) was systemized by introducing information technology service management solutions based on IT Infrastructure Library(ITIL) in order to prepare a standardized management system.

This system improved a process through a single contact of service requests and prepared a foundation for a founding knowledge database. In addition, the quality of service level was enhanced through a standardized and monitoring service for outsourcing companies.

## 13) The Sophistication of Information Technology Architecture and Information Support System

The project for the activation of the efficient information technology architecture followed by the 1st, 2nd, 3rd, 4th and 5th project from 2008 to 2013 was completed.

At the same time, the integrated information management system for monitoring and managing work was established through the achievement based on IT Governance. This enhanced the efficiency of administrative service by actively responding environment changes.

## 14) Assessment for Privacy Information Effect of the Comprehensive Information Service of Food and Drug

In accordance with Article 33, 35 of 'Privacy Act', risk factors of privacy information were investigated and analyzed.

This secured the safety of information system handling personal information, appropriateness of protective management system while actively responding to the strengthened security policy.

### 15) Information Security and Privacy Protection System

Due to the increase in privacy information held by government, DB encryption solutions for securely managing personal information and Intrusion Prevention System(IPS) and Public Key Infrastructure(PKI) were sophisticated in accordance with 'Personal Information Protection Act(September 30, 2011)'.

## 3. Future Plans

Based on the safety information service system of food and drug, a variety of services are to be provided so that user-oriented safety information services are going to be continued.

In addition, a customer-oriented administrative service based on the trust is to be provided with a channel for safety information in the general public application system.

First, the project for sophistication of the safety information service of food and drug will establish a stable operation system and reliable service for people and companies by supporting electronic processes responding to changes in acts, laws and organizations by 2013.

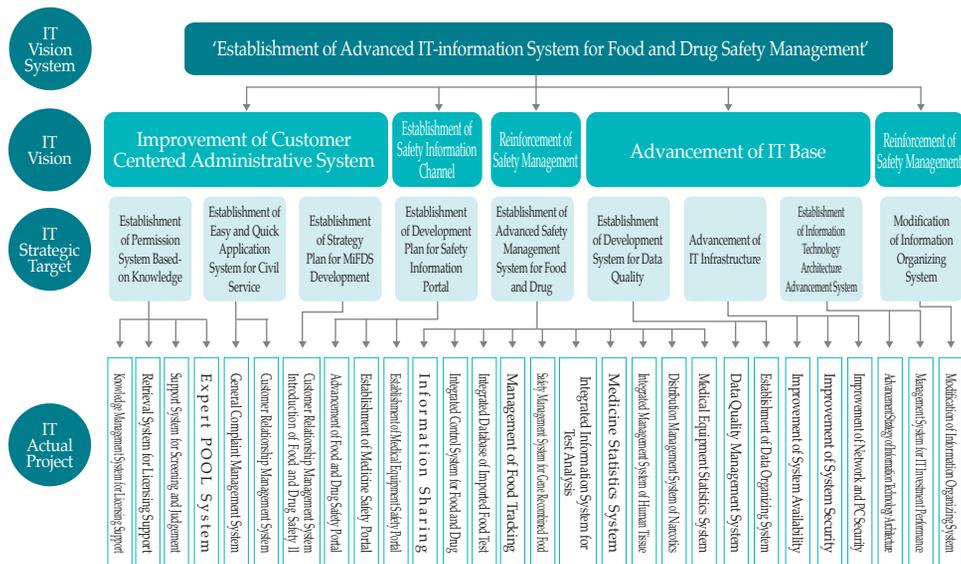
In accordance with the revision of the Government Code in March 2013, the safety of fisheries were confirmed by the import inspection system by blocking hazardous fisheries in advance.

Furthermore, the stabilization of information technology service management system will enhance customer satisfaction by providing a single point of contact of information technology architecture and this will improve consistency of information-based services.

## 4. Expected Effect

It substantially improved the convenience of the service application, productivity and competitiveness of the industry. Expected effectiveness are as the following: First, food safety system and effectiveness of the Research Institute of Public Health & Environment and other

food sanitation test organizations were improved by providing information of medicine and safety. Second, effectiveness of administrative service was enhanced by providing information to related department and officials. Third, safety management for medical equipment was improved through releasing evaluation results, tracking management of the company's safety. Fourth, accuracy, speed and transparency of administration were enhanced by the establishment of civil affairs administration portal. Fifth, customer centered food and drug safety culture was established by customizing the portal which provides the required information. Sixth, the computerized management on testing method of Public Health and Environment Research Institute and food sanitary inspection institutions secured reliability of analyzed results and the simplified reporting process for the inspection result and food safety network enhanced the efficiency of work. In addition, by securing reliable test analysis data for distributed food, the policy decisions for food safety management were objectified. Seventh, the information help service enabled the One-Stop, One-Call Customer consulting service, which improved customer satisfaction. Eighth, the field-oriented smart food safety information management network enabled a rapid response with using real-time information in the event of accident. Ninth, the introduction of information technology service management solutions strengthened the maintenance tasks through standardized and quantified measurement index. Tenth, integrated information management system for monitoring and managing work was



[ Figure 9-3-3 ] Prospect System Plans

established through the achievement based on IT Governance. This enhanced the efficiency of administrative service by actively responding environment changes. Eleventh, the Information Security and Privacy protection system enhanced the appropriateness of protective management while actively responding to the strengthened security policy.

# 04

## Civil Affairs Administration Service

Recently, as the consumer's awareness on qualities in connection with food consumption and purchase increasing, it is fair to state that consumer organizations influenced on the change of consumer's lifestyle.

Consumer organizations are safeguarding the right of consumer's interests, medical services and their health on foods and drugs as well as environment. They are also expanding their boundaries as a spokesman and guards of the public. Its role is to become a check and balance against government policies and advisors as partners for policy making.

### 1. Civil Service and MiFDS System

#### 1) Outline

With the establishment of the Food and Drug Service System, the information service of the nation is improving with the increasing availability of online services for approvals, applications and verifications.

Recently, the development of lifestyles demands higher quality services. Therefore, the General Civil Service Office began to focus on the provision of prompt responses and high quality services.

## 2) Innovation of MiFDS System and Civil Service

The MiFDS system(the Total Information Service of Foods and Pharmaceuticals), which was selected as the 31st project of an e-government, pushed forward an information-oriented strategy in October 2003.

Accordingly, the reform of civil petitions was fulfilled on a full scale through the service improvement for peoples and the construction of system for foods and drugs from December 2004 to December 2006 was completed.

Also, the window for civil petitions made up for several issues which were found under the process of showing an example for three months from September 2006 and enforced the acceptance of civil petitions and the registration of handling results through the administration portal system from January 1, 2007. This transformation enabled the management of civil petitions to be successful which made ready for the betterment of a consumer satisfaction by providing customers with quick acceptance of civil affairs and handling results based on the inquiry and consultation.

Even after the completion of a system construction, the high-degree enterprise of a total information service on foods and drugs was promoted five times in total from the year of 2008 to 2012 by escalating the reliability.

## 3) Civil Service and Professional Consultation Skill

All of those inquires from visits, by fax and mailing, and of approvals of drug and medical devices including applications for food are directly reported to the MiFDS system, which sends the documents of civil affairs to the relevant divisions after making digital documentation. The MiFDS system covers the supplementation, result input, search and delayed request.

It has shown to be more effective than handling paper work. Likewise it gratifies the curiosity of people by notifying the progress through text messages. The system also directly provides the information requested through telephone inquiries.

As a result of our new establishment of administration building to Osong, we offer an expert window for civil petitions to settle the discomfort of civil appeal through a video-consultation system of civil affairs especially in the area of Seoul and Gyeonggi.

[ Table 9-4-1 ] Civil Services Statistics(2011~2012)

(Dec. 31, 2012, Unit : case, Source : Customer Support Officer)

Year	Total	Approval and Registration	Import Registration	Standard and Test Method	National License	General Civil Affairs
2011	618,719	69,194	320,693	5,959	3,755	219,118
2012	670,505	78,918	335,035	5,073	3,598	247,881

[ Table 9-4-2 ] Progress of Civil Services Statistics(2008~2012)

(Dec. 31, 2012, Unit : case, Source : Customer Support Officer)

Year	2008	2009	2010	2011	2012	Notes
Reception	545,796	574,713	618,441	624,947	680,154	
Handling	544,072	569,816	617,823	618,719	670,505	Including the Forwarded Cases from Last Year

## 2. Telephone and Online Counseling

### 1) Outline

The Customer Center is where the representatives meet with the public face-to-face and engage in consultations through the telephone and internet. The number of inquiries is annually growing, handling most of civil service work at the center. By this means of separation, other divisions of the MFDS can focus on their responsibilities in foods, drugs, cosmetics and medical devices.



[ Figure 9-4-1 ] Homepage of General Consultation Center (<http://call.MFDS.go.kr>)

Consultants of the MFDS Customer Center are comprised as a permanent position and provides expert advice or information on legislation and notification that is difficult to understand by the public. The center annually publishes the FAQ collection booklet.

When the incidents of hazardous foods and drugs(such as propofol, benzofiren, and radioactive foods) take place, the role of the General Consultation Center grows larger.

The General Consultation Center works out an amicable and omnidirectional solution for the backlash and reproach from the public and delivers the wholehearted apology of the MFDS. Furthermore, the Center plays a crucial role in primarily notifying the countermeasure of incidents and hereafter policies.

However, the satisfaction of connecting the divisions with the public is all up to the operation of the consultation center.

## 2) Service Requests and Processes

The consultation system introduced the CTI(computer telephony integration) system<sup>1)</sup> and divided the department to each field of food(including health functional food), drug(including quasi-drugs, cosmetics and herbal medicine), medical equipment and others.

Telephone services provide information through the call number : 1577-1255. The service hour is from 9am to 6pm and closes on the weekend and holidays.

For the questions that are difficult to resolve by a consultant, the Return Call system that calls back to the inquirer after discussion with the related department is in operation. In some cases, relevant departments may directly engage in the consultation.

The online service operates the same as the telephone service but for 7 days, through the homepage - National Square - Online Consultation/FAQ.

## 3) Record of Civil Service

Service records slightly decreased after the introduction of the identity verification in 2006, but it is also expected to increase by the continuous advertisement and improvement of capability and quality of the consultation and supplementation of the homepage FAQ.

When it comes to the positive achievements of expedient processing of civil petitions in 2007-2012, the General Consultation Center reaches out a helping hands to civil appeals as follows:

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1) System for managing office calls efficiently by combining computer and telephone

[ Table 9-4-3 ] Record of General Counseling Center(2007~2012)

(Dec. 31, 2012, Unit : case, Source : Customer Support Officer)

Classification	Telephone Counseling					Cyber Counseling					Total
	Subtotal	Food	Medicine and Cosmetics	Medical Device	Others*	Subtotal	Food	Medicine and Cosmetics	Medical Device	Others*	
2007	115,506	46,349	31,502	20,006	17,649	18,859	12,887	4,152	1,614	206	134,365
2008	136,856	68,756	36,432	23,062	8,606	25,473	16,779	6,710	1,766	218	162,329
2009	165,751	82,644	44,222	28,916	9,969	28,659	18,228	8,304	1,649	478	194,410
2010	167,190	87,938	40,284	27,958	11,010	25,718	15,838	7,683	1,730	467	192,908
2012	182,894	100,476	41,901	30,086	10,431	20,351	11,131	7,301	1,525	394	203,245

\*Others : inquiries for information of staff, department, phone number, location and how to use online service





**MINISTRY OF  
FOOD AND DRUG SAFETY**

## **2013 MFDS Report**

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