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2016
Ministry of Food and Drug Safety
White Paper

Ministry of
Food and Drug Safety

Greetings

Development of the international food and drug industry and exponential growth in global trade made the borders between countries blurred, and this global phenomenon shows no sign of disappearing. As development of food and drug industries led to advancement of series of new foods, additives and medical products, safety issue of these products became commonplace in our daily lives.

Against this backdrop, the Republic of Korea is now faced with new opportunities and challenges.

The Ministry of Food and Drug Safety (MFDS) recognizes these changes and makes its every effort to maintain highest safety level of food and drug to ensure people's health and happiness. MFDS is doing its utmost to elevate its food safety control capabilities to the world-class level and we are committed to make food and drug safety management into the new growth engine of Korea.

Food and drug safety is always priority of MFDS. We are ready to take the lead in these changes by preparing and responding in advance.

All staff of MFDS are single-minded to yield better results in food and drug safety management by strengthening communication with the public, relevant industries, international organization and foreign regulatory agencies.

'Ministry of Food and Drug Safety White Paper' is published every year as a guidance to follow MFDS's policies and implementations on food and drug safety over the past year. And the results of our efforts over the last year are summarized into the White Paper.

We are sure that the white paper will be useful for the public, the academic community, and relevant industries alike.

We are determined to be one of the food and drug safety powerhouse through effective control of food safety based on people-centred and on-site oriented policies and implementations.

We hope that this white paper would help to broaden understanding of policies on food and drug safety and to contribute to the development of the food and drug industry.

July, 2016

Minister SOHN, Mungi

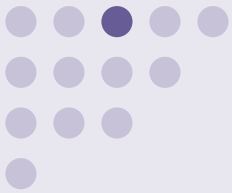
Contents

Contents

Contents

〈Table of Contents〉

〈Image of Contents〉



2016 MFDS White Paper

Ministry of Food and Drug Safety

I

Outline

1. Vision · Objective · Core Strategies
2. Organization · Affiliated Organizations
3. History

Vision · Objective · Core Strategies

"Safe **Food and Drug**
Healthy **People**
Happy **Society** "

SMART LEADER | SMART SUPPORTER | SMART COORDINATOR

MFDS will eradicate unwholesome food from farm to table.

Zero-Concern

- Strengthening prevention of hazards in production and manufacturing stages
- Cutting off inflow of hazardous foods at the source
- Establishment of a structured and seamless distribution management system
- Spreading of a safe food consumption culture

MFDS will be a total-service provider on the field for the businesses.

Globally Competitive Nation

- Promotion of biopharmaceutical industry as the new growth engine
- Comprehensive life-cycle support in advanced, convergence medical devices
- Will support food and pharmaceutical industries in establishing new overseas markets

With better cooperation and communication, MFDS will expand the safety network for the people.

Perceived Safety

- Will reduce health threats through a pan-governmental cooperation
- Will provide 'Easy · Accurate · Scientific · Yearly-Info' that people need
- Will reorganize the safety management network to make it more user-friendly

MFDS will look far beyond into the future and preapre the era of 'homo-hundred'.

Preparing for the future

- Customized management for a low-birthrate and aging population
- Establishment of a system for responding to climate change and infectious diseases
- Establishment of a scientific and preemptive safety management system

Organization · Affiliated Organizations


National Institute of Food and Drug Safety Evaluation
General Affairs Division
Research Planning & Management Division
Vaccines Division
Blood Products Division
Food Safety Evaluation Department
•Food Safety Risk Assessment Division
•Pesticide and Verterinary Drug Residues Division
•Food Contaminants Division
•Food Microbiology Division
•Food Additives and Packages Division
•Nutrition and Functional Food Research Team
•New Hazardous Substances Team
•Novel Food Division
Drug Evaluation Department
•Drug Review Management Division
•Pharmaceutical Standardization Division
•Cardiovascular and Neurology Products Division
•Oncology and Antimicorbial Products Division
•Gastroenterology and Metabolism Products Division
•Bioequivalence Evaluation Division
Biopharmaceuticals and Herbal Medicine Evaluation Department
•Biologics Division
•Recombinant Protein Products Division
•Cell and Gene Therapy Products Division
•Herbal Medicinal Products Division
•Cosmetics Evaluation Division
Medical Device Evaluation Department
•High-tech Medical Devices Division
•Cardiovascular Devices Division
•Orthopedic and Restorative Devices Division
•Dental and Gastroenterology Devices Division
•In-vitro Diagnostic Device Division
Pharmaceutical and Medical Device Research Department
•Drug Research Division
•Biologics Research Division
•Advanced Therapy Products Research Division
•Herbal Medicine Research Division
•Cosmetics Research Team
•Medical Device Research Division
Toxicological Evaluation and Research Department
•Toxicological Research Division
•Toxicological Screening and Testing Division
•Pharmacological Research Division
•Clinical Research Division
•Advanced Analysis Team
•Laboratory Animal Resources Division
Regional Office of Food and Drug Safety
Seoul Regional Office of Food and Drug Safety
•General Affairs Division
•Food Safety Management Division
•Agro-Livestock and Fishery Products Safety Division
•Pharmaceutical Safety Management Division
•Medical Device Safety Management Division
•Import Management Division
•Hazardous Substances Analysis Division
•Imported Food Analysis Division
•Gangneung Imported
Busan Regional Office of Food and Drug Safety
•General Affairs Division
•Food Safety Management Division
•Agro-Livestock and Fishery Products Safety Division
•Medical Products Safety Division
•Import Management Division
•Center for Food & Drug Analysis
– Hazardous Substances Analysis Team
– Imported Food Analysis Team
•Jaseongdae Imported
•Shinseondae Imported
•Yangsan Imported
•New Port Imported
•Tongyeong Imported
•Gamcheon Imported
Gyeongin Regional Office of Food and Drug Safety
•General Affairs Division
•Food Safety Management Division
•Agro-Livestock and Fishery Products Safety Division
•Medical Products Safety Division
•Medical Products Inspection Division
•Import Management Division
•Center for Food & Drug Analysis
– Hazardous Substances Analysis Team
– Imported Food Analysis Team
•Uiwang Imported
•Gwangju Imported
•Incheon International Airport Imported
•Pyeongtaek Imported
•Incheon Port Imported
•Yongin Imported
Daegu Regional Office of Food and Drug Safety
•General Affairs Division
•Food Safety Management Division
•Medical Products Safety Division
•Hazardous Substances Analysis Division
Gwangju Regional Office of Food and Drug Safety
•General Affairs Division
•Food Safety Management Division
•Agro-Livestock and Fishery Products Safety Division
•Medical Products Safety Division
•Hazardous Substances Analysis Division
•Gwangyang Imported
•Gunsan Imported
Daejeon Regional Office of Food and Drug Safety
•General Affairs Division
•Food Safety Management Division
•Medical Products Safety Division
•Medical Products Inspection Division
•Hazardous Substances Analysis Division

History

2016.05 Establishment of the Division of Integrated Food Information Service(Headquarters)

2015.12 Imported Food Analysis Division newly established in Seoul Regional Office of Food and Drug Safety
– Imported Food Analysis Division in the Gwangju Regional Office of Food and Drug Safety abolished

2015.05 Establishment of the Division of Pharmaceutical Safety Evaluation (Headquarters)

2015.01 Establishment of the Division of Health Functional Food Policy and the Division of Medical Device Safety Evaluation (Headquarters)
Establishment of the Division of Novel Food(transferred to the National Institute of Food and Drug Safety Evaluation) and Division of In Vitro Diagnostic Device (National Institute of Food and Drug Safety Evaluation)
Establishment of Imported Food Inspection Center at Incheon Port and Yongin (Gyeongin Korea Food and Drug Agency)

2014.08 Establishment of Quasi Drug Policy(Headquarters)

2013.11 Establishment of the Gamcheon Port Imported Food Inspection Center (Busan Korea Food and Drug Agency)

2013.10 Establishment of the Alcohol Safety Management and Planning Team and the Division of Pharmaceutical Patent Management (Headquarters)

2013.03 Establishment of the Ministry of Food and Drug Safety
1 Headquarters, 7 Bureaus, 1 Planning and Coordination Office 43 Divisions, 1 Institute, 6 Regional Offices 13 Inspection Centers, 1,760 staffs

2012.07 Gwangju Imported Food Inspection Center (Gyeongin Korea Food and Drug Agency)

2012.02 Establishment of the Division of Cellular & Gene Therapy Products and the Division of Advanced Medical Devices (Headquarters)

2011.01 Establishment of the Pharmaceutical Safety Information Team (Headquarters)

2011.01 Korea Food & Drug Administration moved into the Osong Health Technology Administration Complex in Cheongwon, Chungbuk

2011.06 The responsibility for alcoholic beverage safety management transferred to the National Tax Service

2009.11 Establishment of the Blood Product Testing Team in the National Center of Lot Release of the National Institute of Food and Drug Safety Evaluation

2007.09 Establishment of 6 new teams including the Food Poisoning Prevention and Management Team (Headquarters)

2006.08 Establishment of 10 new teams including the counseling center (Headquarters)

2006.01 Establishment of the New Port Imported Food Inspection Center (Busan Korea Food and Drug Agency) and Pyeongtaek Imported Food Inspection Center (Gyeongin Korea Food and Drug Agency)

2004.07 Establishment of the Division of Medical Device Management (Headquarters). Establishment of the Division of Biotechnology Support in the National institute of Toxicological Research

2003.08 Estabishment of Yangsan Imported Food Inspection Center (Busan Korea Food and Drug Agency)

2002.06 Establishment of the Audit and Inspection Office (Headquarters)
Renaming of the National Center of Toxicological Research to the National institute of Toxicological Research

2001.10 Establishment of the Illegal and Junk Food Control Task Force and the Division of Biologics (Food Safety Bureau, Pharmaceutical Safety Bureau)

2001.03 Establishment of the Imported Food Inspection Center at Incheon International Airport (Gyeongin Food and Drug Safety Agency)

1998.02 Inauguration of the Korea Food & Drug Administration having the National Institute of Toxicological Research and 6 Regional Offices(Seoul Busan, Gyeongin, Daegu, Gwangju, Daejeon) as its affiliated organizations.

1996.04 Establishment of the Korea Food and Drug Administration Headquarters and six Regional Offices under the Ministry of Health and Welfare.

2016 MFDS White Paper

Ministry of Food and Drug Safety

II

Food

Section 1

Strengthening of the Food Safety Management System

1. Cooperation between Government Bodies to Eradicate Unwholesome Food

A. Establishment of Pan-governmental System for Eradicating Unwholesome Food

1) Background

The newly inaugurated government in 2013 has realized government's role and responsibility as an issue that people encounter on a daily basis as the 'life security', which is the foundation for people's happiness.

The Ministry of Food and Drug Safety (MFDS), being aware of this recognition, included 'eradication of unwholesome food' in the government agenda called the 'Eradication of Four Major Social Evils', constructed 「Pan-governmental Council for Eradication of Unwholesome Food」 as the control tower of the food safety and took action to eradicate unwholesome food by cooperating with other government bodies.

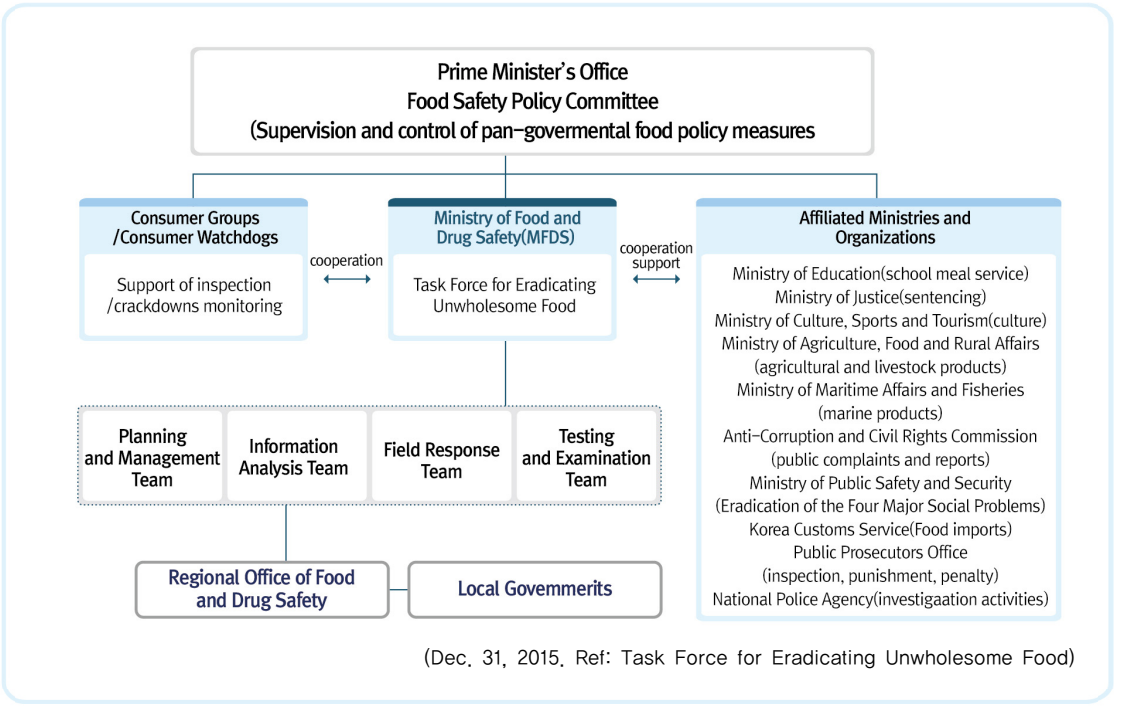
2) Definition of Unwholesome Food

Unwholesome food refers to any food product that fails to meet food related regulations or standards in all stages including production, manufacturing, distribution, sales, etc. These illegal food products that fail to meet legal standards were defined as 'unwholesome food' to make it easier for the people to understand what they are.

3) Establishment of the Pan-governmental Council for Eradication of Unwholesome Food

The 「Pan-governmental Council for Eradication of Unwholesome Food」 which is comprised of 29 government offices including the Office for Government Policy Coordination, Ministry of Food and Drug Safety, Ministry of Education, Public Prosecutors' Office, National Police Agency and local governments (17), is carrying out policies by cooperating with other governmental bodies including management of a thorough network, establishment of

information sharing system, and expansion of safety food culture of eradication of unwholesome food across all stages of production manufacture, import, distribution, consumption, etc.



[Image 1-1-1] Pan-Governmental Commitee for Eradicating Unwholesome Food

B. Achievements after 3 Years of Work to Eradicate Unwholesome Food

1) Establishment of a Foundation for Eradicating Unwholesome Food

Over the past 3 years, MFDS has strengthened the cooperation between government bodies through pan-governmental activities and planned monitoring activities and created a synergic effect of crackdown activities. Also, the Ministry reduced the 'food safety blind spots' such as areas and types of business that the authorities lacked control over and developed and initiated 38 policy improvement tasks to fundamentally eradicate the root of unwholesome food.

Moreover, the Ministry regularized the preliminary consultation (437 sessions) procedure prior to each press release on a food-related investigation and made efforts for prompt recall of unwholesome food products from the market and assure consumer of the food safety, and prevention of unfair damages of food companies.

2) Establishment of a Pan-governmental Information Sharing System

In order to process food safety tasks that are dispersed across different government bodies more effectively, MFDS has also worked on strengthening the cooperative system between government bodies. First, MFDS issued and provided the information analysis reports (monthly, annual) that include analysis of each government office's information, consumer information, national and foreign media information and the information on unwholesome food, to all government offices associated with the 「Pan-governmental Council for Eradication of Unwholesome Food」 and also shared unwholesome food eradication measures of each government bodies on a weekly basis.

Also, MFDS set up a hotline for government bodies to enable communication with people and shared different opinions of the relevant offices to prevent consumer confusion, amplification of issues or spreading of rumors.

3) Spread of the Unwholesome Food Eradicating, Food Safety Culture

MFDS increased public awareness of the food safety and unwholesome food eradicating culture by offering customized food safety education on eradicating unwholesome food, false and exaggerated advertisement, food poisoning prevention, HACCP, selecting safe food and sugar/sodium reduction to the consumers and producers. Also, MFDS created synergic effect of safe food culture through various media. MFDS promoted campaign on reporting unwholesome food and creating food safety environment and continuously carried out low-cost, highly-efficient promotion of public-private-cooperated 「Safe Food」 campaign by collaborating with the Ministry of Culture, Sports and Tourism and the National Police Agency.

4) Establishment of an Efficient System for Eradicating Unwholesome Food

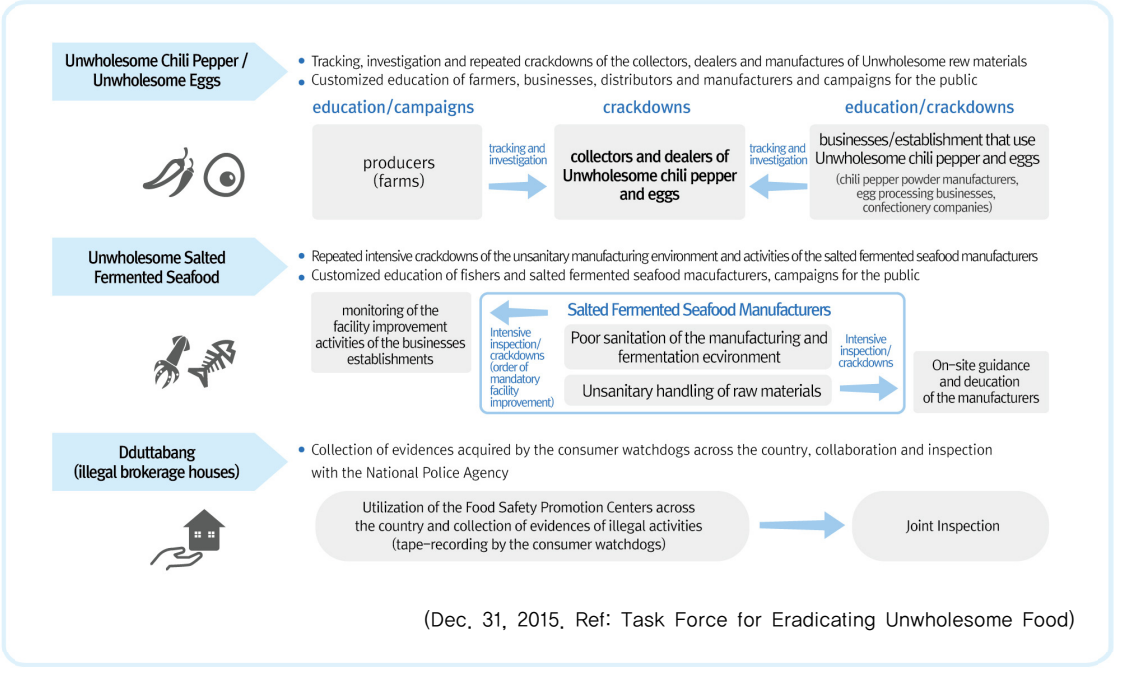
By introducing 'Online System for Blocking Distribution of Unwholesome Food (e-robot)', MFDS carried out 'Online Review System' which is managed by Korea Communication Standards Commission, to automatically search false and exaggerated ads, illegal websites, and promptly review and block these websites that are found to be illegal.

C. Implementation Plan

1) Implementation of a Pan-governmental Joint Monitoring for Eradicating the Four Key Unwholesome Food

After setting up the 'Food Integrity Bureau' and intensive, pan-governmental crackdowns, the number of businesses and establishment with poor sanitary conditions decreased and the food safety awareness of the business operators has improved but repetitive, inveterate illegal activities are still prevalent. Thus, MFDS aims to improve the effectiveness of the unwholesome food eradication plans and suggest new food safety solutions of which the public can actually sense the improvement.

MFDS will implement preventive measures in areas and stages (production, artificial farming) with high prevalence rate of unwholesome food, and carry out periodical and repetitive inspections and crackdowns on each type of business (e.g. dealer), concentrating on eradicating the roof of the unwholesome food and cracking down the illegal activities that occur most frequently and raise the most public concern.



[Image 1-1-2] Plan for the 2016 Planned Monitoring

2) One-Point Monitoring of Other Vulnerable Areas and Special Management of Businesses/Establishments Violating Food Safety Regulations Repeatedly

Other than the 4 key unwholesome food, MFDS will also select food products or areas that are highly relevant to the public that cause controversial issue in the society as well as those food products that become highly popular during the holiday seasons - as priority targets for monitoring and continuously carry out pan-governmental joint monitoring activities to maintain the social awareness of unwholesome food.

MFDS will also add the businesses/establishments that repeatedly violate food safety regulations to a blacklist and apply greater penalty and tax rate to further prevent criminal activities and weed out those violators when improvements are not being made. MFDS plans to carry out monitoring and guidance activities periodically until the violators show improvements on their compliance with the food safety regulations.

The intentional businesses/establishments that violate food safety regulation more than twice a year and those that manipulate and fake expiration dates, will receive administrative actions, be prosecuted and their information will be sent to the National Tax Service. MFDS will strengthen monitoring of these food safety violators until unwholesome food are eradicated from out society and until the public is safe from food safety issues.

3) Strengthening the Collaboration in Collection and Analysis of the Information on Unwholesome Food

By utilizing the Food Administration Integration System in the Integrated Food Safety Information, MFDS plans to expand and strengthen monitoring on information of relevant government bodies (performance of food safety crackdown activities, imports and sampling of non-compliant products), consumer complaints (1399 reports, integrated public reports, national public reports), domestic media, information overseas, the Food Information Utilization System (violation of labeling on agricultural, livestock and fishery products, food safety inspection) and food consumption trends (sales trend, consumption patterns of popular items, etc).

To make the information on unwholesome food readily available for food safety management work, MFDS will collect and analyze information and provide customized information to the demanding organizations and parties. Also, MFDS will provide information to 29 members of the 'Pan-governmental Council for Eradication of Unwholesome Food' and to 13 other organizations including consumer groups, the Korea Consumer Agency and Korea Institute For Food Safety Management Accreditation (HACCP).

4) Education and Campaigns for Spreading a Safe Food Culture

MFDS will carry out customized education of the target groups in all food stages from production to consumption in relation to 'eradicating root of unwholesome food', strengthen effective education by developing and supplying educational textbooks that can be easily learned in the field and maximize synergic effect by jointly implementing crackdown and education/promotion.

To reassure the public, MFDS will promote its achievement on eradicating unwholesome food and by developing public campaign ads with the Ministry of Culture, Sports and Tourism and National Policy Agency, MFDS is anticipating 'safe food culture' to be promoted effectively.

Kang Daejin, Director of Food Integrity Bureau
☎ 043.719.1903

2. Strengthening of Food Production and Manufacturing Safety

A. Establishment of a Basis for Food Manufacturing Safety

1) Promotion of the Food Safety Management Certification System (HACCP, Hazard Analysis Critical Control Point)

A) Background

(1) HACCP

Hazard analysis and critical control points or HACCP is a systematic preventive approach to food safety first developed by the National Aeronautics and Space Administration (NASA) to provide 100% safe food for space expeditions. The HACCP system developed into a food safety management system that monitors, analyzes and controls hazards that can be mixed with food all stages of a food chain, from food production and preparation processes including packaging, distribution, etc.

The mandatory HACCP was first introduced in Korea based on the 2002 「Food Sanitation Act」 and, in August 2003, 6 items including fish paste products were designated as the 'mandatory HACCP-applied items'[1](Kimchi cabbage was added in Dec. 2006). In October 2005,

1) fish meat processed products (fish cake), frozen marine products (fish, invertebrates, flavor-treated processed products), frozen food (pizza, dumplings, noodles), ice cream, non-pasteurized beverages, retort food products, cabbage kimchi

the 「Hazard Analysis & Critical Control Points (Notified by MFDS)」 was revised and enforced from 2006 to 2012 in phases based on the annual sales of the 'mandatory HACCP-applied items' and the number of employees in businesses (Kimchi cabbage from 2008 to 2014).

In May 2014, the 「Enforcement Regulations of the Food Sanitation Act」 was revised and 8 additional items including snack products were included in the list of the 'mandatory HACCP-applied items[2].' This revision became effective in 2014 and will be enforced by 2020 based on the annual sales and the number of employees in 2013 (The food products manufactured and processed by the businesses the previous year's sales exceeding 10 billion won are subject to the regulations by November, 2017).

B) Achievements

The government newly inaugurated in 2013 defined unwholesome food as one of the 'Four Major Social Problems' and has made the 'expansion of HACCP application' a government agenda[3] for eradicating these social problems. The government is also planning to have more than 6,000 business entities to be HACCP certified by 2018.

In this effort, the number of HACCP-certified businesses increased continually from 797 in 2009 to 3,734 in 2015 but the number of HACCP certified businesses are still low compared to the total number of food manufacturing companies (25,191).

[Table 1-1-1] HACCP Certification Status

(Dec. 31, 2015. unit: business entity (cumulative), Ref.: Food Consumption Safety Division)

Category	2010	2011	2012	2013	2014	2015
Total	797	1,163	1,809	2,408	3,029	3,734
Mandatory Application	462	703	1,130	1,417	2,056	2,450
Voluntary Application	429	618	1,008	1,397	1,500	1,995

* The total numbers are different because of the differences in the number of businesses implementing mandatory and voluntary application.

2) snacks·candy, bread·rick cake, chocolate products, fish meat sausage, beverages, instant foods, noodles, instant fried noodles, foods for special uses

3) Government Agenda 79-4: Reinforcement of Safety Management in Production·Manufacture Level - Expansion of mandatory phased HACCP application for most commonly consumed foods and business with sales exceeding 10 billion won

MFDS carried out numerous campaigns to promote the effectiveness and excellence of the HACCP system but about half the country still don't really know what HACCP is. MFDS carried television campaigns on network and cable television and actively utilized consumer groups and food-related organizations to promote the system to the public.

[Table 1-1-2] Consumer Awareness of the HACCP System

(Dec. 31, 2015. unit: %, Ref.: Food Consumption Safety Division)

Category	2008	2009	2010	2011	2012	2014
Ratio (%)	18.1	25.6	30	40.2	48.3	51.6

* In 2013 and 2015, the surveys were not carried because the National Assembly recommended a biennial survey.

C) Implementation Plan

(1) Expansion of Mandatory HACCP Application to Promote HACCP System

The sanitary management of sundae (Korean sausage), eggs (processed egg products) and rice cakes which are very popular in Korea, are poor such that they are detected everytime when inspection activities are carried out. Also, since these products can be found almost everywhere from large restaurants to street stalls, MFDS will implement the mandatory HACCP application by 2017 to improve the fundamental manufacturing environment of these food products.

(2) Improving the Efficiency of HACCP Follow-Up Management (periodic inspections·assessments)

In order to solidify HACCP follow-up management, with the revision of the 「Food Sanitation Act」 in August, 2015, MFDS introduced a regulation that allowed immediate cancellation of the HACCP certification of those businesses that either received less than 60% rating in the periodic inspection/assessment, don't abide by the food safety standards or received HACCP certification by unlawful means.

Also, after the revision of the 「Food Sanitation Act」 in February, 2016, MFDS introduced a regulation to give expiration date to HACCP certification and require a reexamination and renewal every 3 years. This regulation will become effective in August, 2016 and MFDS will first carry out reexamination of the businesses that have been certified prior to August 3, 2013.

(3) Strengthening of HACCP Support Projects

In order to ease the financial burden on the small manufacturing businesses that are subject to the mandatory HACCP system, MFDS will continue to carry out the project in which the businesses are granted subsidies for a portion of facilities repair and renovation costs (50% of investment, limited to 10 million won/maximum of 14 million won for Korean sausage, eggs and rice cake products). Also, to facilitate HACCP certification and technical support works, MFDS will strengthen the role and developmental functions of the Korea Institute for Food Safety Management Accreditation established in January 2014.

2) Managing Foreign Objects in Food

A) Background

After the 2008 incidents where a mouse head was found in a pack of shrimp crackers and a piece of blade was found in a tuna can, in order to resolve disputes and distrust between consumers and food businesses and to promote prompt investigation of consumer complaints, the government revised the 「Food Sanitation Act」 in February 6, 2009 and made it mandatory for businesses to promptly investigate and deal with any customer complaints regarding foreign objects found in food and also to report such discovery of foreign objects to the Ministry of Food and Drug Safety and to the city hall, county office or district office having jurisdiction over the area where businesses are located at.

B) Achievements

In 2015, there were 6,107 reports of discovery of a foreign object in a food item but after implementing the mandatory report policy, the number of reports has been continuously declining. The foreign objects found last year in food items were insects (37.4%), molds (10.3%), metals (7.3%), plastic (4.7%), glass (1.6%) and etc. The cause of foreign objects in food items were 8% through manufacturing process, 10% through consumption and distribution processes, 37.5% uninvestigatable and 44.5% impossible to decide where the responsibility lies.

Also, as a part of the technical support for resolving the foreign object issue, a network (council) has been established between major businesses and small and medium-sized businesses. As a result, the small and medium-sized businesses participating in this network have significantly reduced the mixing of foreign objects in their food products during manufacturing process. Also, a strong foundation for manufacturing, distribution and sale of safe food has been established through field surveys and presentation of successful practices.

C) Implementation Plan

In 2016, MFDS will make that the foreign objects that are more harmful and aversive to be focused and controlled and by promoting the 'Cooperative Network for Foreign Object Control' consisting of mentors and mentees from major businesses and small and medium-sized businesses, businesses will be made to put individual efforts in reducing the mixing of foreign objects in food products.

Kang Seok-yeon, Director of Food Consumption Safety Division
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3) Increased Application of the Livestock Product Safety Management Certification System (HACCP, Hazard Analysis Critical Control Point)

Korea introduced the HACCP system which is a hazard prevention program for production and distribution of safe food, to the slaughterhouses and processing plants in 1998. It established the system that allows to apply the Livestock Product Safety Management Certification across the farm-to-table spectrum by expanding the application to the entire food network including farms and sales points.

Starting with the HACCP certification for livestock processing industry in 1998, Korea made the HACCP certification system mandatory for all the slaughterhouses in 2003, milk producing industry in July, 2014 and dairy processing industry in January, 2015, by its size.

The Livestock Product Safety Management Certification System is the most advanced and efficient means to ensure the safety management of livestock products. In order to improve the safety management of livestock products and for development and wider application of the HACCP system to ensure consumer confidence, MFDS plans to distribute size-specific safety manuals for small facilities and continue to improve the safety assessment standards.

B. Safety Management of the Production and Distribution of Agricultural, Livestock and Fishery Products

1) Background

Since there are only limited number of ways to reduce or eliminate hazards in agricultural, livestock and marine products during the production or distribution stages, if the hazards are

not successfully eliminated during the production stage (cultivation, livestock farming, sea farming), they will most likely reach the final consumers. Thus, a preventive safety management for eliminating hazards in production stage is very important and systematic safety inspection on lands, water and materials used for the production of agricultural, livestock and marine products will need to be carried out.

2) Achievements

A) Safety Management of Agricultural Products

According to the Progress Status of Safety Management of Agricultural Products in 2015, MFDS conducted safety inspections for pesticide, heavy metal residue, etc. on a total of 145,251 samples of agricultural products, etc. including the items that are most commonly consumed, items that are frequently found to be not compliant and agricultural products sold on the public wholesale market. Among them, those products that violated the safety standards were disposed of, or the shipment of those products was postponed. Also, a number of actions including disposal, etc. were taken for non-complaint agricultural products after inspecting 55, 154 agricultural products that are either most commonly consumed or that have a lot of non-compliance records for pesticide, heavy metal, etc. during distribution and sales. In particular, MFDS prevented hazardous agricultural products from being distributed in the market in advance by taking expeditious actions such as disposal of non-compliant agricultural products with rapid on-site inspection in the public wholesale market where more than 60% of the omestic agricultural outputs are distributed.

Meanwhile, according to the production stage safety surveys conducted by the entrusted Ministry of Agriculture, Food and Rural Affairs, 90,097 samples of 290 agricultural food items including sesame leaves, onion and cabbage were tested for pesticide and heavy metal residue and fungal toxin, etc. and 1,232 samples of non-compliant agricultural products were prevented from being distributed or sold on the market in advance by taking actions including disposal, with holding of the shipment or change of the usage. MFDS also has been carrying out continuous inspections and monitoring on the producers of non-compliant products and required them to take appropriate corrective actions.

Moreover, MFDS shared and revealed the information about non-compliant agricultural products in production and distribution stages to local governments, the National Agricultural Products Quality Management Service and the National Agricultural Cooperative Federation, fostered the food-safety awareness by providing producers (or group of producers) with guidance and instruction on safe use of pesticides and created an environment for the safe production of agricultural products.

B) Safety Management of Livestock Products

The safety inspections and surveys on livestock products were carried out for a total of 397,000 samples including 375,000 samples in production stages and 22,000 samples items in processing and distribution stages. The inspections of the production stages were carried out mainly focusing on slaughterhouses (meat) and dairy farms (raw milk).

Livestock sanitation testing laboratories in 17 city and province across the country carried out tests for a total of 143 types of hazardous substances including antibiotics and synthetic antimicrobials in over 152,000 samples of cattle, pig, etc. As a result, it was found that 350 samples of the tested livestock animals had residual substances exceeding the maximum permissible level (violation rate: 0.2%). The farms which owned such livestock animals were designated as the violated farm and their shipments were restricted and precautionary actions were taken such as conducting inspections when products are released. Also, as a result of testing for antibiotics and synthetic antimicrobials in 4,825 eggs collected from farms, quinolones type of substances were detected (violation rate: 0.12%) in 9 samples. Accordingly, precautionary actions were taken for those violated farms including conducting inspections when products are released. While investigating the status of sanitation control in facilities for livestock products, microbiological tests were carried out at slaughterhouses, meat packaging facilities and meat shops to figure out the sanitary condition of meat. According to the test results, 82 samples (1.2%) were shown to exceed the recommended microorganism content limit. The safety management was enforced for those facilities that have exceeded the recommended limit by analyzing the cause of contamination through inspection and by providing technical guidance to reduce microbial contamination.

As a result of testing for 14,000 samples of processed livestock products being distributed in the market, 228 samples (1.58%) were found to be not compliant with the relevant standards and specifications. Consequently, appropriate measures including disposal and with drawl of the products were taken and administrative actions on business operators were taken.

C) Safety Management of Fishery Products

In 2015, a total of 25,815 samples of fisheries including the most commonly consumed fishery products, fishery products that have a non-compliance records, and fishery products by region, type and season were tested for animal medicine, heavy metals, shellfish poison, Vibrio parahaemolycius Norovirus, etc. As a result, 255 samples were found to be not compliant, and the safety was ensured by withdrawing and disposing of those non-compliant products and by taking administrative actions to the businesses operators.

Approximately 13,000 samples of domestic fishery products that are most commonly consumed in Korea and that have recorded high rate of non-compliance in the distribution and sales stages were collected and tested. As a preemptive safety management for summer fish, 1,527 domestic fishery products were collected and tested.

Meanwhile, according to the production stage safety surveys which have been entrusted to the Ministry of Oceans and Fisheries, as a result of testing for heavy metals, antibiotic substances, toxins, dioxin, radiation and Vibrio parahaemolycius on 12,700 samples of fishery products including flatfish, eel, blue mussel, sharks and catfish, a total of 205 samples exceeded the food safety limit for such substances. These items were either disposed of, withheld from being shipped or put to other use, and the distribution and sales of such products were prevented in advance.

3) Implementation Plan

A) Safety Management of Agricultural Products

For the safety management of agricultural products in 2016, MFDS plans to perform safety testing on around 13,000 samples of agricultural products by strengthening its safety management of the agricultural products that have potential to pose health risk and that are being handled in poor sanitary conditions.

For the safety management of agricultural products in the distribution and sales stages, MFDS plans to collect and test a total of 55,000 samples of agricultural products by designating the top 20 food items including perilla leaves and crown daisies, which are repetitively found to be not compliant every year, and by collecting and testing those 20 top food items on a monthly basis in terms of more focused safety controls on agricultural products which pose a health concern.

For the safety control of radiation which is one of the most concerning food safety issue to the public, MFDS plans to perform radiation testing on around 900 samples of 31 key agricultural product items including the most commonly consumed products like rice and potato as well as the agricultural products cultivated outdoors such as chili pepper and cucumber.

MFDS will also carry out surveys coupled with testing and sampling, and instruction for facilities where processing agricultural products such as dried persimmon and peeled garlic that are not fall under the regulatory system for minimal processing methods such as peeling, cutting, heating, drying, freezing and packaging. MFDS will also promote the sanitary conditions

of processing facilities by issuing and distributing guidance book on the safety management standards to assure the distribution and sales of safe agricultural products. In order to prevent hazardous agricultural products from being distributed or sold beforehand, MFDS plans to preemptively enhance the safety management by disposing of the non-compliant agricultural products through rapid on-site inspections in the public wholesale market.

Meanwhile, through the production stage safety surveys which have been commissioned to the Ministry of Agriculture, Food and Rural Affairs (National Agricultural Products Quality Management Service), MFDS plans to carry out tests for heavy metals, antibiotic substances, pathogenic microorganisms and radiation on a total of 75,000 samples including 9,500 samples of agricultural products cultivated from livestock burial lands and near closed mines, 15,000 agricultural products which include 6 agricultural food items most commonly consumed agricultural products and 94 agricultural food items that have a history of non-compliance and 500 domestic agricultural food items for radiation tests.

B) Safety Management of Livestock Products

For the safety tests of livestock products, MFDS has established a cooperative system with various government bodies in resetting targets and reevaluating the testing subjects, quantity and items and apply the changes into the plans for the following year's livestock safety tests through consultations with the Ministry of Agruculture, Food and Rural Affairs, regional offices of MFDS, and regional testing laboratories.

Also, MFDS has reinforced the efficiency of testing by focusing on product items with high detection frequency and by considering the monitoring results on domestic animal medicine that are most commonly consumed, rather than merely increasing the food items subject to and a number of samples for testing. In line with increased efficiency of testing, MFDS has conducted test taking into account violation rate by increasing the cases of regulatory inspections of meat products from 28,000 to 29,000, in which the residual substances are highly likely to violate the maximum permissible level.

In addition to the periodical inspections, MFDS has endeavored to prevent outbreaks of health risks in advance by carrying out special monitoring activities such as cracking down on false or exaggerated advertising claims on internet, etc. and investigations on storage and logistic businesses.

C) Safety Management of Fishery Products

As to the safety management of fishery products in 2016, in order to prevent the fish farms

with non-compliance records from repeating the same safety issues, MFDS plans to carry out safety investigations and to enhance training and instruction. MFDS also plans to perform safety inspections on around 21,000 samples by reinforcing heavy metal testing on sharks, etc. which have shown high non-compliance rate and by consistently strengthening the safety controls on fisheries that are managed in poor sanitary conditions.

For the safety management of fishery products in the distribution and sales stages, and more specifically to prevent hazardous fishery products from entering distribution and sales channels, MFDS plans to select 15 fishery items that are subject to special management because of high non-compliance rate and 41 fishery items that are most commonly consumed and collect and test around 2,000 samples of fishery products being distributed. It also plans to perform testing for heavy metals, antibiotic substances, toxins, pathogenic microorganisms and shellfish poison on around 4,900 fishery products including pollack, squid, shrimp, saury, small octopus and short-neck clam which are commonly distributed and used for institutional meal service, and testing for radiation on 2,100 samples of 41 fishery products including squid, anchovy, seaweed, kelp saury and cod.

Meanwhile, through the production stage safety surveys which have been commissioned to the Ministry of Maritime Affairs and Fisheries (National Fishery Products Quality Management Service), MFDS plans to perform safety investigations for heavy metals, animal medicine, dioxin, shellfish poison and radiation on a total of 12,000 samples, which includes 6,600 samples for fishery products from 60 most commonly consumed items and 16 specially managed fishery items, 1,200 samples of domestic fishery products including oceanic fish and coastal fish for radiation testing 3,600 samples of certified fishery products for testing, and 200 samples of 10 fishery items subject to hazardous microorganism management for testing.

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3. Improving the Level of Safety Management for Foods Being Distributed and Consumed

A. Nationwide Joint Inspections

In order to prevent foodborne illnesses or injuries in advance and to secure food safety,

every year, for special times and seasons, MFDS, local governments and relevant organizations have been carrying out joint inspections of businesses that have a history of repetitive and willful violation of food safety regulations, products that are most frequently detected to be defective or unsuitable and products that have become controversial topic in the country.

The joint inspections were carried out nationwide on popular food products during the holiday seasons and summer months in 2015, on school cafeterias preparing for a new school semester, youth training centers, and 32,829 food businesses. Among those businesses, 740 (2.3%) were found to be violating food safety regulations and corrective measures were applied and accordingly.

B. Strengthening of Collection and Testing of Foods Being Distributed

MFDS, local food & drug administrations, cities and provinces maintain food security by collecting and testing food products that are being distributed in the country. MFDS establishes and manages the master plan, local food & drug administrations collects and inspects samples for planned investigations and, cities and provinces establish detailed plans according to the master plan established by MFDS.

In 2015, over 210 thousand agricultural, livestock, marine and processed food products were collected and tested and 1,455 products that did not meet food safety standards were seized and disposed. The rate of defect was 0.7%.

Among the products that have high distribution share, those that showed high defect rates in the tests over the past 3 years, were designated as the 'special control target items'[4]. A total of 33,620 products were collected and tested. Also, taking the temporal patterns of food consumption into account, collections and inspections were carried out for cold buckwheat noodles and cold bean-soup noodles which are highly consumed products during summer months, and for highly consumed products during holiday seasons.

In 2016, the food products that have potential risk of hazards will be effectively collected and tested based on the statistical data on defect history acquired over the years.

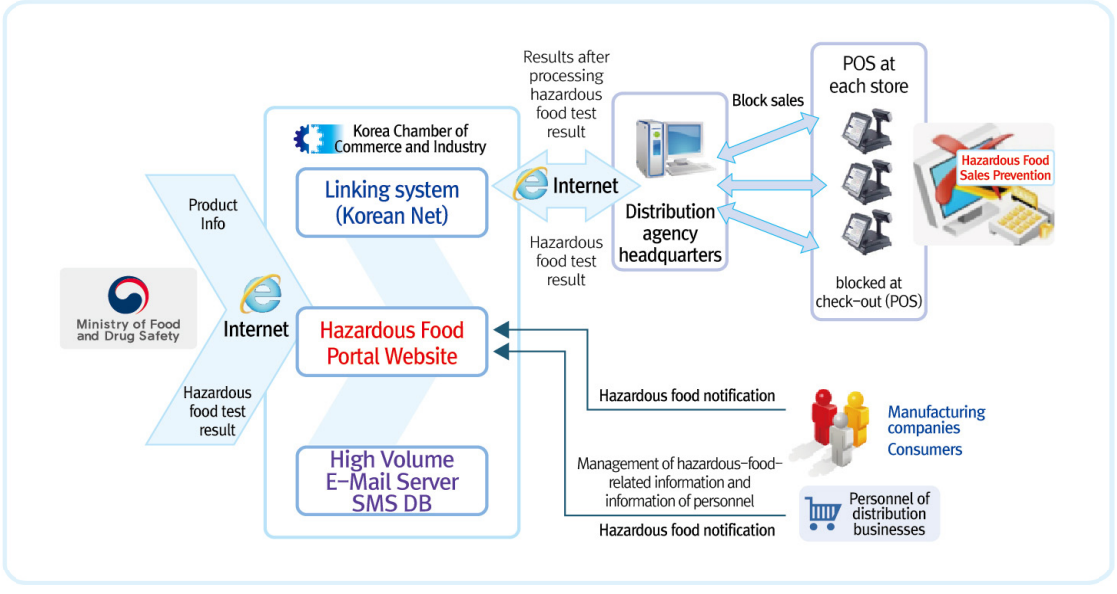
4) 2014 Special Control Target Items: coffee, kimchi, noodles, soybean milk, instant foods, fish cake, jellied food, candy, fish meat sausage, sesame oil, perilla oil, soya-based products, dried red pepper powder, dried fish, liquid tea, cabbage kimchi, rice cake, instant foods.

C. Hazardous Food Sales Prevention System

Product quality and safety are checked through MFDS' and other government ministries' collections and inspections of food products that are being distributed in the market and also through food manufacturing businesses' regular, self-inspections and quality audits of their own products.

The information about all the defective products are gathered through all these tests and inspections are reported to MFDS in real-time and MFDS operates the 'Hazardous Food Sales Prevention System' which enables MFDS to prevent consumers from purchasing the defect/hazard reported products by sending the information about such products, in real-time, directly to check-out counters in convenient stores, supermarkets and etc.

As of 2015, the 'Hazardous Food Sales Prevention System' has been installed nationwide at a total of 64,060 stores including major supermarkets, department stores, electronic home shopping stores (online stores), small and medium-sized distributors, convenient stores, small shops and etc. And as a result, about 24 million people which account for approximately 93 percent of the economically active population, are able to use and purchase products safely at stores where the 'Hazardous Food Sales Prevention System' is installed.



[Image 1-1-3] Flow Chart of the Hazardous Food Sales Prevention System

* Increase in the number of stores (cumulative): (2009) 8,771 → (2013) 42,134 → (2014) 52,966 → (2015) 64,060
* Average Daily Beneficiaries: (2009) 5.07 million → → (2013) 17.78 million→ (2014) 21.68 million → (2015) 23.83 million

MFDS will continue to operate the 'Hazardous Food Sales Prevention System' and install the System at even small and medium-sized distributors to effectively prevent sales of hazardous foods.

D. Food History Tracking & Management System

1) Background

There is a standard for taking measures such as cause analysis, tracking, recalls and etc when hazards occur in foods or in health functional food products. MFDS has prepared and is currently running the 'Food History Tracking & Management System' to take measures such as cause analysis, tracking, recalls and etc when hazards occur in foods or in health functional food products, improve food safety and provide more accurate information to consumers.

The system will be mandatorily applied from 2014 to 2017 in phases to the businesses manufacturing, processing, importing and distributing baby food products and health functional foods which can be especially hazardous when food safety problems occur in them and those large-scale food retailers.

2) Achievements

A) Revision of Statutes to Improve the Food History Tracking & Management System

The Enforcement Decree of 「Food Sanitation Act」 and the Enforcement Decree of 「Health Functional Foods Act」 have been revised to facilitate the implementation of the Food History Tracking & Management System. Currently the 2nd phase (Dec. 2015) of the mandatory application of the System for businesses that import, manufacture or process infant and baby foods or health functional food products with annual sales exceeding certain level and other food product retailers operating business on stores exceeding certain level of size, is complete. Also, for the follow-up management of the System, MFDS has been made that the relevant standards (history tracking & management system for foods and health functional food products) to be investigated and assessed every 2~3 years.

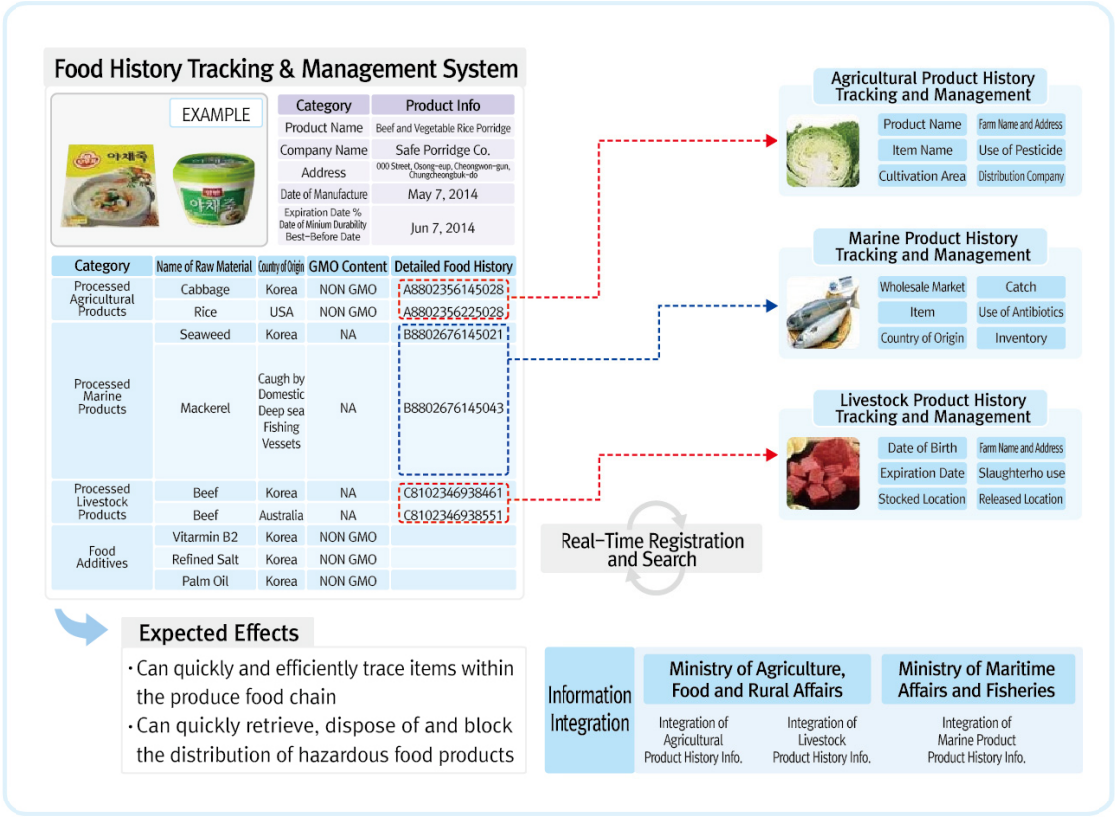
B) Promotion of the Food History Tracking & Management System

In 2015, to promote mandatory and voluntary application of the Food History Tracking & Management System, information meetings (seminars) were held 37 times for businesses, 54

sessions of training were carried out at a place exclusively established for the training and an online training was carried out for a total 230 persons. MFDS also offer field consultations to 2,542 establishments, operated campaign booths, carried out public campaigns (7 times) and as of 2015, 2,016 food-related businesses were registered to the Food History Tracking & Management System.

C) Linking the Food History Tracking & Management System

In order to establish plans for linking and applying the Food History Tracking & Management System from production to sale, a council comprising MFDS, the Ministry of Agriculture, Food and Rural Affairs and Ministry of Maritime Affairs and Fisheries, was established and 2 working-level meetings and 2 council meetings were carried out. In the council meetings, the council members discussed carrying out research projects for laying the groundwork for linking the Food History Tracking & Management System, revising the Framework Act on Food Safety, sharing the information gathered from the History Tracking & Management System, plans for pan-governmental promotion activities and etc.



[Image 1-1-4] Structure of Linking Food History Tracking & Management System

3) Implementation Plan

A) Phased Mandatory Application of the Food History Tracking & Management System and Increased Application

The year 2016 will be the 3rd phase of the mandatory application of the Food History Tracking & Management System. The mandatory system will be applied to businesses that import, manufacture or process infant and baby foods or health functional food products and other food product retailers operating business on stores exceeding 300㎡.

Also, with the enactment and implementation of the 'Special Act on Safety Management of Imported Food', on top of the food products and health functional products that were already being imported, livestock products (except for the imported beef according to the 「Act on History Management of Livestock Products」) became subject to the registration of the imported food distribution history management system and MFDS is currently newly enforcing (2016~2018) a phased mandatory registration of imported milk formulas to the history tracking & management system and the year 2016 will be the 1st phase of the mandatory registration system. For managing the milk formulas produced domestically, MFDS is currently working on revising the statutes under the 「Livestock Product Sanitary Control Act」.

B) Support for Business Operators Getting Registered in the Food History Tracking & Management System

The mandatory is being applied by phases to businesses that import, manufacture or process infant and baby foods or health functional food products and other food product retailers operating business on stores exceeding 300㎡ and MFDS has decided to establish and operate a quick response call center to support the System and its regulations. Also, by providing training, online education and customized educational program and by improving the History Tracking & Management System, MFDS will enhance the System and make it more user-oriented and accessible to businesses.

MFDS will also improve the History Tracking & Management System, increase the availability and usability of the System to businesses and provide more field support such as information meetings and field consultations.

C) Linking the Food History Tracking & Management System

The Food History Tracking & Management Council comprising the Ministry of Agriculture, Food and Rural Affairs, Ministry of Maritime Affairs and Fisheries and MFDS, will hold working-level meetings more than once every half year and discuss plans for linking the History Tracking & Management System from production to sale. Also, a history tracking & management council including outside experts, will be formed and have in-depth discussions of plans for linking the History Tracking & Management System from production to sale. Also, the 「Framework Act on Food Safety」 to establish legal grounds for linking the Food History Tracking & Management System.

E. Establishment of a System for Recalling Hazardous Food Products and Increased Information Sharing for Consumers

In order to reduce and prevent consumer injuries and damages caused by food safety hazards and defective food products, it is important to promptly recall defective products and cut-off the distribution and sale of such products. MFDS shares information about defective products (hazardous food products) with relevant organizations, distributors and consumers through website announcements and through various other methods. In 2015, MFDS has developed a smartphone application (‘Food Safety Watchdog’) which enables consumers to personally check hazards in food products which they are looking at on site.

Also, MFDS additionally installed the ‘Hazardous Food Sales Prevention System’ at 10,000 establishments every year and as of 2015, the system was running in 64,060 establishments

F. Improving Food Labeling System to Provide More Accurate Information to Consumers

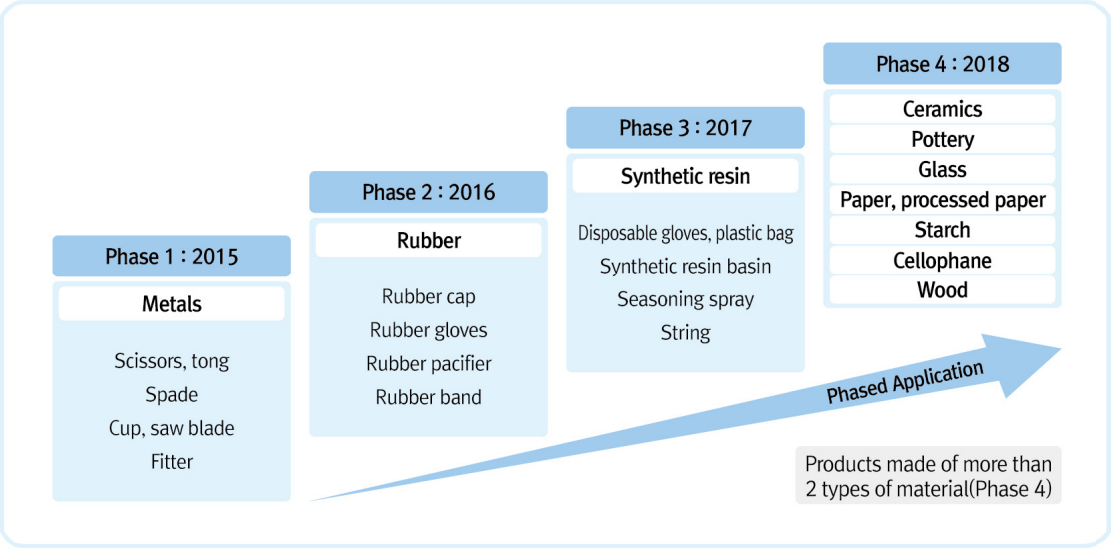
1) Background

To provide consumers with more accurate information on food products, MFDS established and implements the 「Food Labeling Standards」 which specifies regulations and standards for labeling product name, ingredients, manufactured and expiration dates, net contents, identity and principle place of business, nutrition information, instructions for safe storage and etc on packaging and container.

2) Progress

MFDS also reviews and revises the 「Food Labeling Standards」 every year to make it more fit and in tune with the changing times. Also, to establish a social consensus with stakeholders on consumers' diverse and complex demands for improvement in the food labeling system, MFDS undergoes opinion gathering processes and makes improvements in the labeling system. To make the opinion gathering processes more efficient and structured, in June 2013, MFDS prepared and announced the 「Regulation on the Management of the Advisory Council for Food Labeling Standards as a directive. The advisory council comprising consumer groups, industries, the academia, associations and relevant ministries and offices gather and discuss opinions to revise food labeling standards rationally and in ways that both consumers and businesses can be satisfied with.

Moreover, after it was pointed out that there had been cases where equipment for food-related use and equipment that are not for food-related use, are being used by people interchangeably, on December 26, 2013, MFDS established the 'Food-related Equipment Labeling System'. This system requires food-related equipment to be labeled with a special label indicating that they have been manufactured as food-related equipment according to the standards specified in the 「Food Sanitation Act」 and the system is intended to prevent consumers from getting injured or harmed by using unsafe, non-food-related equipment on foods. In order to adopt this system, MFDS carried out surveys on food-related equipment labeling systems established in foreign countries, developed a mark or label for food-related equipment and carried out multiple sessions of opinion sharing process with stakeholders and have made decision on equipment subject to food-related labeling, labeling method, labeling placement and implementing period. Taking into account the urgency of the system application and businesses' practiceability, the implementation period of this system will be separated by type of material(labeling for metal in 2015 → labeling for rubber 2016 → labeling for synthetic resin in 2017 → labeling for other types of material 2018) and be made mandatory in stages. MFDS expects that this system will help consumers in selecting safe, food-related equipment that meet the standards of the Food Sanitation Act.



[Image 1-1-5] Implementation Phases of the 'Food-related Equipment Labeling System' by Material Type

Also, while implementing the 'Food-related Equipment Labeling System', MFDS also made and distributed promotional leaflets about the System to help people better understand it.

To prevent consumers from getting harmed or injured by food allergens and to provide them with accurate food-related information, on December 26, 2014 and April 8, 2015, MFDS revised the 「Food Labeling Standards」 on 8 items including the specification of food allergen precautionary statements, expansion of the range of food products subject to allergen labeling and improvements for labeling methods. Also, to help people better understand the system, MFDS is carrying out information sessions for food-related government officials and industries.

3) Implementation Plan

With the implementation of the 'Food-related Equipment Labeling System' (Jan. 1, 2015), MFDS is currently carrying out nationwide campaigns to facilitate the stabilization of the system. Although current food labeling provides a lot of information, the content of the label is somewhat difficult to read so MFDS will revise the 「Food Labeling Standards」 to improve the readability of the current food labeling system.

G. Monitoring of False·Exaggerated Advertising

People's interest in increased quality of life is greater than ever and false or exaggerated

advertisements that either indicate or promote therapeutic effects of food or those ads that can confuse people to think of those products as pharmaceuticals are subject to MFDS' systematic monitoring and inspections.

In 2015, by monitoring false and exaggerated advertisements, 552 cases of advertisement violations were found and the violators received administrative penalties and prosecuted. In regars to illegal foreign websites, MFDS requested the Korea Communication Standards Commission to block access to those sites and tried to prevent consumer damage from false and exaggerated advertisements. Moreover, to provide consumers with accurate information on the scope of false and exaggerated advertisements and violation cases, MFDS set up a section called, 'Information on False and Exaggerated Food Advertisements (www.foodnara.go.kr/kwanggo)' on its website.

MFDS will continue to monitor false and exaggerated advertisements and educate and guide web portals, online shopping mall advertisers and etc to prevent consumer damage.

H. Operation of the 'Consumer Food Sanitation Watchdog' System

To promote consumers' active participation in sanitation monitoring activities and to secure fairness, reliability and transparency in those activities by utilizing experts such as consumer groups, MFDS is currently running a system called the Consumer Food Sanitation Watchdog.

In 2015, a total of 11,895 people were appointed as consumer food sanitation watchdog. Also, a total of 145,100 people participated in food sanitation monitoring activities and inspected the sanitary conditions of over 691,142 food-related businesses.

MFDS will continue to provide support for the facilitation of the Consumer Food Sanitation Watchdog System to increase consumers' participation in food sanitation improvement works and to increase people's trust in food sanitation administration.

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4. Strengthening Safety Management of Imported Foods

A. Strengthening Inspection and Management of Imported Foods

1) Background

Korea's food self-sufficiency rate increased from 47.5% in 2013 to 49.7% in 2014. And, with the signing of the Korea-Europe FTA (July, 2011) and Korea-US FTA (March, 2012) and the globalization of the world economy, the number of imports and volume of import increased 36.3% and 9.4% to 426,272 imports and 14,740,475 tons in 2015 compared to 2011.

However, a survey on the level of perceived food safety showed that 5 people out of 10 (56.6%) are still feeling unsafe towards imported foods and this reflects the nation's need for strengthening safety management of imported foods.

2) Achievements

A) Strengthening of 'Pre-Safety Management' of Imported Foods

After the enactment of the 「Special Act on Safety Management of Imported Foods」 (Feb. 2015) which was established for pre-registration of foreign manufacturers overseas and for preventing import food hazards that increase every year, MFDS worked on making sub-regulations. MFDS also further strengthend the safety and sanitation of imported foods by establishing the Foreign Manufacturer Online Registration System (Dec.) and preparing 'standards and procedures for evaluating sanitation of livestock product export countries (Dec.).'

B) Strengthening of Customs Inspection on Imported Foods

In Korea's food safety, safety management of imported foods is becoming more important every day and with all the risks of hazards that can easily cut across regions and borders as we have seen from the 2008 Chinese melamine milk scandal and the 2011 Japanese nuclear disaster, the risk of hazard is greater than ever. So, MFDS strengthened field survey and inspection on manufacturers that have a history of handling defective and unwholesome products and those with a high import volume and also, established a preliminary prediction import inspection system called, OPERA which classifies the ratings of imported foods through analysis of food defect history, potential hazards, importers and manufacturers.

MFDS also analyzed the hazard detection history by country, item and substance, applied

differential rates of random sample test according to the hazard levels, selected the items subject to in-depth inspection test and utilized the preliminary prediction import inspection system OPERA for random sample tests to screen potentially hazardous imported foods.

To safely manage imported foods from Japan after the nuclear disaster (March, 2011) in Fukushima, the import of 27 items from 13 prefectures that are subject to Japanese government's distribution prohibition action was temporarily suspended and the attachment of the Japanese government's official certificate has been made mandatory for every Japanese food item imported to Korea. The import of Japanese foods that show radiation contamination was basically cut off because even when a small amount of radiation is detected through a radiation inspection, the importers of such products must provide inspection certificate on radioactive nuclides (strontium, plutonium and etc). To let people know of the current status of food safety management towards radiation, MFDS releases the details of radiation inspections and status of Japanese food on its website. Also, to further improve the nationwide awareness of food safety and accessibility to safety information, MFDS distributes radiation-related news and information to over 600 organizations including the media, consumer groups and etc.

C) Strengthening the Responsibility of the Importers on Imported Food

The diligent report ratings determined by the 「Diligent Report Evaluation System」 were reflected on the preliminary prediction import inspection system, OPERA and, in 2015, out of 4,581 cases, 39 defect cases were detected (defect rate: 0.9%). Also to improve the effectiveness of the education order policy, MFDS improved the policy to allow sanitary education personnel as well as business operators to receive education and carried out education on a total of 576 people over a total of 20 training sessions. MFDS also carried out a capacity building program with food sanitation management personnel (1 session, 20 people) to strengthen the capacities of public officials in charge of food import works and carried out a imported food inspection program (10 sessions, 201 people. online course) to improve the understanding of the imported food inspection system.

3) Implementation Plan

A) Strengthening On-Site Safety Management of Foods Prior to Import

By implementing the 「Special Act on Safety Management of Imported Foods」 which has changed the paradigm of food import safety management from the 「Customs-level Safety Management」 to 「Local Safety Management Prior to Import」, registering foreign manufacturers and manufacturing sites, strengthening safety management of the local environment in export

countries, applying differential inspection through the analysis of importers and imported goods and establishing a system for tracking the history of imported foods, MFDS will further strengthen the safety management of foods prior to import.

To secure objectivity, transparency and efficiency of the on-field inspection, MSDS will invest more in sensory inspection tools and initiate the preliminary prediction import inspection system (OPERA) to control potentially hazardous foods by measuring and scoring the hazard level through analysis of information about products' defect history, potential hazards, importers, manufacturers, low-priced products and etc.

B) Expanded Implementation of the Inspection Order Policy on Potentially-Hazardous Food Importers

In addition to the 'Inspection Order' currently being implemented, MFDS will apply an instruction order policy to the imported foods with high defect rate, enhance business operators' sense of responsibility and ethics, implement the education order policy to prevent defects, increase the scope of education recipients to improve the effectiveness of the education and set up a highly-accessible, online education course.

After implementing the inspection order policy for imported foods (Mar. 29, 2012, MFDS analyzed and improved the weaknesses in the policy, prepared the 「Regulation on Foods Subject to Inspection Order」 and started to applied the regulation on 3 cases (Indonesia, snacks) on Feb. 29, 2016. Also, MFDS will provide real-time information about defective products and manufacturers to all the importers to prevent them from importing hazardous and defective products and also carry out import report education programs to train and educate the importers' personnel in charge of import report to establish a safe import environment.

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B. Strengthening of On-Site Inspection in Exporting Countries for Precautionary Safety Management

1) On-Site Inspection of foreign food facilities

A) Background

With the signing of the FTA (Free Trade Agreement, FTA) etc, the number and weight of

food imports have continuously risen and there are limitations to cover and ensure safety of processed food and agricultural products at the customs, which take up the largest percentage of the total food imports at 68% (weight 95.4%) as of 2015.

Therefore by establishing and enforcing 「Special Act on Imported Food Safety Management」, on-site inspection of foreign food manufacturing facilities are considered to be more important than before.

B) Achievements

MFDS carried out on-site inspections of foreign food manufacturing facilities that export large amount of products to Korea or that show a record of non-compliant products. Also, MFDS held information sessions in attempts to provide better understanding of food standards and specifications for stakeholder and relevant organizations in exporting countries.

Also, MFDS promoted 「Good Importer Registration System」 which encourages importers to be responsible for safety of their food imports on their own. By this way, MFDS has increased number of safely managed food products.

C) Implementation Plan

MFDS will continuously carry out on-site inspections in countries of which the facilities have many records of manufacturing non-compliant products or manufacture 'children's favorite foods' including China, as well as Vietnam and Indonesia, etc.

Also, MFDS is planning to promote good importers by implementing the 「Good Importer Registration System」 and by holding information sessions on precautionary safety management system to inform objectives and plans. Also, MFDS will strictly follow-up on good importers regularly to create environment for importing excellent products.

2) On-Site Inspection of Facilities in Livestock Product of Exporting Countries

A) Background

Korea's food self-sufficiency rate has been showing a decreasing trend from 54.0% in 2010 to 49.7% in 2014 and there has been risks of safety incidents or contamination of hazardous material during production and distribution process with increased imports of livestock products. MFDS understands that securing safety of imported food through inspections at the customs are insufficient and that safety must be managed by carrying out on-site inspections of the facilities and to ensure imported livestock products in advance.

B) Achievements

MFDS ensures food safety by strengthening functions which prevents hazardous livestock products and also by permitting imports of only the livestock products manufactured from facilities which the on-site inspection has been completed in advance as approved and registered foreign facilities (has been mandated in 1993) that has equivalent sanitation level as Korea, accordingly to enacted and implemented import sanitation requirement between the countries that has gone through 8 steps including livestock diseases and sanitation assessment for pre-import safety management. In 2015, MFDS has carried out sanitary inspections on 71 overseas facilities in 9 countries including the US, China, France, Italy, etc.

In particular, safety management has been strengthened from sanitation management aspect based on livestock sanitation condition and sanitation management system of exporting countries at BSE and food-and-mouth disease when permitting import of livestock products by implementing livestock sanitation assessment and registration of foreign facility (February 4, 2016), accordingly to 「Special Act on Imported Food Safety Management」.

C) Implementation Plan

MFDS will hold briefing sessions regularly for Embassy in Korea and foreign facilities regarding imported livestock products system that is being changed by implementation of the Special Act to promote establishment of such system and MFDS will cooperate with Ministry of Food and Rural Affairs for products that are overlapped and prepare for facilitative implementation.

Also, a sanitation manual for on-site inspection in foreign facilities will be prepared and training will be held to establish a standardization and expertise of the on-site inspection team.

From the aspect of customs level of livestock product imports, inspection will be tightened for products that are likely to be subject to hazardous material and will strictly manage in order to encourage exporters to be responsible by implementing administrative management followed by detection of hazardous material.

3) On-Site Inspection of Manufacturing Facilities for Fishery Product in Exporting Countries

A) Background

The establishment of the World Trade Organization (WTO) in 1995 and the number of FTAs Korea have signed in the past 10 years have increased the trades of fishery products. However,

due to continuous contamination of the ocean from industrial disaster such as leakage from radioactive material from Japan's nuclear power plant, oil leakage from damaged ships, etc, new hazardous materials are being investigated such as endocrine disrupters that have not been detected in the past.

MFDS has signed and has been implementing sanitation agreements with major fishery product trading countries to ensure precautionary safety of imported products by cutting off imports of unsafe marine products and to protect people's health and lives. Currently, 7 agreements with 6 countries including Vietnam, China, Indonesia, Thailand, Russia and Ecuador are in effect (China: sanitation agreement for fishery products and fresh fish). Through these sanitation agreements, measures are taken so that manufacturing facilities in countries that have signed the sanitation agreement mandatorily register the facility, construct dual inspection system of precautionary safety management and customs inspection at the import before exporting from the country of sanitation agreement, and prohibit imports from manufacturing facilities when non-compliant products are detected.

Moreover, MFDS has made it mandatory for exporters that wish to export frozen edible fish heads [heads of cod, southern hake, tuna, and all the edible parts of all the edible fish (except for puffer fish)] and internal organs of frozen fish intestines [edible fish pollock intestine, roe, squid nidamental gland (except for puffer fish)] (known as 'by-products') to Korea to have their manufacturing facilities registered. The countries that wish to export these fishery by-products must send the list of manufacturing facilities in the country to MFDS. Also, exporters that are importing fishery by-products to Korea for the first time or wish to export new fishery products to Korea must request MFDS for on-site sanitation inspection of the facilities and acquire an import approval to check sanitation condition of the foreign food facility.

B) Achievements

In 2015, MFDS and the Ministry of Oceans and Fisheries carried out joint sanitary inspections on 64 processing facilities in countries that have signed the sanitation agreement and MFDS carried out inspections independently on 3 by-product manufacturing facilities and requested the facilities for sanitary improvements and corrective actions after the inspections.

In particular, MFDS has consulted with the person in charge from the countries that have signed the sanitation agreement for sanitation safety management of fishery products in order to identity the cause of non-compliance from the facilities and prevent from happening again when inspecting countries under sanitation agreement and on-site manufacturing facilities of fishery by-products under the guidance of on-site sanitation advisor.

C) Implementation Plan

With the implementation of Special Act on imported food safety management, precautionary safety management of foreign food facilities of fishery products has become more important and in order to ensure safety of imported fishery products, a system will be constructed with Ministry of Oceans and Fisheries and MFDS will prepare for a facilitative implementation. When there is an issue with fishery exports and imported, both MFDS and Ministry of Oceans and Fisheries will correspond together. In particular, the fishery products imported from 6 countries that have signed the sanitation agreement take up approximately 63% (6 countries: 659,051 ton/ Total: 1,039,085 ton as of 2015) of the total fishery product imports and therefore MFDS will strengthen and improve the sanitary management for foreign manufacturing facilities and closely watch to prevent entry of hazardous fishery products to Korea.

Also, MFDS will expand and strengthen sanitary inspection of fishery by-products of exporting countries so that sanitarily managed fishery by-products are imported when exporting countries request for a import approval to Korea, especially because Korea's eating habits include roe, intestines, fish heads, etc. MFDS is also planning to conduct sanitation inspection with facilities with higher percentage of import to Korea as priority through periodic monitoring of approved fishery by-products.

Moreover, MFDS is planning to prohibit non-compliant fishery products and import only the safe fishery products to Korea in order to strengthen priority inspection on hazard information and fishery products with non-compliant record.

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C. Reinforcing Safety Management of Novel Foods including Genetically Modified (GM) Foods

1) Background

Genetically modified organisms(GMO) are being grown in 28 countries throughout the world and the cultivation area is expanding rapidly. However, Korea's self-sufficiency rate of grain is very low at only 23.1% (statistics of 2014년 Ministry of Agriculture, Food and Rural Affairs) and as a result, the country is highly dependent on imports of soybeans and corns for food processing. In 2014, GMO soybean and corn imports made up 77% and 52%, respectively,

of the total imported soybeans and corns. Since 1999, MFDS has approved GMOs concluded to be safe for food by safety evaluation of GMOs with scientific and systematic verification processes. MFDS also carries out re-evaluation of those approved GMOs every 10 years to confirm their safety.

Through pre-import inspections, year-round collection and analysis of hazard information, and exchanges of information with foreign countries, MFDS makes sure unapproved GMOs are not sent to or brought into Korea and to guarantee consumers' right to know, it was made mandatory to label the products manufactured and processed using GMO foods approved for food. MFDS also carries out follow-up management for genetically modified foods in the manufacturing and distribution stages after import approval and receipt of report. Meanwhile, to provide accurate information on GMOs and to strengthen communication with people, MFDS provides information regarding the status of examination and approval, labeling and follow-up management, various kinds of video and education materials through its website. Also, MFDS offers learning programs on GMOs to business owners and consumers such as homemakers and students as well as e-learning program and social networks service(SNS) to allow and promote two-way communication between the Ministry and the public. Also, since 2010, MFDS has been examining and approving novel agricultural, livestock and marine products introduced for the first time according to the 「Temporarily Standards and Regulations for Food Products」. Up until 2015, a total of 9 new food materials including two-spotted cricket have been approved and it is expected that the scale of the domestic food and food research and develop will continue to expand with increasing scope of food materials.

2) Achievements

A) Evaluation of the Safety of GMOs

By 2015, a total of 155 events have been approved by MFDS and they are 134 events of GM agricultural products(69 corns, 25 cotton, 21 soybeans, 13 canola, 4 potatoes, 1 sugar beet and 1 alfalfa), 2 events of GM microorganism and 19 events of GM food additives. The re-evaluation of 17 events also have been completed.

B) Safety Management of GMO Imports

To import survivable and proliferable GMOs (hereinafter referred to as the Living Modified Organisms, LMOs) which have been approved by the safety evaluation, importers must apply for a permit for every import according to the Article 8 of the 「Act on the Transboundary

Movements of Living Modified Organisms」. After the import has been improved, the importer must declare the import by submitting the import permit to the import management division of a regional office for food and drug safety which has the jurisdiction over the customs location. When the import declaration is submitted, the submitted documents are examined. After the imported items is tested through a sensory test, an in-depth test or a random test, the final decision on the import declaration is made based on the test results and finally, the imported items undergo an official customs procedure.

C) Labeling and Follow-up Management of GMOs

To secure the safety of GMOs and maintain the trust of consumers, MFDS and local governments continuously and periodically carry out guidance and inspections on the labeling of GMOs in manufacturing and distribution stages and 5 cases of labeling violations occurred in 2015.

Also, with the revision of the National Government Organization Act in 2013, the duties of inspecting labels of GMOs were transferred from the Ministry of Agriculture, Food and Rural Affairs to MFDS. MFDS carried out collection, inspection, guidance and testing of GMOs and no labeling violation was found in 2015.

D) Safety Management of the Unapproved GMOs

The safety of the genetically modified agricultural, livestock and marine products intended for human consumption are examined according to Article 18 of the 「Food Sanitation Act」 and those products that did not undergo safety tests and those products that are found unsuitable are prohibited from import, distribution and sales according to the Article 4 and 5 of the 「Food Sanitation Act」.

To prevent those unapproved food items from flowing into the country, MFDS focuses greatly on collecting and analyzing relevant information and with these information, MFDS checks all the products that can be imported into the country for the content of unapproved GMOs to strictly block those products unapproved.

In 2015, among 5 crops including rice, maize, flax, papaya and wheat, 3,817 cases of tests were carried out to test the content of the 12 items that are not approved for import. 6 items including Chinese papaya extract power showed content of the unapproved GMO (PRSV-YK, PRSV-SC) and all of them were disposed of or returned.

E) GMO Labeling System

GMO labeling system is used by over 20 countries around the world, including Korea, Japan and EU, to provide consumers with accurate information about food. Each country has its own way of labeling GMOs and its own list of GMOs as each country has different food self-sufficiency and socioeconomic circumstances. Korea has been implementing the system since 2001.

MFDS is in charge of the safety management of genetically modified agricultural products and processed products. And, with all the different GMO labeling standards specified under the 「Food Sanitation Act」, 「Agricultural Products Quality Control Act」 and 「Act on the Transboundary Movements of Living Modified Organisms」, there was a need to unify them into one. So, first, MFDS standardized the terms, 'genetically recombined' and 'genetically modified' being used into 'genetically modified' and made a legal framework for managing the GMO labeling standards more systematically by enacting the comprehensive '「Labeling Standards for GMOs」(MFDS Notification No. 2014-114)' which combined individual labeling standards.

F) Education and Campaigns on GMOs

In order to provide accurate information on GMOs, MFDS works with consumer groups and carry out customized education programs. In 2015, for 2,700 people including homemakers and middle school and high school students, MFDS carried out 51 sessions of a commissioned education program called, 'Know Your GMOs'. Also, MFDS carried out 'Junior Food and Drug Safety Program' for middle schools students, 25 sessions of 'GMO Learning Program' for college students and held a GMO seminar (Aug. 10) for journalists.

MFDS also set up 'GMO Communication Supporters' and the recruited university students who use social networks like Facebook or blogs, posted articles introducing the definition, developmental status and safety of GMOs. Also, MFDS carried out a GMO learning event (Oct 6. ~ Oct 12., 2,377 participants) on its Facebook page to communicate with consumers and provide them with more accurate information about GMOs.

G) Temporary Approval of New Food Materials

Since 2010, according to the '「Temporarily Standards and Regulations for Food Products」(MFDS Notification No. 2014-147)', the agricultural, livestock and marine products newly introduced to Korea and the food materials acquired from extraction, separation and cultivation

of those products have to be examined and approved based on the safety documents submitted by the entities intending to use those products and based on the review of experts. The characteristics, origin, details for the development of those products, manufacturing methods, safety information (consumption standards, health and physical impact, toxicity test results) and international and domestic data on these products are examined.

To share the standards and regulations for novel food and current status of the development of these products, MFDS cooperated with the Ministry of Agriculture, Food and Rural Affairs and other relevant organizations and also held seminars. In 2015, 4 novel foods were approved including two-spotted cricket after carrying out field inspection and experts advisory meetings.

Also, by revising the Korean Food Standards Codex (MFDS Notification No. 2015-78, Oct. 29, 2015), MFDS prepared a basis for temporarily approving new food materials to be used as general food materials. To establish the objectivity, consistency and expertise of the examiners, MFDS issued a guideline for saftery evaluation for each type of new food materials, providing details standard examination criteria for evaluating the safety of plants, animals (insects) and microorganisms.

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5. Establishment of an Alcoholic Beverage Safety Management System

A. Background

As the size of the alcoholic beverage industry and consumer demands increase and as the environment of the alcoholic beverage industry changes more rapidly, the safety management of alcoholic beverages must be strengthened. In June 2010, MFDS and the National Tax Service signed a MOU (Memorandum of Understanding) for alcoholic beverage safety management and revised the 「Enforcement Decree of the Food Sanitation Act」 (became effective on July 1, 2013) to require alcoholic beverage manufacturing license holders to be registered as food manufacturing and processing operators.

However, to implement effective alcoholic beverage safety policies, different management

systems need to be revised and integrated and various relevant ministries and authorities need to cooperate and harmoniously work together.

B. Achievements

1) Establishment of a Foundation for the Safety Management of Alcoholic Beverages

The 「Enforcement Decree of the Food Sanitation Act」 which requires mandatory registration of licensed alcoholic beverage manufacturers as 'food manufacturing and processing business operators', was revised and the works for the registering process were delegated to regional offices of food and drug safety. Also, the 「Enforcement Regulations of the Food Sanitation Act」 was revised to allow traditional Korean alcohol beverage manufacturers the use of 'wood' under 'food facility' considering their traditional manufacturing processes. The alcoholic beverage labeling which was controlled under the Liquor Tax Act was integrated into the 'Food Labeling Standards' and MFDS set up a cooperative system with the National Tax Service and Ministry of Agriculture, Food and Rural Affairs to resolve the confusion caused by diversified business management responsibilities. Moreover, to promptly stabilize the systems and regulations, MFDS held policy information meetings and discussion sessions on business registration, policies for product labeling and manufacturing reports.

2) Improved Sanitary Level of Alcohol Beverage Manufacturers

There is a total of 1,098 alcohol manufacturers (as of 2015) and more than 90% of those manufacturers are small businesses with less than 10 employees. In order to manage these businesses that show drastically different levels sanitation and safety management and to efficiently manage these businesses with limited administrative resources, in 2012, MFDS adopted and operated the 'Classification-Based Management System' and differentially managed alcohol businesses according to their classification. outstanding businesses, businesses requiring general management and businesses requiring critical management. In 2015, MFDS revised and improved the System and changed it to the 'Sanitary Management Grading System', which monitors and controls hazards in raw materials, water and manufacturing processes. MFDS guaranteed operational autonomy for the business with excellent sanitary management grades and provided guidance, inspection, training and technical support to those with unsatisfactory sanitary level.

3) Strengthening Alcohol Manufacturer Support Projects

MFDS established regional alcohol safety management centers across the country, carried out practice-oriented technical training for small alcohol manufacturers and provided field consultations to improve the safety management capacities of the manufacturers.

Also, MFDS developed and operated field trips to excellent alcohol manufacturing companies and provided field-oriented training that can be applied in the field.

4) Increased Sharing and Promotion of Alcohol Safety Information

To establish safe alcohol manufacturing and consumption culture, MFDS set up and operated a alcohol safety information website (‘Sullejapki’) and provided alcohol safety information and alcohol consumption guidelines to promote safe drinking culture.

C. Implementation Plan

1) Implementation of the Master Plan for Alcoholic Beverage Safety Management

MFDS plans to continue to implement the “Master Plan for Alcoholic Beverage Safety Management” that meets the demands of the public and according to the changing environment of the alcohol industry.

2) Improving Alcohol Regulations and Promotion of Communication

To strengthen communication and the cooperative network between relevant organizations and also to promote alcohol industry and the preservation of traditional Korean alcoholic beverages, MFDS plans to prepare and implement a reasonable plan for making improvements and revise relevant laws and regulations taking into account of the uniqueness of alcoholic beverages and the industry.

3) Strengthening of the Safety Management of Alcohol Manufacture and Distribution Processes

MFDS plans to continue to implement the ‘Sanitary Management Grading System’ which allows intense supervision of the businesses and establishments with poor sanitary level and

'self-monitoring' for those that have excellent sanitary level and ultimately improve the overall sanitary conditions of alcohol businesses.

Also, MFDS will strengthen the foreign object control of the alcohol manufacturers and require the alcohol distributors to implement the self monitoring system for storage and distribution standards.

4) Responding to New Changes in Alcohol-Related Environment

To figure out the changes in alcohol consumption patterns, MFDS will carry out alcohol consumption surveys. Also, in regards to the newly created small-scale alcohol manufacturing permit, MFDS will strengthen its support for small alcohol manufacturers by implementing the 'Good Hygiene Practice'. To prevent alcohol-related accidents, MFDS will continue to manage the safety blind spots in alcohol manufacturing stages and to improve the safety management level of small alcohol companies, MFDS will establish 4 new alcohol safety management centers for each district. Moreover, it will offer customized, selective support for alcohol companies, taking into account of the uniqueness of each business type and also include consumption and distribution stages in the scope of safety management.

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Section 2 Internationalization of Scientific Food Standards and Specifications

1. Improving Food Safety Standards and Specifications

A. Background

With the increase in food trades between nations, there is a growing need to safely manage those residual substances, hazardous pollutants, food poisoning bacteria that are not yet specified under any standards in Korea. Since the amount of toxic substance intake can vary depending on the changes in climate and in food consumption pattern, it is necessary to establish, monitor and re-evaluate a system for managing people's total amount of exposure to toxin substances through surveys of food contamination level and food intake. In order to strengthen the safety management of pesticides and residual substances, the Positive List System (PLS) which applies a set standard (0.01ppm) to pesticides that don't have maximum residue limits established, will be applied to tropical fruits starting from December 2016 and applied to other agricultural products by December, 2018. There is also a growing demand for statistically conceptualized microorganism standard that can give reliability and representability to microbiological tests.

B. Achievements

1) Management of Food Standards and Specifications

A) Residual Pesticides

In 2015, maximum residual limits were set for 173 items of 73 types of newly registered pesticides including Ipfencarbazone and maximum pesticide residual limits including the Cyantraniliprole residual limits were set for 83 items of 23 agricultural products including almond. Also, according to the 「Basic Plan for Managing Standards and Specifications on Food and Etc.」 MFDS reevaluated the maximum residual limits set to 40 types of pesticides including Glyphosate out of 202 types of pesticides which have been applied with foreign standards in the past.

B) Hazardous Pollutants

For scientific and systematic reevaluation of the standards and specifications on food, MFDS established the「1st (2015~2019) Basic Plan for Managing Standards and Specifications on Food and Etc.」. Also, to control human exposures to hazardous pollutants, MFDS carried out pollution tests on food products through 6 regional offices of food and drug safety and 16 cities and provinces and carried out assessment of human exposure level to 6 heavy metal types that need to be re-evaluated in 2015, according to the「2015 Implementation Plan for Managing Standards and Specifications on Food and Etc.」.

C) Microorganisms

By 2015, MFDS completed introducing statistically conceptual microorganism standards to 167 out of 218 Hygiene Index Bacteria standards and 58 out of 83 food poisoning bacteria standards.

D) Others

MFDS allows the use of deep-sea-water-processed water (deep seawater, concentrated water, mineral-enriched desalted deep seawater, mineral-concentrated water) as water products. It allows the imports of toothfish heads and revised the relevant regulations, standards and specifications to reduce the industrial conflicts and issues. Also, through the 'Korea-China Experts Council on Food Standards', MFDS agreed on 'removing the application of the specifications on colon bacillus group' for the Korean kimchi products exported to China and registered Codex on Mancozeb used for cultivating ginseng in Korea to resolve issues in exporting Korean products.

2) Management of Livestock Product Standards and Specifications

A) Livestock Product Processing Standards and Component Specifications

MFDS established the standards on basic nutrients (protein, fat, carbohydrates) needed for growth and development in milk formulas, established calorie specifications and strengthened the safety management of milk formulas. It also increased (increased the number of testing specimens to 5) the application of the statistical sampling method to the specifications on Bacillus cereus in milk formulas, specifications on bacterial count in processed egg and milk products and specifications on bacterial count in ice cream products (mix, powder). Also, to invigorate the processed milk product market, MFDS set up the standard specifications on

Clostridium perfringens in natural and process cheese to alleviate the limitations on product development from excessive heat processing. MFDS also distinguished blood spots and meat spots that are naturally occurring and harmless to humans from eggs that contain blood and, allowed them to be used for manufacturing and processing materials. MFDS also limited glucose removal only to dried albumen (egg white powder) and allowed removal of the freezing and hardening procedures when making sherbet and soft ice cream.

B) Setting MRL on Animal Medicines

To manage the safety of animal medicines being distributed without having set MRL due to lack of scientific data, MFDS set an equal standard MRL (0.01 mg/kg) on 26 types of animal medicines including Yohimbine. Also, for the 5 types of animal medicines including Novobiocin which the names of the food products that use those medicines are uncertain, MFDS disambiguated the term 'meat' to 'muscle' and developed a multi-residue testing method for livestock and marine products to improve the reliability and strengthen the safety management of animal medicines.

C) Preparation of the 「Standards on Approving Temporary Standards and Specification of Livestock Products」

There was a legal basis for approving temporary standards and specifications for livestock products but no standards for it. MFDS established the standards approving temporary standards and specification of livestock Products, combined them with the 「Standards on Approving Temporary Standards and Specification of Food」 to specify approval procedures and subjects.

C. Implementation Plan

1) Management of Food Standards and Specifications

According to the 「1st (2015~2019) Basic Plan for Managing Standards and Specifications on Food and Etc.」 and 「2016 Implementation Plan」, MFDS continue to carry out pollution level surveys on 19 types of hazardous pollutants through 6 regional offices of food and drug safety and 16 cities and provinces. In 2016, MFDS will carry out assessment of human exposure level to 6 types of fungal toxins and revise the standards and specifications thereof.

In order to strengthen the safety management of residual pesticides, the Positive List System

(PLS) will be first applied to tropical fruits starting from December 2016 and applied to other agricultural products by December, 2018. To do this, MFDS will quickly establish pesticide MRL for smallholder agricultural products and continue to set MSLs on unregistered pesticides in imported food products.

For scientific safety management of microorganisms, MFDS will continue to apply statistically conceptualized microorganism standards. Also, in regards to the food poisoning bacteria which cause food poisoning frequently in Korea or those that have international standards, MFDS will establish the standards and specifications for them.

2) Management of Livestock Product Standards and Specifications

In order to improve the safety of livestock products and invigorate export trades and product development, MFDS is planning to establish a basic plan for setting practical and scientific standards and specifications that are in harmony with international standards and specifications like the CODEX standards. Also, to resolve various issues and regulatory conflicts that occur due to the regulations that are realistically difficult follow on livestock product sites, MFDS will simplify the types of cheese and processed cheese which are categorized into milkfat and milk solids and allow the use of milk serum for making natural cheese. Moreover, MFDS will prepare standards on food poisoning bacteria to invigorate efficient production and development of various livestock products and continue to develop statistically conceptualized microorganism standards to enhance the reliability of microbial tests. Also, for the animal medicines that are being approved and distributed without MRL (maximum residual limit), MFDS will set MRLs utilizing the Threshold of Toxicological Concern (TTC) approach to effectively manage the safety of residual substances in food.

2. Improving and Reinforcing Standards and Specifications on Food Additives, Equipment, Containers and Packaging

A. Management of Food Additive Standards and Specifications

To strengthen the safety management of food additives, MFDS comprehensively examined various international standards and the current status of the use of food additives in the country and established food additive standards as well as the standards of food products that use

edible tar coloring. Also, to revise the food additive classification system, MFDS initiated the 2nd revision since the first revision in 2011. The 2nd revision includes the revision of standards and specifications for classifying 31 uses of food additives and the standardization of loanword orthography which include the revision of the names of 46 types of food additives and revision of the basic rules and standardized guidelines for using nutritional fortifiers. To make is easy for the people to check whether certain food additives are officially registered as food additives, MFDS set up a basic information including (name, synonym, INS number) and a table chart specifying the uses by food additive (Administrative pre-announcement, Nov. 27, 2015).

Also, to consolidate the process for approving the food additives derived from genetically-modified microorganisms, MFDS worked on developing a regulation that will allow for the safety test of genetically modified food and evaluation of food additive to be carried at the same time when requesting for approval of temporary standards and specifications for food additives. Also, in regards to enzyme supplements, MFDS aligned the scope of the toxicity data submitted with the applications requesting for approval of temporary standards and specifications, with the data range set under international standards (Administrative pre-announcement, Dec. 10, 2015)

On the 14th Food Safety Day, MFDS held an academic seminar and public a forum under the topic of 'Know Your Food Additives.' Also, to facilitate spreading of accurate information about food additives, MFDS held UCC developing and poster drawing contests and posted excellent works on YouTube. MFDS also corrected some inaccurate food additive information on elementary school textbooks and notified 5 publishers to publish revised textbooks. MFDS carried out educational 'Know Your Food Additives' program on 1,623 people including elementary, middle and high school students and inspectors from food safety inspection institutions and achieved 85% food additive education satisfaction rating and 69.3% conversion rate for positive awareness. MFDS also published the 'Handbook of the History of the Establishments and Revisions of Food Additive Standards and Specifications', 'Know Your Food Additives' booklets (flavorings, nutritional fortifiers) and the revised version of the 'Handbook of Food Additive Registration Status'. MFDS also set up a Q&A section on the website, specifying safe uses of disinfectants and equipments.

In 2016, to strengthen the safety management of food additives, MFDS will reevaluate the feasibility of current standards and specifications. MFDS will revise the standards and specifications that are unreasonable compared to international standards. Also, MFDS will develop the mobile Korea Food Additives Code application to make standards and specification easily accessible. It will carry out promotional activities, campaigns and educational programs

to improve the awareness of food additives and provide more accurate information. It will correct inaccurate food additive information on school textbooks, set up a micropage for providing food additive information, develop food additive story articles and infographics to provide the public with more relevant and accurate information.

B. Management of Standards and Specifications on Equipment, Containers and Packaging

MFDS gave administrative pre-announcement on partial standards and specifications revisions for efficient safety management of equipment, containers and packaging. It covered, 1) the inclusion of the standards on processing agents such as anti-static agents and release agents which are used in equipment, container and packaging manufacturing, in the manufacturing standards, 2) revision of the specifications on residual melamine which is raw material of melamine resin and 3) revision of the standards on solution leaching from the equipment used for special purposes. As a result, a new regulation clause that allows purpose-based use of the 4 leaching solvents used for equipment manufacturing. MFDS also set up a Q&A section on the website to provide life-related use of paper products and ceramics.

In 2016, MFDS will reevaluate the ingredients of printing inks and establish the safety management standards for the use of inks on equipment, containers and packaging. It will continue to improve various standards and specifications on equipment, containers and packaging by aligning and harmonizing them with international standards. Also, to monitor and manage raw materials of equipment, containers and packaging, MFDS will examine foreign standards and regulations, the current practices in domestic industries and prepare guidelines on raw materials allowed in equipment, containers and packaging. MFDS will review and provide useful, life-relevant information to the public and establish a Q&A section for proper use of synthetic resin containers and packaging.

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Section 3

Expansion of Healthy Dietary Environment

1. Strengthening Food Safety Management

A. Expansion of the Management of Meal Service Sanitation and Nutrition

1) Efficient Operation of the Centers for Children's Food Service Management

A) Background

For children who are the future of a nation, something safe to eat is essential for their health. During infancy and childhood, cognitive abilities develop dramatically with brain and physical development and during these early years of life, children develop their senses and understanding of food and dietary habits. Therefore, taking nutritious and well-balanced foods and forming healthy eating habits are very essential for growing children.

The increasing participation of women in the economic, social, cultural, civil and political affairs of society, the government's review of its policy of providing free child care for children and the increasing demands of the parents for professional child care services have led to dramatic increase in the number of children cared in kindergartens and child care facilities from 0.8 million children in 2002 to 1.41 million children in 2014. However, parents are not satisfied with safety of children's meal services. Certainly, most of children's meal services are doing their best to provide children the safest and healthiest food possible but the ones that are small in size face difficulties employing experienced professional dietitians and this in turn increases the risks of food safety issues.

For the safety management of children meal service facilities, since 2011, MFDS established the centers for children's food service management with local governments and carried out sanitary and nutritional management of children meal service facilities with the experts and dietitians at the center.

B) Achievements

(1) Strengthening of the Operation of the Centers for Children's Food Service Management

22 centers for children's food service management were established in 2012, 88 centers

in 2013, 142 centers in 2014 and 190 centers in 2015 (as of December 31). By the end of 2015, MFDS supported food safety management for a total of 19,105 children's meal service facilities and 710,000 children.

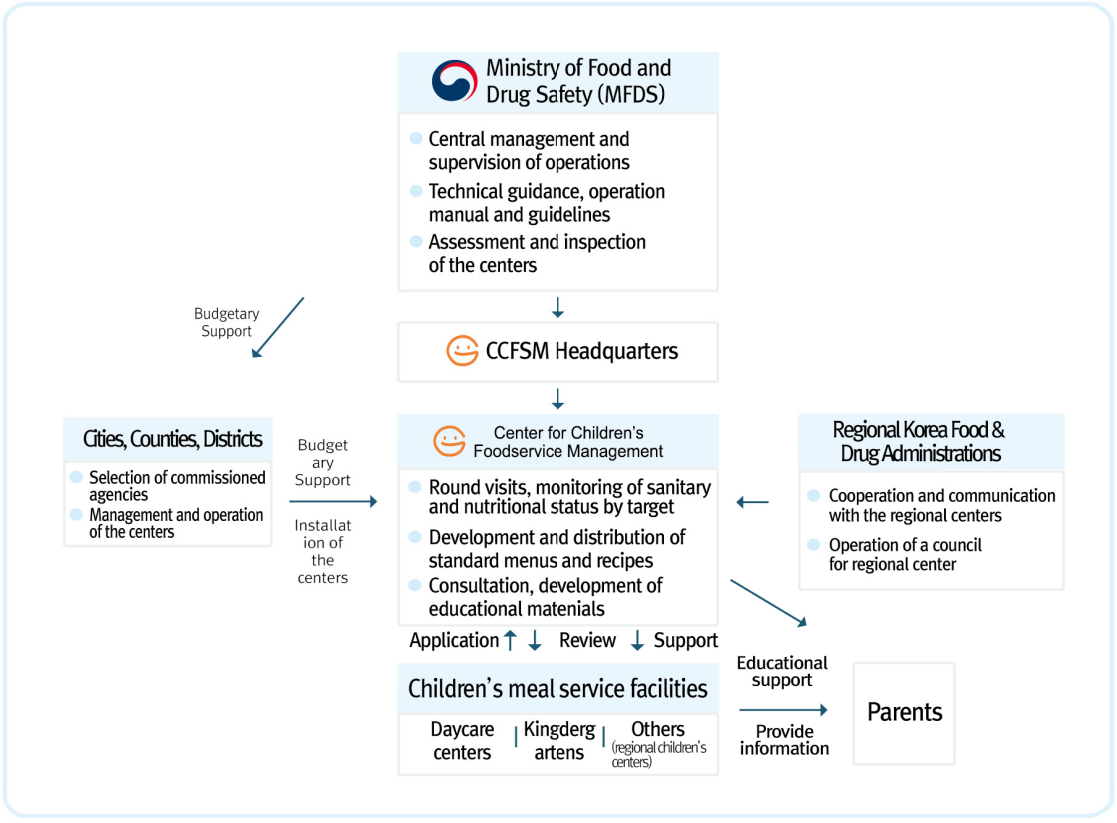
The main roles of the centers for children's food service management include, regular round visits to daycare centers and kindergartens to guide sanitation safety and nutritional management, development of menus for children's meals, development of sanitation education materials, development of sanitation and nutrition management guidelines, development of nutrition education materials and programs, and figuring out present status of meal services and establishing plans and directions for support.

The surveys on directors and teachers at daycare centers and kindergartens that are supported by the Centers showed high satisfaction scores of 86.8 points in 2013, 89.6 points in 2014 and 91.0 points in 2015. The Centers' efforts received a lot of support and positive response from the parents since the sanitary practices of the cooks have shown great improvements and more children learned to wash their hands before meals and eat balanced meals. A survey on the cost-effectiveness of the Centers' efforts showed a at around 11.1~15.7 which amounts to a maximum 1.356 trillion won.

Moreover, to promote the important roles that these centers for children's food service management carry out for the safety, sanitation and nutritions of our children's meals, MFDS made booklets, posters, leaflets, activity booklets for the directors and teachers at daycare centers and kindergartens.

(2) Establishment and Operation of the Headquarters for Children's Food Service Management Centers

To effectively support and manage the centers for children's food service management that are being established across the country, MFDS needed an exclusive organization that can supervise the centers. Also, there has been an issue of inefficiency and inconsistency in the regional centers' works related to providing educational materials about sanitation and nutrition, meal menus, recipes and sanitary food information. To solve this issue and to improve the works of the regional centers, the 「Special Act on Safety Control of Children's Dietary Life」 was revised (Jan. 28, 2014, effective on Jan. 29 2015) and the Headquarters for Children's Food Service Management Center was established. With these changes, the regional centers were able to focus on field-oriented works and the Headquarters management center supported and supervised efficient, standardized services of the regional centers.



[Image 1-3-1] Operation of the Centers for Children's Food Service Management

By efficient managing and dividing responsibilities between the Centers for Children's Food Service Management (CCFSM) and the CCFSM Headquarters, instead of managing sanitary conditions in the short-term, we can now manage, monitor and establish safe dietary life and nutrition for the children in the long-term. MFDS expects that children's dietary safety and nutritional quality will improve with various beneficial activities of the centers,

C) Implementation Plan

With the Centers for Children's Food Service Management established to support children and the child care centers that accommodate less than 100 children and the CCFSM Headquarters established to supervise all the regional centers' operations, MFDS will strengthen the system for supporting the regional centers and meal service facilities across the country, improve the quality of meal services and establish an efficient food safety management system that can assure parents of children's food safety.

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B. Strengthening Safety Management of Children's Food

1) Strengthening Safety Management of Children's Food

A) Background

The obesity rate in children and adolescents (elementary, middle and high school students) is increasing every year and since childhood obesity and adolescent obesity can easily lead to adult obesity, it is crucial to supervise and manage children's diet from their early ages.

Due to medical advancement and abundance of food, the life expectancy has increased rapidly over the years. But living healthy is as important as living long and this value has changed the paradigm of food safety from providing safe food to providing safe and nutritionally excellent food.

B) Achievements

(1) Designation and Management of the Children's Green Food Zones

In order to improve the food environment located near schools and which are often beyond parents' guide and control and to enable children to have a safe and well-balanced dietary life, MFDS designated the areas within a 200-meter radius of schools as 'Green Food Zones' and regularly carries out inspections and guidance activities. Also, MFDS dispatched the 'Children's Food Safety Agents' to monitor and promote preparation, display and selling of safe and sanitary children's food within these zones.

As of December, 2015, there were 8.578 green food zones and 2,698 'exemplary children's food stores' across the country.

(2) Improvement of the Distribution Environment for Children's Food

Since 2008, the changes in diet and increased consumption of high-calorie, high-fat and high-sodium foods such as chips, crackers, beverages, pastries and ramen noodles rather than fruit or milk have contributed to increasing obesity rates in children. The consumption of processed food including carbonated drinks have increased by 1.8 times since 1998.

In order to encourage children to select healthy and safe foods, MFDS designated children's foods that have higher calories and lowerer nutrition than as specified in certain standards and those that are likely to cause obesity or imbalance of nutrition, as 'high-calorie and low-nutrition foods', and prohibited the sale of such foods in schools or in stores with 'exemplary rating'.

In July, 2013, the 「Special Act on Safety management of Children's Dietary Life」 was revised and along with the high-calorie, high-fat and high-sodium foods, the advertisement of and the sale of high-caffeine foods in schools and stores with exemplary rating were banned.

Moreover, for sellers convenience and to guarantee consumers' right to know, MFDS regularly update and post a list of high-calorie and low-nutrition foods on the website.

MFDS also has launched and has been operating the 'Children's Food Quality Certification System' that promotes manufacture, process, distribution and sale of nutritionally balanced and safe children's food.

(3) Restriction on and Prohibition of Advertisement of Children's Food

Globally, the regulations on advertisements are being reinforced in efforts to reduce and prevent obesity in children and to promote healthy diet. For instance, recently, the city of San Francisco passed a new legislation requiring health warning labels on sugary beverages and prohibiting advertisements of them (June, 2015).

In Korea, under the 「Special Act on Safety Control of Children's Dietary Life」, the advertisement for high-calorie, low-nutrition and high-caffeine foods and the ads that incite children's food purchase are prohibited. Also, prohibits and limits these TV ads during 5:00 ~ 7:00 in the afternoon and during children's television programs.

(4) Education and Promotion for Safety Control of Children's Dietary Life

In order for the children to choose healthy food, not only there needs to be safe dietary environment but also, the children need an ability to choose the food that are right and healthy for their health.

The Article 13 (Education and Promotion of Children's Food Safety and Nutrition) of the 「Special Act on Safety Control of Children's Dietary Life」 specifies that food safety and nutrition education and promotion should be carried out in a way that helps the children develop the ability to select healthy foods by themselves and put healthy and suitable dietary life into practice. It also specifies that principals of elementary schools should regularly provide food safety and nutrition education required for children's dietary life control.

By using the level-by-level 'Nutrition and Dietary Life' textbooks (for elementary school students), MFDS has been carrying out food safety and nutrition education since 2011. To provide these education in middle and high schools, MFDS developed textbooks for middle and high school students in 2013 and introduced them in 2014.

Also, MFDS held the 'Outstanding Education Contest' since 2012 for school dieticians teaching food safety and nutrition courses and held the 'Children Dietary Life Safety Poster Contest'

to increase children's awareness of proper and healthy dietary habits.

MFDS continuously carries out national campaigns on healthy dietary habits to create a safe food environment for children and to improve children's ability to select healthy food.

C) Implementation Plan

(1) Designation and Reinforcing Control of the Green Food Zones

To enhance the perceived food safety near schools, MFDS is planning to work with local governments and relevant ministries on carrying out guidance activities and inspections continuously for stores that prepare and sell foods in the Green Food Zones. MFDS is also planning on reinforcing control of cheap foods that children enjoy, imported children's foods and their manufacturers and carry out policies in various ways for the safety management of children's foods.

(2) Improving the Distribution Environment of Children's Favorite Food

To establish a safe distribution environment for children's food, MFDS will make HACCP mandatory on 8 food items including chips, candy, beverages, pastries, chocolate and cup noodles until 2020. Also, MFDS is planning to ban coffee vending machines in schools to prevent children's consumption of high-caffeine foods and introduce a mandatory labeling system for high-calorie and low-nutrition foods to help children make proper food choices.

Moreover, to improve the food environment near schools, MFDS will designate parent and children 'Officers of Children's Food Safety' and carry out the 'Zero Concern.'

(3) Restriction on and Prohibition of Advertisement for Children's Food

Child obesity is a serious issue in our society and MFDS limits and prohibits advertisement of high-calorie, low-nutrition and high-caffeine foods and also requires those TV ads for children's food to indicate health warnings. Also, to establish and manage a safe food environment for children, MFDS monitors sale of high-calorie, low-nutrition and high-caffeine foods within the Green Food Zones and in 'exemplary children's food stores' across the country.

(4) Education and Promotion for Safety Management of Children's Dietary Life

To enhance children's ability to choose the right, healthier food for themselves and to hel them learn healthy dietary habits, MFDS is planning to increase the children's participation in food safety and nutrition education from 141,000 children (5.2) in 2015 to 170,000 children in 2016.

Through agreements with various children-related organizations, in 2016, MFDS will integrate its work with the programs offered by these organizations to provide children education on proper dietary practices.

MFDS will also introduce this food safety and nutrition education in middle and high schools to improve the dietary habits of adolescents.

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2. Reduction of Food Poisoning through Development of a Safe Eat-out and Meal Service Environment

A. Strengthening a Food-Poisoning Prevention System and Intensive Management of the Facilities at High Risk of Food Poisoning

1) Background

Due to changes in diet, 32.4% of people eat out at least one meal a day (National Health and Nutrition Survey, 2014), 25.7% uses meal service facilities (Korea Institute for Health and Social Affairs, 2012) and 72% of food poisoning incidences were due to eating out or meal service facilities.

Also, since climate change has become another great factor that contributes to higher risk of food poisoning and food safety issues, it is very important to take preemptive and preventive management actions to reduce food safety issues.

2) Achievements

In 2015, the number of food poisoning incidents and people who suffered from food poisoning dropped by 5% and 20%, respectively, to 330 food poisoning incidents and 5,981 people. The number of people who got food poisoning at school dropped 52% and the people who suffered from Clostridium perfringens and salmonella bacteria which were two biggest causes of food poisoning in 2014, dropped significantly in 2015.

This improvement can be the result of the strengthening of the 「Establishment of Council on Food Poisoning Countermeasures」 operations, cooperative works between the relevant

organizations, joint monitoring of schools with the Ministry of Education and local governments, special education on food poisoning prevention carried out for school principals and dieticians during school breaks and customized and preventive safety activities.

3) Implementation Plan

A) Strengthening of Monitoring and Guidance on Schools and Areas with High Likelihood of Food Poisoning Incidence

To achieve this year's goals, MFDS will strengthen the operation of the 「Establishment of Council on Food Poisoning Countermeasures」, carry out food poisoning simulation training in regional governments and carry out periodical inspections and guidance activities targeting schools, businesses, social welfare facilities, collective catering and meal facilities and food stores all year round.

B) Season-by-Season and Target-by-Target Guidance and Warning on Food Poisoning and the Nature of Their Occurrence

MFDS will develop and distribute season-by-season, targe-by-target educational materials utilizing the media (radio, TV) all year round, select key issues for each season and carry out more interactive and participatory warnings and campaigns such as the UCC Contest for Promoting Hand Washing, board games, 'germ stamp collecting' instead of simply showing video campaigns.

C) Strengthening a Scientific Basis for Solving the Causes of Food Poisoning

MFDS will continue to monitor the occurrence and risks of food poisoning and pollution during the food production, distribution and import stages, analyze the genotype of food poisoning bacteria isolated, share the bacterial information with the Korea Centers for Disease Control and Prevention and the Ministry of Agriculture, Food and Rural Affairs and, develop a DB for 2,100 food poisoning cases by 2016.

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3. Improving the Regulation of Health Functional Foods and Invigoration of the Market

A. Background

1) Introduction of the Health Functional Food System

Due to societal aging and the increase in chronic degenerative diseases and lifestyle diseases from dietary, people's interest in self-health care and the number of health functional foods have increased dramatically in recent years. To reduce national medical costs and to improve national health, the 「Health Functional Foods Act」 was enacted in Aug. 2002 and came into effect on Jan. 31, 2004.

2) Status of Health Functional Food Manufacturing

Starting from 250.6 billion won in 2004 when the health functional food system was enforced, the manufacture increased to 1 trillion and 368.2 billion won in 2011, a 5.5 times increase from 2004; 1 trillion and 409.1 billion won in 2012, 1 trillion and 482 billion won in 2013, and 1 trillion and 631 billion won in 2014, showing continuous growth every year.

B. Achievements

1) Advancement of the Management of Standards and Specifications of Health Functional Food

A) Health Functional Food Certification System

Functional raw materials or ingredients (hereinafter "functional raw materials") are classified into 1) the functional raw materials which the Minister of Food and Drug Safety specifies and announces along with the standards and specifications for the raw materials and ingredients according to the Article 14 (1) and Article 15 (1) of the 「Health Functional Foods Act」 and, 2) the functional raw materials which that are not specified in the Article 14 (2) and Article 15 (2)of the same Act. but are recognized individually after review of the documents submitted by the business operators on standards, specifications, safety and functionality of the raw materials or ingredients.

B) Enactment and Revision of Standards and Specifications for Health Functional Foods

In 2014, a basis for production of various kinds of health functional foods was set up by adding the functionalities of green tea extract, phosphatidylserine, Chitosan/chitooligosaccharide, creating standards and specifications for hyaluronic acid, Rhodiola extract, bilberry extract and garlic, and changing the oil fat contents of omega-3 fatty acid to EPA and DHA contents.

C) Certification of the Functional Raw Materials of Health Functional Foods

In 2015, the total number of the individually certified raw materials increased 5.9% from the previous year (529 cases → 560 cases), and 11 cases out of 31 cases of certified functional raw materials were domestically developed raw materials, putting domestic development ratio at 26%.

☆ Domestic development ratio: 23% (2008) → 26% (2012) → 26% (2012) → 59% (2014) → 35% (2015)

2) Production and Distribution Control of Health Functional Foods

A) Businesses

As of the end of Dec. 2015, 487 health functional food manufacturers, 3,586 health functional food importers, 89,878 health functional food stores, 2,502 health functional food distributors were in business after obtaining business approval and license, and a total of 18,956 health functional foods were reported and this was 16.5% increase from 16,632 items in 2014.

B) Production

After implementing the 'Health Functional Food Act' in 2004, the manufacture market entered the 1 trillion won mark for the first time in 2010, with a record of a total of 1 trillion won and 67.1 billion won. It then increased to 1 trillion and 368.2 billion won in 2011, 1 trillion and 409.1 billion won in 2012, 1 trillion and 482 billion won in 2013, and 1 trillion and 631 billion won in 2014, showing 10.1% increased from 2013.

Among the manufactured health functional food items, the manufacture amount of red ginseng was 633 billion won, making up 38.8% of the total health functional foods and showed continuous increase every year. The manufacture amount of the individually certified functional raw material products was 317.6 billion won (19.5%), vitamin and mineral products was 141.5 billion won (8.7%) and probiotics products was 138.8 billion won (8.5%). The amount of exports in 2014 was 67 billion won, a 11.1% decrease from the previous year.

C) Establishment and Support of the Foundation for Manufacturing Excellent Health Functional Foods

To secure and improve the safety and quality of health functional foods and to manage the manufacturing and quality control of health functional foods in more structured and systematic way, the 'Excellent Health Functional Food Manufacturing Standard(Good Manufacturing Practices, GMP)' system was prepared and is currently being implemented. As of the end of 2015, a total of 216 businesses were subject to the GMP system and they amounted to 50.2% of a total of 414 professional manufacturers.

D) Establishment of a Sound Distribution Order

A lot of potential hazards including drugs and new types of harmful substances such as sexual performance enhancers and depressants are being distributed and, to maintain the safety of health functional foods and to prevent consumers from getting harmed or injured due to illegal, false and misleading ads, MFDS has been carrying out collections, inspections and monitoring of health functional foods in markets and thorough follow-up management.

E) Monitoring and Analysis of the Adverse Events Related to Health Functional Foods

In order to manage the adverse events related to health functional product intake systematically based on scientific grounds, MFDS has established a 'System for Reporting Adverse Events related to Health Functional Food.' Since then, the System has been used for receiving adverse event reports and collecting relevant information. In January 2013, MFDS consolidated the scattered management works for the adverse event reports, into the National Food Safety Information Service. On January 1 2014, it was made mandatory to indicate 1577-2488, the number to report possible adverse events from taking health functional food, on the package and container of health functional food.

F) Customized Education and Promotion for Establishing a Safety Culture

MFDS has been conducting educational and promotional activities to help consumers better understand and select healthy and proper health function foods, to prevent side effects by misuse or abuse of health functional foods, to improve people's awareness of health functional foods, to prevent consumers from getting harmed or injured from false and misleading ads and illegal sales and ultimately to establish a sound food distribution culture.

C. Implementation Plan

1) Certification of Functional Raw Materials

To facilitate development of various kinds of health functional foods and to invigorate the industry, MFDS will continuously try to increase the number of certified health functional food products and, develop and distribute guidebooks and manuals on individual certification of functional raw materials.

In addition, MFDS will expand the scope of functions by establishing a social consensus and scientific grounds for various functions. Moreover, since small and medium-sized businesses may lack sufficient resources to invest in product development, MFDS will continuously try to improve and revise the evaluation guidelines on the existing 32 functions and try to lower the barrier to market entry for small and medium-sized companies.

2) Production and Distribution Control of Health Functional Foods

The health functional food industry is regarded as the future's creative industry with an enormous market potential. Therefore, to protect consumers' right to choose health functional foods and to strengthen the safety management of health functional foods, MFDS will continue to put efforts into improving the necessary regulations and into invigorating the market.

3) Strengthening Technical Support for Improving the Competitiveness of the Health Functional Food Industry

In 2016, to provide useful and practical information to the functional raw material researchers and developers, MFDS will prepare and provide assessment guidelines on various functions including health benefits such as void urinary tract health and also offer customized, case-oriented education to assist businesses preparing to apply for approval and certification of functional raw materials.

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4. Strengthening of Safety Management of National Nutrition

A. Efforts to Reduce the Nutrients including Sodium which are linked with increased rates in chronic disease If consumed in excess of recommeded guidelines

1) Expansion of a National Movement to Reduce Sodium Intake

A) Background

The association between sodium intake and chronics diseases such as cardiovascular diseases and high blood pressure is already well-known and WHO strongly recommends a reduction in sodium intake for healthier life. In Korea, the average daily sodium intake of 4,878mg in 2010 was reduced by 20%, to 3,890mg in 2014 and various policies are being implemented but the average sodium intake is more than twice than the daily recommended amount. Since 2010, MFDS has been trying to reduce excessive sodium intake by carrying out sodium intake reduction projects and campaigns.

MFDS' goal for 2017 to reduce the intake to 3,900mg (20% decrease compared to 2010) has already been achieved and it set up a second reduction goal to reduce sodium intake to 3,500mg by 2020.

B) Achievements

(1) Improvement of Consumers' Awareness and Dietary Habits

To reduce sodium intake, individual consumer's awareness and dietary habits must first be improved. To achieve this, MFDS currently utilizes the media, transportation system, outdoor advertisement (billboards) in heavily populated areas, residential building elevators, major supermarkets and hospitals to promote information that are deeply relevant to people's lives and to gain a national consensus on the sodium reduction movement.

(2) Establishment of a 'Sodium-Reduced Food Consumption Environment'

Consumption of processed food products and dining out are continuously increasing due to changes in diet and advancement of processing technologies and MFDS is constantly working to reduce sodium in processed foods, catering services, diners and restaurants.

(3) Expansion of the National Sodium Intake Reduction Campaign

A person's dietary habits cannot be changed in a single day and since food businesses are

deeply catering to consumers' taste, it is very difficult to reduce sodium in food products we consume everyday. Nevertheless, MFDS carries out the national sodium reduction movement with consumer groups and experts from various fields.

C) Implementation Plan

In 2016, MFDS will continue to carry out the national sodium reduction movement and campaigns, work on changing consumers' dietary habits and awareness of healthy food and encourage the food businesses to reduce sodium in food product. MFDS will also introduce and implement a labeling system which will include a readily visible sodium content comparison chart.

2) Sugar Intake Reduction Project

A) Background

World Health Organization (WHO) provides information about the association between obesity and high blood pressure and excessive consumption of sugar and sodium, gives recommended consumption of these nutrients and recommends that the consumption of these nutrients should be reduce based on scientific grounds.

B) Achievements

According to the national health and nutrition survey from 2007~2013, in 2015, the average national sugar intake was 72.1g and 44.7g was consumed from processed food products. This showed dramatic increase in sugar intake compared to the average sugar intake and sugar intake from processed food products at 59.6g and 33.1g, respectively recorded in 2007. 3~29 year olds' sugar intake from processed food products accounted over 10% of the total energy intake. Also, the sugar intake of 46% of 6~11 year olds and 19~29 year olds exceeded the WHO's recommended sugar intake. To reduce this excessive sugar intake, MFDS will set up a systematic sugar reduction goal along with the sodium reduction plan.

C) Implementation Plan

To reduce the population sugar intake, the first plan is to promote low-sugar diet. MFDS will initiate a sugar-reduction movement, promote education on low-sugar diet for children and adolescents and provide customized support for sugar intake monitoring. Secondly, MFDS will establish an environment with access to low-sugar foods. MFDS will further strengthen

the nutrition labeling policy and provide more information about sugar content in foods. Also, MFDS will promote development of sugar-reduction technology that can be applied to foods which are major sources of sugar, promote those sugar-reduced food products and limit children and adolescents' access to sugar foods. Third, MFDS will establish a basis for sugar-reduction policy. It will strengthen the scientific and statistical foundation of the policy and cooperate with relevant government ministries and consumer groups.

3) Trans Fat Intake Reduction Project

A) Background

Korea's average trans fat intake in 2006 was 0.37g and this is fairly low compared to WHO's recommendation that trans fact intake should be less than 1% (less than 2.2g, for 2,000kcal dietary intake) of dietary energy intake. But recently, in the US, partially hydrogenated oils (PHOs), the major source of added trans fats in the diet, became no longer 'Generally Recognized as Safe (GRAS)' (June, 2015), and this led to a new awareness of trans fat in Korea.

B) Achievements

MFDS started planning on the trans fat reduction policy in 2003 and carried out a survey on snacks, fast foods, takeaways and restaurant foods in 2004. Then, in 2005, along with the food industry, MFDS implemented the trans fat reduction policy and in 2006, Korea became the first Asian country to prepare an information-based food management policy and made nutrition labeling mandatory for all the foods that required to label nutrition facts.

C) Implementation Plan

In 2015, in the US, the use of PHOs was prohibited unless any interested party seeking approval for one or more specific uses of PHOs provide data demonstrating a reasonable certainty of no harm of the proposed use(s). MFDS will monitor the trans fat nutrition labeled on the processed food products that are being distributed and examine the content of trans fat in pastries and bread in which PHOs have been used.

4) Expansion of Nutrition Labeling and Provision of Nutrition Information Service to People

A) Background

Recent increases in income and the number of two-working-parent families have led to

changes in diet, increase in eating out, westernized diet and ultimately to excessive nutrition, nutritional imbalance, obesity and cardiovascular diseases.

To create an environment that allows the people to choose healthy foods and to guarantee consumers' right to know, MFDS requires nutrition labeling not only on processed foods but on takeaways and restaurant foods as well. MFDS also developed a nutrition analysis system which serves as a basis for nutrition labeling on restaurant foods, and provides reliable nutrition information through a website and mobile application.

B) Achievements

(1) Establishment of a Healthy Dietary Environment through Nutrition Labeling

① Nutrition Labeling on Processed Foods

In 2006, contents of sugar, saturated fat, trans fat and cholesterol were included in the mandatory nutrition label and a regulation on the amount per serving was established to allow consumers to get information about the calorie and nutrient intake. As a result, the nutrient label that includes amount of calorie, carbohydrates, sugar, protein, fat, saturated fat, cholesterol and sodium was applied for each product.

② Nutrition Labeling of Children's Favorite Foods

In January, 2008, starting with the fast food restaurant chains (Lotteria, McDonald's, Popeyes, KFC, Burger King), MFDS implemented voluntary nutrition labeling on pizza restaurants, coffee shops and bakery chains. Then, starting in January, 2010, with the implementation of the 「Special Act on Safety Control of Children's Dietary Life」, all parties (comprised of more than 100 stores) that cook or sell hamburgers, pizza, bakery products and ice cream were required to label the nutrient facts that includes amount of calorie, carbohydrates, sugar, protein, fat, saturated fat, cholesterol and sodium.

③ Voluntary Nutrition Labeling of Restaurants

After the implementation of the mandatory nutrition labeling on children's favorite foods, MFDS needed to implement a voluntary nutrition labeling policy due to the increasing demand for further application of the nutrition labeling policy. With continuous efforts to expand voluntary nutrition labeling, as of July, 2015, there were 7,166 restaurants participating in nutrition labeling.

(2) Nutrition Services for People

① National Food Nutrient Management Network

Since 2009, through establishment of the 'National Management Network for Nutritional Content in Food', selection and gathering of samples and by operating a quality analyzing system, MFDS has been providing nutritional information through a national database to allow people to select healthy foods for themselves.

② Development and Distribution of a Mobile Nutrition Management Program

MFDS first developed and distributed the 'Calorie Coordination' program(application), a personal nutritional intake assessment and management after calculating individual's physical activity and etc. The program provided the number of nutritional information gradually to offer user's convenience.

③ Nutrition Service for Dietary Life Management by Life-Cycle

In 2011, MFDS developed "A Nutrition and Dietary Life Guide for Healthy Mom-to-Be" as a part of an effort to supply useful information for managing dietary nutrition. In 2012, MFDS published and distributed 'A Guide to Prevent Obesity and Eating Disorder' for children and youth and 'Eat Smart Get Healthy' to improve children's eating habits and to promote healthy physical activities, 'A Practice Guide of Nutritious Dietary Life for Healthy Life of Youth and Adults', 'A Health Recipe for Pregnant Women', 'A Nutritious Dietary Life Guide to Healthy Breast-Feeding', 'A Nutritious Dietary Life Guide for Pregnant and Lactating Women', and 'A Nutritious Dietary Life Guide for Women of Childbearing Age' as well.

C) Implementation Plan

To help people's dietary life actually benefit from the nutrition labeling system, MFDS will expand education and campaigns on nutrition labeling for various types of consumers.

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III

Medicinal Products

Section 1

Medicine

1. Introduction and Stabilization of GMP that is in Harmony with International Standards

A. Background

1) Introduction and Improvement of the Internationally Harmonized Pharmaceutical Good Manufacturing Practice Regulations

In 1969, at the 22nd World Health Assembly, WHO released requirements for Good Practices in the Manufacture and Quality Control of Drugs (Good Manufacturing Practices, GMP) and recommended that member states adopt the regulation and, on June 28, 1977, Korea started implementing the GMP. After the enactment of Article 22 [Appendix 4] 「GMP」 of 「Enforcement Rule of the Pharmaceutical Affairs Act」 in July 1994, MFDS has continuously improved the system in order to strengthen its competitiveness among leading pharmaceutical companies in the global market by securing overall quality of APIs and finished products, introducing a system for inspecting manufacture and quality control of medicinal products by dosage form, requiring GMPs for APIs and finished products, transitioning from evaluation by dosage form to evaluation by item and introducing the 'validation' system.

2) Joining the Pharmaceutical Inspection Co-operation Scheme (PIC/S) and International Harmonization of GMPs

The Pharmaceutical Inspection Co-operation Scheme (PIC/S) was formed to improve pharmaceutical quality control system and to internationally standardize GMPs by minimizing confusions and conflicts that may arise during exports and imports due to differences in GMP regulations between nations. The Pharmaceutical Inspection Convention (PIC) which was founded in October 1970 by the 18 nations of the European Free Trade Association (EFTA) later in 1995 expanded to the Pharmaceutical Inspection Co-operation Scheme.

After the 2007 Presidential Advisory Medical Industry Advancement Committee decided on joining PIC/S and signing Mutual Recognition Agreement with advanced countries, MFDS

prepared to apply for PIC/S by creating a consultative body consisting of experts from home and abroad in 2011 and submitted the application in April, 2012. worked continuously on internationally standardizing Korean GMPs.

B. Achievements

1) Joining and Acting as a Member of the PIC/S

The application process for joining the Pharmaceutical Inspection Cooperation Scheme (PIC/S) takes generally about 4 - 5 years. After an on-site audit conducted by the audit team of PIC/S experts, in Jan. 2014, Korea's Ministry of Food and Drug Safety (MFDS) was finally approved (effective on July 1) at the PIC/S committee meeting held at Rome, Italy. It only took 2 years, the shortest period in the history, for Korea to join the PIC/S and it was a meaningful result that is comparable to Korea's joining of OECD since it significantly improved the global trust in Korea as well as in Korea pharmaceutical industry. It was more meaningful since it was the first experience for Korea to join an international pharmaceutical instrument through strict evaluation processes. In addition, MFDS joined PIC/S with its entire regulation as it is, without having to change the system by adopting the PIC/S GMP. This is another great achievement in that Korean GMP regulation has been internationally recognized.

As a member state of the PIC/S, Korea's MFDS is currently implementing various policies to support Korean pharmaceutical industry in entering into overseas markets. In January 2015, MFDS held a PIC/S-organized, API workshop in Korea and around 140 people including policy authorities and industry representatives around the world participated in the workshop. In April 2015, MFDS invited policy authorities from ASEAN nations, held the KOREA-ASEAN Pharmaceutical GMP Cooperation Conference and promoted Korea's joining of the PIC/S and quality domestic pharmaceuticals to the world. MFDS has also requested the listing of Korea in EU's whitelist (exempt from having to provide written confirmation of compliance for APIs exported from the country). MFDS submitted the application in January 2015 and is currently awaiting EU's approval.

2) Stabilization of Internationally Harmonized GMPs for Korea

To harmonize Korean GMP with PIC/S GMP, MFDS made necessary changes to relevant regulations and standards.

In Aug. 21, 2014, the 「Regulation on the Safety of Pharmaceuticals, etc.」 was revised

and promulgated (July 1, 2015). Its main contents are ▲Introduction of the validation system on herbal medication and post-release stability tests on drug products, ▲Development of separate standards on pharmaceuticals for clinical trials and the APIs that were regulated by the GMPs of drug products, ▲Introduction of new GMPs for radioactive medicine and medical high-pressure gas. In addition, the 「Regulation on the Safety of Pharmaceuticals, etc.」 was revised on Oct. 10, 2014 to introduce the "GMP Compliance Certification System". With this system, a 3 year expiration date was set up to the evaluation result of GMP for manufacturers so that evaluation can be carried out regularly. So, by changing the system for pharmaceutical quality control from 'quality control at pharmaceutical approval stages' to 'quality control after sales', a foundation for supplying quality-assured medicine was established.

Also, the 「Regulation on Good Manufacturing Practices (GMP)」 which reflects the 16 annexes of the GMP regulations established by the Pharmaceutical Inspection Cooperation Scheme (PIC/S) was enacted in June, 2015, and implemented in July. MFDS also held seminars to stably establish the new GMPs for medical, high-pressure has and radioactive pharmaceuticals and also established the field administrative support system in January 2015 at MFDS and 6 of the regional offices of food and drug safety to provide guidance to and gather feedbacks from the manufacturers implementing GMPs.

C. Implementation Plan

For continuous international harmonization of GMP regulations, MFDS plans to establish a public-private consultative body with the pharmaceutical industry, periodically review PIC/S' GMP Guide revisions, apply them to Korean GMP regulations and if possible, share PIC/S' GMP revisions with the pharmaceutical industry. In 2016, MFDS will apply PIC/S' GMP Guide Part 1 (Guide to GMP for Medicinal Products) and GMP Annex 15 which describes the principles of qualification and validation used for the manufacture of medicinal products into Korean GMP guidelines.

Based on the improved country rating of Korea after joining the PIC/S, MFDS will hold the 2nd Korea-ASEAN. Pharmaceutical GMP Cooperation Conference to promote Korean pharmaceutical companies' overseas business. Many advanced PIC/S member states such as the US and European countries have recently become more serious on strengthening the management of the manufacturing facilities for beta-lactam antibiotics which often cause hypersensitivity reactions. To reduce the risk of cross-hypersensitivity and to create a safe pharmaceutical environment, MFDS plans to make it mandatory to separate the processing

facilities for carbapenem antibiotics and monobactam antibiotics as the international guidances for beta-lactam antibiotics facility suggest. Also, for those companies having difficulties in introducing GMPs for radioactive drugs and medical, high-pressure gas, MFDS will provide administrative field support through the GMP Administrative Support System. MFDS will also share useful information about GMPs and provide guidance by holding seminars in 6 regional offices of drug and food safety.

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2. Internationalization of Medicine Approval and Evaluation System

A. Establishment of a Globally Competent Medicine Approval and Evaluation System

1) Operation of Good Review Practice (GRP)

MFDS has been operating the 'Good Review Practice(GRP)' since 2004 to secure consistency, transparency and reliability in medicine evaluation, and continuously revised it so that it can be effectively used for evaluation or when the applicant applies for the approval of medicine. Also. in 2015, MFDS revised the Manual of Policies and Procedures (MaPP) to include 7 item approval and management work sub-manuals including the sub-manual for 'approval of pharmaceuticals for manufacture, sale and import and of change in approval status'. MaPP includes work procedures and guidelines for official documentary format. According to the type of users and the contents, the 24 sub-manuals of the MaPP were categorized into approval standards (24 types), approval works (8 types), other works (7 types), information release (1 type) and training/education (1 type) for efficient use and for the convenience of the users.

2) Disclosure of Medicine Approval Process Results

In order to ensure people's right to know and to support pharmaceutical companies' research and development, MFDS has been disclosing medicine approval results since 2004. Also to make Korea's current level of information disclosure which is limited compared to those of advanced countries, MFDS is continuously increasing the level and extent of information

disclosure. In March, 2015, MFDS changed the scope of pharmaceuticals requiring an approval document from 'new drugs' to 'pharmaceuticals accompanying supporting documents' and, released the status of incrementally modified drug designation under the 'approval document' section.

3) Development of Pharmaceutical Evaluation and Approval Standards through International Harmonization

To clarify the evaluation standards for pharmaceuticals and to enhance the predictability of the approval process, MFDS has prepared and has been providing a guideline on pharmaceutical evaluation. Also, to reinforce global competitiveness of Korean pharmaceutical industry, MFDS has been applying the enactments and revisions of International Conference on Harmonization (ICH) guidelines to the pharamaceutical regulations and guidelines in Korea.

In 2015, MFDS established the 'Guidelines on Evaluating Genetox Impurities in Pharmaceuticals' and 'Statistical Principles for Clinical Trials' based on ICH's guidelines.

4) Efforts to Internationally Harmonize the Pharmaceutical Evaluation System

Korea has steadily participated in the ICH Assembly since 2006, and since June 2011, Korea has been directly participating in the guideline development process of ICH. In addition, Korea also has been participating in the International Pharmaceutical Regulators Forum, (IPRF), shared key policy improvements in Korea and announced the activities and future plans of the IPRF Biosimilars Working Group where MFDS is participating in as the chair. In the meeting in December 2015, MFDS shared the results from the 2015 International Generic Drug Regulatory Program (IGDRP) which MFDS had organized and held.

APEC Harmonization Center (AHC) is an official education organization of APEC, approved at the ministerial meeting and summit meeting of Asia-Pacific Economic Cooperation (APEC), and it was officially established under MFDS (National Institute of Food and Drug Safety Evaluation). It held a total of 27 workshops by 2015 since the establishment in June 2009. It held a total of 5 workshops in 2015 at home and abroad and it supported Korean companies' exports as well as capacity building programs for the regulatory authorities in APEC regions.

The International Generic Drug Regulatory Programme (IGDRP) is a council formed in 2011 by regulatory authorities of USA, Canada, Australia and various other nations to facilitate cooperation and harmonization of regulations on generic medicine. MFDS has been participating in meetings since the pilot meeting which was held in 2011 and participated

in a project that compared and analyzed the regulatory differences between regulation organizations for biowaivers and pharmaceutical ingredients (APIs) and recognizing the regulatory differences, MFDS has since been working continuously to establish regulatory harmonization. The 2nd IGDRP Assembly was held in Nov. 2015 in Seoul.

WHO's Pre-qualification (PQ) is a system that evaluates quality, safety and effectiveness of medicine supplied by WHO to underdeveloped countries. Medicine regulatory authorities from all over the world participate and jointly evaluate medicine being procured. MFDS sends Korean evaluators every year to participate in the joint evaluation team. In addition, to share information obtained through the joint evaluation process, with domestic companies who wish to get into the market of WHO-supplied medicine, MFDS arranged a forum (2014) to provide information on WHO's pre-qualification system, held PQ workshops and offered customized technical consultation (2015) to support advancement of Korean companies into WHO.

On April 2, 2012, MFDS signed an MOU with the United States Pharmacopoeia Convention (USPC). After the signing of the MOU, MFDS held a joint symposium for international harmonization, dispatched experts for research of advanced pharmaceutical regulatory management systems and carried out a project for developing standardized items for the Korean Pharmacopoeia and United States Pharmacopoeia. Developing standardized items for the Korean Pharmacopoeia and United States Pharmacopoeia will allow the Korean pharmaceutical products to be registered in the highly regarded United States Pharmacopoeia and to be recognized in the US market as well as the pharmerging markets and ultimately bring tremendous export incomes.

Choi Young-joo, Director of Drug Review Management Division
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B. Invigoration of Cooperation with Foreign Regulatory Authorities

1) Pharmaceutical Official Development Assistance (ODA) Invitational Training

A) Background

In November 2009, Korea became the 24th member state of the Development Assistance Committee (DAC) of OECD (Organization for Economic Cooperation and Development). Also Korea became an exemplary model for many beneficiaries by becoming the first nation to have transformed itself from an aid beneficiary to a donor nation.

B) Achievements

In May 2012, MFDS, the Ministry of Foreign Affairs and Korea International Cooperation Agency initiated the 「Drug Safety」 program to train public officials from developing countries in pharmaceutical management areas. The 1st Drug Safety Program was carried out in 2012 and the 2nd Program which was held for 20 days from Oct. 5 to Oct 24, 2015, 16 medicine regulators from 8 countries including Ghana, Nepal, Burundi, Mongolia, Sri Lanka, Ethiopia, Uganda and Egypt received training.

Based on its experience of 「Drug Safety」 training program in 2012 and 2013, MFDS expanded a multi-year (2013~2015) 「Drug Safety (Asia)」 training for public pharmaceutical regulatory officials. This training program was planned based on the demands for medicine safety management training in 4 countries, and it included advanced courses of intensive training on pharmaceutical monitoring, medicine manufacturing and quality control. The first-year training started with 18 regulatory public officials in November,2013, the second-year training with 17 public officials and 1 professor (Pharmacy of Hochimin in Vietnam) in April, 2014, and the third-year training with 16 public officials in August-September, 2015.

C) Implementation Plan

MFDS shall expand pharmaceutical safety and intensify global regulatory authorities and public-private cooperation through supporting strengthening capacities of pharmaceutical regulatory authorities of developing countries by carrying out Official Development Assistance (ODA) invitational training.

2) International Coalition of Medicines Regulatory Authorities (ICMRA)

A) Background

Since 2006, to develop international cooperation projects for improving global health, develop cooperation plans and exchange information, major pharmaceutical regulatory authorities and agencies around the world have held private the Summit of Heads of Medicines Regulatory Authorities[5] every year.

B) Achievements

The 10th International Summit of Heads of Medicines Regulatory Agencies held in Mexico

5) Most of these agencies are also in charge of regulating medical devices, and therefore medical devices are included in the agenda

City in November, 2015, had detailed exchange of opinions on safe supply chain for pharmaceuticals, innovation for pharmaceutical evaluation and approval processes, changing global paradigm of clinical trials and cooperation plans for capacity building. The participants assented to necessity for integration and sharing of production and distribution information of medical products, and expressed necessity for an international discussion on supply shortage issues.

MFDS is currently participating in three working groups; 'Mapping' Working group, GMP Inspection Working Group, and Generic Medicines Working Group.

C) Implementation Plan

By actively participating in the pilot projects of the International Coalition of Medicines Regulatory Authorities (ICMRA), MFDS will exchange information and works with other regulatory authorities, expand the domestic safety management network for pharmaceuticals, improve the global trust in Korea's safety management network for pharmaceuticals, and promote Korean pharmaceuticals to foreign markets.

3) Expanding Cooperation with Foreign Regulatory Authorities

A) Background

As the research and development capacities of Korean pharmaceutical companies are improving, globally competent pharmaceutical products developed in Korea are progressively entering the foreign markets.

B) Achievements

MFDS signed a Memorandum of Understanding (MOU) with China (2009), Singapore (2010), Indonesia (2012), Poland (2013), Ecuador (2014) and Brazil (2014) for capacity building education and training, exchange of information including safety information and on further cooperation.

To expand the scope of information exchange and to carry out tasks including exchange of experts, evaluation and approval, MFDS also signed Confidentiality Agreement (CA), which is available to exchange confidential information, with Uganda (2013), Germany (2013), Denmark (2013), UK (2013), Swiss (2014), France (2014) and Italy (2014).

C) Implementation Plan

MFDS will expand of MOUs and contract of Confidentiality Agreement (CA), and push ahead approval and review of drugs, exchange information of GMPs, and exchange personnel resources.

Kim Sang-bong, Director of Pharmaceutical Policy Division
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C. Modernization of Pre- and Post-Management of Clinical Trials

1) Continued Efforts to Internationally Harmonize the Clinical Trial Approval System

A) Background

Korea's clinical trials market has rapidly grown in the last 10 years and the clinical trial capacities of Korea have been highly recognized by the global market, Korea's domestic market ranking 9th globally in 2015. With the growing competitions between emerging countries like China and India for dominance in clinical trial market, international regulatory harmonization and cooperation will be needed more than ever.

B) Achievements

By revising the 「Regulation on the Approval of Pharmaceutical Clinical Trial Plan」 in 2013, MFDS allowed submissions of quality, non-clinical and clinical data in the Common Technical Document (CTD) format and eased the requirements on non-clinical data submissions for early clinical trials with anti-cancer drugs. Also, to promote and attract Multinational Phase I Clinical Trials in Korea, MFDS revised the 「Regulation on the Approval of Pharmaceutical Clinical Trial Plan」 in 2014 and allowed submissions of English clinical trial plans.

Moreover, MFDS prepared an internationally harmonized 'Standards for Manufacturing and Quality Management of Drugs for Clinical Trials' reflecting the characteristic of various drugs used for clinical trials and the 「Regulation on the Safety of Pharmaceuticals, etc.」 including those standards was amended on August 1, 2014 and implemented on July 1, 2015.

C) Implementation Plan

In line with changes in domestic clinical environment, in 2016, MFDS plans to improve

the clinical trial approval system as follows.

First, the documents to be submitted when applying for approval of clinical trial plan will be specified in the 「Regulation on the Safety of Pharmaceuticals, etc.」 and the matters to be included in the clinical trial plan will be specified according to international standards to secure effectiveness of the clinical trial approval system.

Second, revisions will be made to the regulations of the Pharmaceutical Affairs Act, to require approval when changing the study purpose or when making changes that may affect the reliability of the study results and safety of the trial participants and allow other minor changes such as the change in testing institution to be exempt from the approval process and only be reported.

Third, revisions will be made to the regulations of the Pharmaceutical Affairs Act to make the matters to be included in the clinical trial plan and the scope of the documents to be submitted when applying for the approval of bioequivalence test plan as same as the clinical trial, and to require bioequivalence tests be carried out in accordance with the Standards on Management of Pharmaceutical Clinical Trials.

2) Continued Operation of the 'Differential Evaluation System' for Clinical Trial Agencies

A) Background

(1) Legal Basis

Clinical trials are research studies conducted to collect data regarding the safety and efficacy of new drug and to determine adverse drug reactions. To carry out clinical trials scientifically and safely, the Good Clinical Practice (GCP) harmonized with the 'International Conference on Harmonization - Good Clinical Practice, (ICH-GCP)' must be followed. In addition, it is regulated that clinical tests must be carried out only by the agencies designated by MFDS in accordance with the Article 34(2) of the Pharmaceutical Affairs Act, and a total of 174 agencies are designated as of Dec. 31, 2015.

(2) Introduction and Implementation of a "Differential Evaluation System" for Pharmaceutical Clinical Trial Agencies

MFDS carries out periodical inspection on clinical trial agencies. With the number of domestic clinical trials increasing and the capacities of clinical trial agencies improving, MFDS needed an efficient management system. In 2013, MFDS the 'Differential Management System' for clinical trial agencies and changed the inspection system from the existing simple, management

system to a post-management system that differentiates the cycle of inspection according to clinical trial agencies' ratings.

B) Achievements

MFDS carried out the 'differential' evaluation on a total of 43 institutions in 2013. 28 among them were given 'Excellent' rating and 19 'Average' rating. 36 institutions were evaluated in 2014 and 17 were given 'Excellent' and 19 'Average'. Also, in 2015, out of 24 institutions that were evaluated, 1 was given 'Excellent' rating, 19 'Average' and 4 institutions that needed to improve their operational system of clinical trials were given 'Insufficient' rating.

C) Implementation Plan

MFDS completed conducting the differential evaluation on all the clinical trial agencies by 2015 and so in 2016, it plans to manage clinical trial agencies more efficiently by differentiating the inspection cycle according to the ratings which the agencies have been given.

3) Strengthening Education and Training of Personnel Involved in Clinical Trials

A) Background

Generally, a clinical trial is participated by the client (pharmaceutical companies), investigator and an evaluation committee independently established for the evaluation of the clinical trial plan and for the protection of the trial participants. Thus, to safely and scientifically conduct a trial error, the personnel participating in the trial must carry out the trial with an ethical mind and sufficient knowledge about the relevant regulations.

B) Achievements

Since 2012, MFDS secured the necessary budget (commissioning expenses) and selected external training agencies. 6 training sessions on clinical trial were held for a total of 363 people in 2012, 9 sessions for a total of 635 people in 2013, 7 sessions for a total of 733 people in 2014.

Also, to improve the expertise and capacities of the personnel conducting clinical trials and to protect the trial subjects and participants, MFDS revised the Pharmaceutical Affairs Act (Jan. 28, 2015) and made it mandatory for those conducting clinical trials to receive necessary training. Also, MFDS revised the 「Regulation on the Safety of Pharmaceuticals, etc.」 (Sep.

25, 2015) and prepared a legal basis for the details of training of the personnel conducting clinical trials and for the designation of training agencies. Also, by enacting the 「Regulation on Training of the Personnel Professionally Involved in Clinical Trials and Bioequivalence Studies and on Designation of Training Institutions」 (Dec. 30, 2015), MFDS specified the training hours for each personnel type, detailed requirement for designating training institutions and the necessary documents to be submitted.

C) Implementation Plan

In 2016, MFDS plans to designate and manage clinical trial and training institutions according to the revised the Pharmaceutical Affairs Act. The designated training institutions will carry out education and training of the clinical trial supervisors, investigators, study conductors, clinical trial evaluation committee, clinical trial coordinators as well as the monitoring personnel of the institutions commissioned to do clinical trials.

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3. Strengthening Safety Management of Approved Pharmaceuticals

A. Cutting Off Distribution of Illegal and Unwholesome Medicine and Activation of a Monitoring Network

1) Background

Illegal and Unwholesome pharmaceuticals refer to ① those that have not been approved according to the Pharmaceutical Affairs Act (= Unauthorized), ② those that have active ingredients (AI) which are different from the AI allowed or have significantly insufficient amount of AI (= Defect), ③ counterfeits or fake pharmaceuticals similar to the medicine already approved (= forgery, counterfeit)(Article 3 of 「Act on Special Measures for the Control of Public Health Crimes」). In the past, distribution of illegal pharmaceuticals in the normal distribution channel was controlled by restricting manufacture (import) of those pharmaceuticals, but changes in social environment and improvement in the quality of people's life since 2000 led not only to the increased number of diverse and hidden distribution channels and increased

illegal distribution through social networks, websites or mobile message service but also led to blurred international borders in terms of illegal distribution of those drugs referred to as 'happy drugs' that are highly likely to be abused or misused.

2) Achievements

By amending the laws and regulations, MFDS has established the 'Certificate of GMP Compliance of a Manufacturer' which is an internationally standardized GMP evaluation policy. MFDS carried out periodical GMP evaluation on 125 pharmaceutical manufacturers and conducted field surveys in 20 overseas manufacturing sites to establish a DB for registering overseas manufacturing facilities and to analyze potential hazards.

MFDS also established a computerized basis for preventing the public from getting injured or harmed from hazardous durgs by developing and successfully carrying out a pilot project with the 'Hazardous Pharmaceuticals Sales Blocking System' that could quickly transfer information on hazardous drugs to pharmacy and wholesalers across the country. MFDS also strengthened its safety response actions such as hazard warning, hazard monitoring and international cooperation for drugs being illegally distributed through online.

3) Implementation Plan

A) Innovation of the System for Manufacturing and Quality Management of Drugs

With the GMP 'Certificate of GMP Compliance of a Manufacturer' policy introduced, MFDS plans to investigate and evaluate GMPs of all the pharmaceutical manufacturers in the country and issue the certificate with 3-year expiration date based on their GMP rating. Also, based on the results of the 3-year (2015-2017) investigation on the GMPs of the manufacturers, MFDS will establish a hazard-focused pharmacist monitoring system and, to be able to monitor the overseas manufacturing sites on the field, MFDS will register all the overseas manufacturing facilities, set up a 'Standard for Importing Pharmaceuticals' and promote an import reporting policy to safely manage imported drugs.

B) Strengthening and Expanding the Responsive Actions Against Pharmaceuticals being Illegally Distributed Online

MFDS will sign MOUs with more web portals so that the web portals can independently block illegal drug distribution online. MFDS will also monitor illegal online activities with an e-Robot. MFDS will prepare legal grounds for punishing the illegal online drug brokers and

advertisers as well. Moreover, by appointing the 'Pharmaceutical Safety Keepers', MFDS will develop and distribute various campaign materials for warning hazardous drugs and those illegally distributed drugs that do not guarantee safety or efficacy.

C) Improving Systems for Minimizing Drug-related Hazards

In order to prevent hazards that can occur during drug use, MFDS will set up a 'Joint Response Task Force for Medical and Pharmaceutical Hazards' and carry out quality inspection on pharmaceutical being distributed, taking into account of the social changes like low birthrate and societal aging and also reflecting the demands of specific groups of consumers. MFDS will integrate climate and disease control by monitoring and sharing treatment methods and the disease patterns that are changing with climate changes and global warming and, establish a pharmaceutical supply system that is prepared for climate changes.

Kim Chun-rae, Director of Pharmaceutical Management Division
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B. Adverse Drug Reaction Relief System

1) Background

Every medicine has side effects (adverse events) due to its diverse features and side effects may also occur even with proper use depending on people. A adverse drug reaction relief system in which the government compensate the victims who die, get injured or hospitalized due to side effects was introduced and implemented.

2) Achievements

Social consensus, financial operation of damage expenses, preparation of a system for evaluating the causality between side effects and medicine are the premise for stable introduction of a damage relief system against side effects of medicine. In this regard, in 2012, MFDS established an 'industry-academy-government committee for pharmaceutical adverse drug reaction' comprising of pharmaceutical associations, consumer and citizens' groups and experts from various fields and prepared a adverse drug reaction relief system that fits Korea's circumstances. After discussing with the National Assembly, finally on March 18, 2014, the

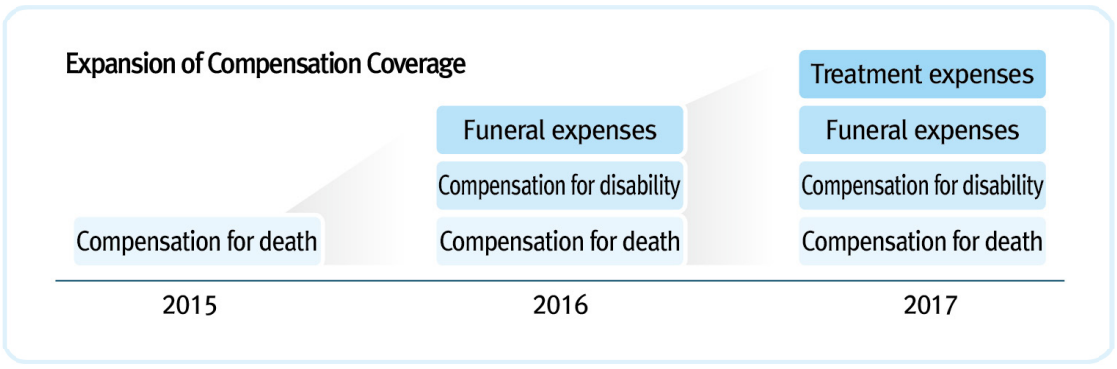
amendment of the Pharmaceutical Affairs Act for introducing adverse drug reaction relief system was announced and was implemented on December 19, 2014.

Accordingly, MFDS secured about 2.5 billion won by imposing the damage relief costs from pharmaceutical companies in 2015, compensated about 560 million won for 8 out of 20 death cases (lump sum death compensation of 69,973,200 won for each case).

3) Implementation Plan

Under adverse drug reaction relief system for pharmaceutical adverse drug reaction, compensation will be given for deaths in 2015; cover disabilities and funeral expenses as well by 2016 and include treatment costs by 2017.

To establish a safe social environment and to compensate the damages the victims suffer from adverse drug reaction even with proper use of medicine, MFDS will continue to investigate and evaluate the damages and fairly operate the compensation.



Lee Soo-jung, Director of Pharmaceutical Safety Evaluation Division
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C. Collection, Evaluation, Production and Supply of Safety Information about Released Drug Products

1) Background

All drugs come with curative benefits as well as the risk of side effects (adverse events). So, when a drug's benefits are determined to be exceeding the potential risks, then the drug

is approved for use. Clinical trials which are conducted as a part of pharmaceutical approval process, are participated by a number of planned and selected participants and by a limited number of children, elders, pregnant women and patients, making the amount of pharmaceutical safety information very limited. However, after drugs are released in the market, random people get to use them and since all individuals have different physical and health conditions and since some drugs can be used for a long period of time by chronically ill patients, some serious side effects which have not been shown or discovered during the approval process do occur later.

MFDS collects reports of side effects in Korea from consumers, hospitals, drug stores, medicine manufacturers (importers) and regional pharmaceutical safety centers to manage pharmaceutical safety. It was made mandatory to report adverse events promptly within 15 days of their occurrence. MFDS also collects safety information from international organizations, foreign governments and foreign media. The collected information are developed into new safety information through scientific statistical analysis, documentary surveys, investigation of overseas approval, experts' advise and feasibility evaluation. Safety information results are followed by appropriate safety actions such as change of approval status, ordering of investigation or research, suspension of sales, recovery and withdrawal, and, the relevant information are provided to consumers, doctors, pharmacists and related institutions.

2) Achievements

A) Collection of Pharmaceutical Safety Information

Thus far, MFDS has made some changes to the regulations related to the safety management of pharmaceuticals by making education and designation of safety manager at pharmaceutical companies mandatory and periodical and immediate reporting of pharmaceutical side effects mandatory as well. Also, by establishing the Korea Institute of Drug Safety and Risk Management (Jan. 2012), it set up exclusive divisions in charge of collection, analysis and management of safety information including pharmaceutical side effects and also established regional medicine safety centers. As a result, the reports on side-effects in Korea increased from 92,375 reports in 2012 to 183,260 in 2013, 183,554 in 2014 and 198,037 in 2015, showing 2 times increase in the last 3 years and the number of accumulated reports reached 860,224. The number of reports on side-effects per 1 million persons was about 4,000 in 2015, showing even more voluntary reports compared to some advanced countries such as the US with 3,400 reports, Japan 2,400 reports and UK 3,800 reports.

B) Safety Actions Carried out Based on Domestic Pharmaceutical Safety Information

Through statistical analysis, documentary surveys and consultation of the Central Pharmaceutical Affairs Council on the drug side effects reported in the country, MFDS developed 'signals (safety information)' and took safety actions including change of the approval status of 17 ingredients.

These safety actions have continued to increase, starting from 3 cases in 2012, 11 cases in 2013, 14 cases in 2014 and 17 cases in 2015.

C) Safety Actions Carried out Based on Overseas Pharmaceutical Safety Information

Overseas safety information were collected with real-time monitoring of international organizations, foreign governments or overseas mass media, and timely safety actions were taken by distributing safety letters on 3 cases including a Varenicline-related case. In addition, MFDS changed the efficacy, usage, dosage and precautions for the use of medicines that contain Domperidone which is used for treating digestive system problems, and also changed the approval status of about 1600 items that contain 55 ingredients.

3) Implementation Plan

A) Introduction of the 'Good Pharmacovigilance Practice (GVP) for Released Drug Products'

MFDS will introduce a standard called, 'Good Pharmacovigilance Practice (GVP) for Released Drug Products' for monitoring the safety of medicines that have been released to the public and revised the relevant laws. By doing this, medicine safety information in all processes can be systematically managed from the approval process to use by establishing drug monitoring plans, strategies to reduce risk of medicine, monitoring side effects after sales, developing periodical reports on side effects and carrying out analysis of clue information.

B) Safety Management of the Released Drug Products through Integrated Analysis

Instead of using the conventional way of manually collecting information on side effects, the US, EU, Japan and Canada have established and are currently operating an automatic pharmaceutical monitoring system that could collect and integrate a large amount of medical information and information on pharmaceutical side effects. To utilize and analyze the medical records, computerized insurance claims and treatment history which hospitals, clinics and the National Health Insurance Corporation hold, MFDS is currently working on integrating those

information through a 'pharmaceutical and medical information integration system'. Once the systematic foundation for integrating and analyzing various medical information and information on pharmaceutical side effects is established and more information is analyzed, MFDS will be able to provide more reliable and relevant safety information to the public and implement safety management actions for the released drug products.

Lee Soo-jung, Director of Pharmaceutical Safety Evaluation Division
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4. Strengthening the Competitiveness of the Pharmaceutical Industry by Stable Operation the Patent-Regulatory Approval Linkage System

A. Background

As part of the 2007 Korea-US Free Trade Agreement ("KORUS FTA"), the patent-regulatory approval linkage system has been officially implemented on March 15, 2015.

B. Achievements

MFDS introduced the 'Generic Exclusivity' which is reflected the characteristic of Korean pharmaceutical industry with competitiveness in generic pharmaceutical. It will promote generic pharmaceutical industry and protect pharmaceutical patents.

Moreover, to help people better understand and utilize the 'Prohibition on Sale of Generic Drug' and the 'Generic Exclusivity,' MFDS prepared a comprehensive guide, held policy seminars for pharmaceutical companies and established a cooperative network with the Korean Intellectual Property Office, Korea Fair Trade Commission and other relevant organizations.

Also, with the 'Patent Informatics DB', comprising the collected and analyzed patent and approval information needed in pharmaceutical development, MFDS provides the patent and approval information about 651 drug ingredients. MFDS also developed a professional training program on the patent-regulatory approval linkage system and implemented other support policies for strengthening capabilities of pharmaceutical companies related to patent.

C. Implementation Plan

In 2016, to strengthen the competitiveness of the domestic pharmaceutical industry, MFDS will secure relevant budget and utilize it in various practical and effective ways. MFDS is planning to support a maximum of 10 million won to each small-to-medium-sized pharmaceutical company for the professional consultation costs needed for patent analysis and patent strategy establishment. Moreover, by setting up a Patent Informatics DB, MFDS will analyze foreign pharmaceutical patent cases and the information is needed for developing drugs and establishing strategies to the pharmaceutical companies. Also, MFDS will provide reliable patent information of Central and South American countries like Brazil and Mexico to support Korean pharmaceutical industry's overseas business.

Lee Nam-hee, Director of Pharmaceutical License and Patent Division
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5. Establishment of a Management System for Preventing Abuse and Misuse of Narcotic Drugs

A. Background

Abuse and misuse of narcotic drugs like Propofol is continuously occurring in our society and especially the 'Doctor Shopping' of patients and excessive prescription being given by hospitals or clinics are also serious problems in our society.

For instance, in one case, propofol (general anesthesia) was used 71 times on an individual over a period of months for treating a sleep disorder. Also, in another case, an individual got prescription for 4,139 days worth of zolpidem from 93 hospitals over a period of 1 year.

The main causes of such abuse or misuse seem to be the illegal use of such medicine by medical institutions and an overall lack of information about proper use and distribution of these narcotic drugs. Also, since the shipping and inventory information between the distributors and the receiving parties during the distribution process are unclear and difficult to obtain, it is very difficult to prevent narcotic drugs from being illegally released through documentary manipulation and fabrication. Also, currently, the information on the use of non-covered medicine (administration in hospitals and clinics, medicine sold in pharmacy)

which are more likely to be misused or abused and the level of use by patients are insufficient.

Thus, to obtain more information needed for preemptive and preventive safety actions, a comprehensive system that can manage computerized information on handing of medical narcotics and monitor those information was needed and the joint crackdown inspection with the Public Prosecutors' Office·National Police Agency and other relevant organizations needed to be reinforced.

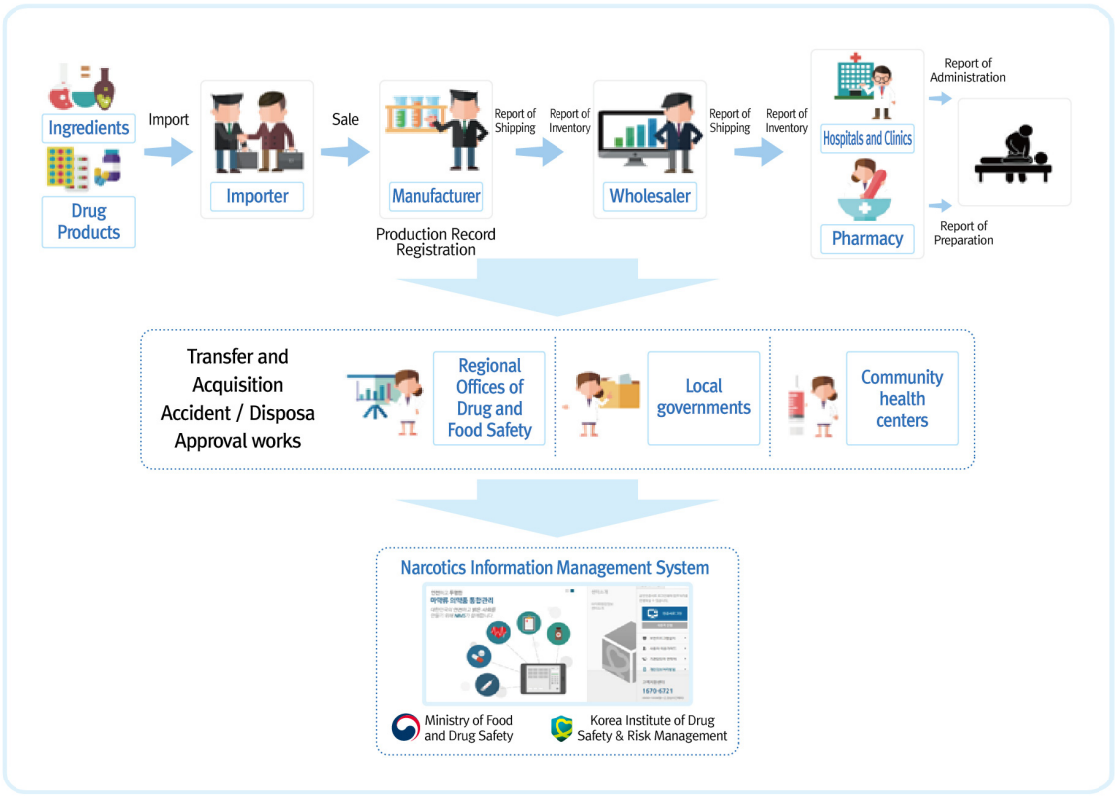
B. Achievements

1) Establishment of an 'Narcotics Information Management System'

To prevent illegal distribution and abuse of narcotics through transparent management of narcotics distribution and use, in December 2014, using the Radio Frequency Identification (RFID) technology, MFDS developed an **'Narcotics Information Management System'** that can not only monitor production, distribution, and administration of narcotic drugs for medical use but also, collect and manage comprehensive information about the current status and research on distribution and use of the ingredients, drug testing, quality tests and etc.

With the serial numbers on the system, MFDS can prevent illegal release and use of the drugs being produced or imported by tracking down them throughout the distribution channel from wholesaler to hospitals or pharmacy. It is expected that misuse or abuse of narcotics will decrease since the system will enable big-data management of the insurance-covered and non-covered narcotic drugs used for each patient and in each hospital.

Also, to establish a legal basis for real-time reporting and monitoring of narcotics use through the Integrative Narcotics Control System, the Act on the Control of Narcotics, Etc was amended in May 2015 to include details on expanding medical institutions' duty to report drug administration and on designating the Center for Narcotics Information Management for operating the control system. The reporting of the use of narcotic drugs, psychotropic medications and narcotics in veterinary medicine will be made mandatory in phases.



[Image 2-1-1] Narcotics Information Management System

2) Joint Response with the Public Prosecutors' Office, National Policy Agency and Other Relevant Organizations

In 2015, MFDS·Public Prosecutors' Office·National Police Agency and other relevant organizations have conducted joint inspections on 109 stores handling Propofol, ADHD medications, psychotropic appetite suppressants and other narcotics that are likely to be abused or misused. Among them, 27 stores were found to be violating the 「Act on the Control of Narcotics, Etc」 (strike rate 24.8%). The Public Prosecutors' Office and National Police Agency are currently investigating illegal distribution and use of narcotics as well.

MFDS also monitored illegal narcotics being distributed online and caught 1,094 illegal activities last year. The illegal websites that were caught were closed down by the Korea Communication Standards Commission and the National Policy Agency carried out further investigations on those sites.

C. Implementation Plan

MFDS will make a year-round reporting of handling medical narcotics on the 'Narcotics Information Management System' mandatory in the second half of 2016 and completely mandatory by May, 2018 in phases. Also, by using the results obtained from the pilot project with the companies handling narcotics, MFDS will make improvements to the system. MFDS is also planning to initiate another pilot project with 1,000 entities including pharmacy, hospitals, clinics, wholesalers, pharmaceutical companies handling psychotropic medications.

In 2016, MFDS·Public Prosecutors' Office·National Police Agency and other relevant organizations will also carry out a semi-annual joint crackdown inspection for narcotic analgesics and sleeping medication and other narcotics with a risk of being abused or misused and hold working group meetings to share information and monitoring methods and, continue to work to prevent abuse and misuse of narcotics.

Kim Sung-jin, Director of Narcotics Policy Division
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Section 2

Biopharmaceuticals and Cosmetics

1. Safety Management and Quality Improvement of Biopharmaceuticals (Human Tissues)

A. Safety Management and Quality Improvement of Biopharmaceuticals

1) Background

Unlike the chemical synthetic pharmaceutical field which has already reached maturity in terms of market status and technology for product development, the biopharmaceutical field which includes gene recombinant products, cell therapy products and gene therapy products manufactured with advanced technologies as well as those traditional biological products such as vaccines and blood products, still shows a growing number of new products using rapidly advancing, state-of-the-art technologies. The biopharmaceutical industry can grow enormously depending on market potential or technologies and many countries all over the world view the biopharmaceutical field as their future, growth engine industry and are making continuous investments in the field. MFDS, too, is currently working on introducing 'Quality by Design (QbD)' for manufacturing and quality management of advanced pharmaceuticals.

2) Achievements

A) Strengthening of Inspection on Overseas Manufacturing Facilities of Imported Biopharmaceuticals and Sharing of Inspection Information through Joining PIC/S

After joining the Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme (PIC/S) in 2014, to align Korea's standards on manufacturing and quality management of pharmaceuticals with the internationally harmonized standards of PIC/S, MFDS established the 「Regulations on Manufacturing and Quality Management of Pharmaceuticals」 (June 17 2015) and prepared 16 new detailed components including the [Attached Table 2] Manufacturing of Biopharmaceutical Ingredients and Products and [Attached Table 12] Manufacturing of Pharmaceuticals Derived from Human Blood or Plasma. Also, MFDS provided

the results of the inspection on standards on manufacturing and quality management of pharmaceuticals to companies to improve the transparency pharmaceutical manufacturing and quality management.

B) Improvement of the National Lot Release

By revising the 'Regulations for the Methods and Procedures for the Approval and Designation of the Pharmaceuticals for National Lot Release' which specifies the government's inspection and overall review of the manufacturing procedures and quality management practices of pharmaceutical manufacturers, MFDS changed the national lot release policy from a negative listing system under which test items are selected after examining the performance of the entire test items, to a positive listing system under which key hazard test items are designated. Also, MFDS prepared a hazard evaluation system that allows MFDS to evaluate the overall hazard factors that may can influence the quality of products and apply differential test items (July 2015).

C) Establishment of a Foundation for Safe Use of Vaccine throughout the Life-Cycle and Technical Support for Certification of WHO's Prequalification Programme

To support Korean vaccine developers and manufacturers in WHO's Prequalification Programme and ultimately pave the way for the export of Korean vaccines, MFDS provides administrative and technical support for those who apply for the support and by the end of 2015, 4 companies obtained WHO's PQ for 10 vaccines (15 products).

Also, MFDS published and provided the 'Vaccine Storage Management Guidelines' which consists of the details about vaccine inventory management, precautions for handling vaccines and maintenance of vaccine storage equipment.

D) Development of a Biopharmaceutical QbD Model

MFDS has been carrying out internal and external education projects to introduce the 'Quality by Design (QbD)' in Korea. First, MFDS prepared the 「Roadmap to Introducing the QbD System」 (2013) and 「Procedures for Developing QbD-applied Model」(2014). Then, in 2015, MFDS initiated a QBD model development project by utilizing gene recombinant products which have quite well-established manufacturing process and, developed a model that focuses on cultivation and fermentation processes and established the guidelines for the model.

E) Improvement of the Good Manufacturing Practices (GMP) and Safety Management Regulations for Blood Products

MFDS changed took over the role of the managing authority for raw plasma needed for manufacturing plasma derivatives from the Republic of Korea National Red Cross and expanded the targets of management from foreign plasma exporters to domestic and foreign plasma manufacturers and exporters (Dec. 2012). MFDS also carried out current-status inspection and established the Plasma Master File (PMF) and the Look-Back Reporting System.

MFDS laid the foundation for supply of high-quality blood product by enacting (Apr. 2014) and revising (Jun. 2015) the 'GMP Guidelines for Blood Products' based on various aspects (small-quantity production, simple manufacturing process). MFDS also revised the 「Regulations on Safety of Pharmaceuticals, etc」, eased relevant regulations by harmonizing the standards on the composition of manufacturing managers (Aug. 2014) and facilities (Feb. 2014) of blood product manufacturing companies with the standards specified under the Blood Management Act and, established the Guidelines for Blood Product GMP.

F) Improvement of the Drug Monitoring System for Post-Release of Stem Cell Therapies

To gather as much information as possible about the safety in the use of stem cell therapies after their release, MFDS made it mandatory that a total inspection be carried out with all the patients administered with stem cell therapies for 2 years after the release of the stem cell therapies (Jul. 2015). MFDS also made it mandatory that a 'long-term follow up study' be carried out on stem cell therapies that have the potential to remain in the body or be integrated into unintended tissues so that serious abnormal incidents that may occur in the long-term can be monitored (enacted in Dec. 2015, revision on Jan. 1 2017).

3) Implementation Plan

Taking into account various factors such as inspection history and results, domestic and overseas incidents of quality issues and import history which may influence the domestic market, MFDS will select 23 companies, evaluate their risk rating and carry out periodical inspection for risk analysis. Also, to improve the national lot release system, MFDS will strengthen the quality assurance system which is used for evaluating risk based on scientific data and, by harmonizing Korea's national lot release system with foreign lot release systems, MFDS will changed the lot sampling method from the current method of sampling carried out by public officials to the new method in which the applicants (manufacturers) submit

their own lot samples.

MFDS will also provide more structured and extensive support to vaccine developers and manufacturers for WHO's PQ Programme in 2016.

In order to introduce the QbD system in biopharmaceutical field, there needs to be governmental support. So, following the development of cultivation and fermentation models for gene recombinant products in 2015, MFDS will develop models that focus on the retrieving and refining process and also publish necessary guidelines for the process.

In order to harmonize the standards on the manufacturing facilities for biological products with the European and PIC/S standards, MFDS is currently working on revising the 「Regulations on Safety of Pharmaceuticals, etc」 and clarifying the ingredients, substances and equipment that need to be isolated or have exclusive facilities.

In order to improve the credibility of GMP inspection, MFDS currently runs various programs for training internationally competitive GMP inspectors. MFDS is also an official GMP training institution designated by WHO and its training will improve MFDS' international credibility.

For safe use of biopharmaceuticals and to strengthen the drug monitoring, MFDS will establish an integrated management system for monitoring and sharing adverse events related to vaccines and, prepare a plan for developing the said system to collect, analyze and evaluate adverse (reactions) events after vaccine administration.

Moreover, to improve the completeness and accuracy of vaccine administration history records and for the convenience of consumers and medical institutions, MFDS came up with a plan for a 'sticker label' which can be put on the baby vaccination record book and is currently planning to carry out a pilot project for promoting the sticker system and provide technical support for manufacturing and distributing these sticker labels.

In regards to blood products, MFDS will work on legalizing the guidelines for the blood product GMP by taking into account of the characteristics of blood products and circumstances of blood banks and, carry out a blood product GMP study project.

Gene therapeutic agents or gene drugs are those pharmaceuticals that contain genetic material. Since these drugs can remain in a human body for an extended period of time and have an extended effect on a human body, a long-term safety evaluation is imperative. So, MFDS will strengthen ex-post factor safety management of these advanced biopharmaceuticals to establish a safe environment for the consumers.

MFDS will also revise the current re-evaluation process for new drugs and analyze the safety in the use of drugs during a set period of time as well as the voluntary reports on hazard incidents to provide more complete safety information to consumers.

B. Safety Management and Quality Improvement of Human Tissues

1) Background

Along with medicines and medical devices, human cells and tissues are very important resources that can treat diseases, prevent disabilities and restore essential physical functions and imperfections. The demand for human tissue is continuously increasing with the rapidly aging society and, human tissue import is also continuously increasing.

Accordingly, the safety management of imported human cells and tissues have become more important and the safety of human tissues is managed thoroughly from the donation stage.

2) Achievements

A) Establishment of the Regulations for Mandatory Good Tissue Practices (GTP) and Improvement of the Act on the Safety Management of Human Tissues

To allow distribution of only safe human tissues that have been approved under the stage-by-stage management standards on human tissues in collection, processing, storage and distribution stages, the phased mandatory good tissue practices has been enforced in July 2015 and will be applied including all tissue processors by July 2015, medical institutions and non-profit organizations by January 2016 and all tissue importers by January 2017.

B) Strengthening of inspection on Foreign Manufacturers of Imported Human Tissues

MFDS carries out periodical inspection (since 2006) on domestic tissue banks and started investigating foreign manufacturers of the human tissues being imported to Korea in 2011. MFDS strengthened safety in the tissue donation process by making tissue banks to review medical and pharmaceutical backgrounds of the tissue donors through the Korean Health Insurance Review & Assessment Service.

All of the safety management functions except for the donation process were transferred to MFDS in March 2013 and MFDS unified all the relevant policies and policy executions. MFDS also established the ‘Comprehensive Development Plan for Safety Management of Human Tissues’ in July 2013.

C) Establishment and Operation of an Integrated Computerized Network for Safety Management of Human Tissues and Introduction of Mandatory Standard Code and Barcode System

To systematically manage the safety of human tissues, MFDS established and has been

operating an integrated computerized network for safety management human tissues called 'HuTis'. MFDS also required a standard code and a barcode to be put on the container and packaging of human tissues, making human tissues more easily traceable. The medical institutions using human tissues for transplantation operations can check these codes and guarantee the safety of the human tissues being used.

3) Implementation Plan

A) Strengthening Safety Management of Imported Human Tissues

In addition to periodic inspection, MFDS also carries out special inspection on foreign manufactures of imported human tissues. The manufactures for inspection are selected based on a risk evaluation and MFDS is planning to carry out an inspection for 1 manufacturer this year. MFDS is also planning to cooperate with the Korea Customs Service and utilize the Hutis to investigate illegal imports of unapproved human tissues.

B) Education for the Personnel Working in Tissue Banks

Since 2012, MFDS has carried out education for the personnel working in tissue banks. To improve their understanding of regulations and GTP related to human tissues, this year, MFDS will carry out basic and in-depth education programs instead of carrying out the existing education program which have been used to strengthen the safety management capacities of the tissue banks.

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2. Safety Management of Herbal and Natural Medicine

A. Background

The public's interest in and demand for herbal medicine are increasing due to the societal aging and increase in chronic diseases and accordingly, the social demand for safety and quality management of herbal medicine is increasing as well. MFDS puts a great deal of effort to establish the safety and improve the quality of herbal medicine.

To establish a safe herbal medicine manufacturing environment from herb ingredients to final herbal medicine products, MFDS adopted the 'Good Manufacturing Practice (GMP) for Herbal Medicines (hGMP)' in June 15, 2012 and made it fully mandatory in January 1 2015 requiring all herbal medicine manufacturers to follow the policy. Also, MFDS carried out customs inspection on medicinal herbs being imported as the ingredients of herbal medicines and started carrying out GMP inspection on those overseas manufacturers that have been approved by the government.

However, since defective products are continuously being discovered during collection and inspection of medicinal herbs being distributed and there has been a question on the appropriateness of managing overseas manufacturers that have been approved prior to the implementation of the mandatory GMP policy, MFDS feels the need to further strengthen the safety management.

B. Achievements

In 2015, MFDS strengthened safety and quality management of herbal medicines by continuously carrying out monitoring, inspection and providing necessary support to manufacturing companies.

First, to stabilize the mandatory 'hHMP' MFDS held policy seminars with the relevant organizations and companies to promote and share information and policies for the GMP policy. Also, to reduce the burden of quality management cost on small manufacturing companies, MFDS operates an open laboratory at Yangnyeong, Seoul.

Moreover, as part of the management and monitoring project for preventing distribution of fradulent and defective medicines, MFDS strengthened customs inspection of imported medicinal herbs through random sample monitoring, cross-checking and sensory tests which are carried out by testing and inspection organizations and also, carried out inspection on overseas manufacturers. MFDS continued to work to reduce hazardous substances in natural medicines, added 17 additional APIs of herbal medicines into the list of registered herbal API's, focusing on those substances that are used frequently and those herbal medicines that are being produced a lot.

To improve the standards and specifications for the distribution of herbal medicines, MFDS reviewed the existing standards and specifications of the official compendium and strengthened internal and external communication and cooperation by operating departmental natural medicine industry development committees.

C. Implementation Plan

In 2016, MFDS will continue to push forward and strengthen the projects that have been carried out since 2015. MFDS will increase the number of monitoring and cross-checking inspection cases of imported medicinal herbs and continue to carry out periodic inspection of overseas manufacturers.

MFDS will also increase the number of natural medicines subject to benzopyrene monitoring, figure out the content in medicines through phased collection and inspection activities and make a benzopyrene reduction policy mandatory if needed. MFDS will aos revised the 「Regulations on Approval and Declaration of Herbal (Natural) Medicines」 that requires the applicants applying for approval of their herbal medicines to submit supporting documents on residual pollutants.

To resolve various issues that the natural medicine field currently faces, MFDS will operate the natural medicine industry development committee, strengthen the cooperation and communication between the industry, academia and relevant organizations and participate in international meetings to strengthen international cooperation as well.

Moreover, by adopting scientific analysis and advanced testing methods, MFDS will conduct research to re-examine various medicinal herbs and continue to revise and improve the 「Korean Pharmacopoeia」 and 「Korean Herbal Pharmacopoeia」.

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3. Consumer-Centered Safety Management of Cosmetics and Quasi-Drugs

A. Safety Management of Cosmetics

1) Establishing a Safe Environment for Use of Safe and Proper Cosmetic Products

A) Establishment of Regulations and Safety Standards on Cosmetics

After a full revision of the 「Cosmetics Act」(effective on Feb. 5, 2012), the government reinforced the businesses' responsibilities to secure quality and safety of cosmetics and

facilitated prompt release of products into the market by focusing on supervision and ex-post facto management of products in the market.

Also, to invigorate the industry by facilitating development of new cosmetic ingredients and to internationally harmonize relevant regulations, MFDS adopted a negative listing system by specifying the ingredients that can't be used in cosmetics.

Moreover, the regulations on safety standard of cosmetics was revised to specify standards on use of restricted or prohibited ingredients as well as standards on safety control of cosmetics. Also, by collecting cosmetics safety information at home and abroad and through a risk assessment, MFDS revised the safety standards for cosmetic ingredients to improve the safety of cosmetic products.

Also, MFDS tried to improve the safety of cosmetics by revising material and product standards based on safety information at home and abroad and through hazard assessments.

MFDS will continue to examine hazard incidents at home and abroad, carry out risk assessment and improve relevant regulations and standards on the use of cosmetic ingredients that need control and restriction. Also, it will internationally harmonize the safety management standards for the cosmetic products that are being distributed in the market.

B) Certifying the Companies Complying with the 'Good Manufacturing Practices for Cosmetics (CGMP)'

MFDS advisers cosmetics manufacturers to comply with the 'Good Manufacturing Practices for Cosmetics (CGMP)'.

In March 2011, MFDS began to carry out assessment and evaluation of 'CGMP' of cosmetics manufacturers and as of 2015 (as of June, 2015), a total of 77 businesses were found to be complying with the CGMP. Also, to promote the application of CGMP, MFDS allowed some cosmetics processors to receive evaluation on their performance in CGMP and, changed the evaluation system from product-based evaluation to business type-based evaluation. Also, to reduce the administrative and cost burden on applicants applying for an evaluation of CGMP implementation, the evaluation process was shortened from 120 days to 90 days.

To secure international competitiveness in quality of domestic cosmetic products and to increase the productivity, CGMP must be widely used across the country. To do this, MFDS will offer a customized consultation service to those companies that wishes it and give them technical and administrative support in improving their cGMP. MFDS will also delegate CGMP evaluation to regional offices of food and drug safety to establish consistency in CGMP evaluation and ex-post facto management.

2) Strengthening of Industrial Competitiveness through Productive Safety Management

A) Strengthening the Control of Harmful Substances in Cosmetics

There was a need to set a maximum permissible limit on unintentionally generated substances for when prohibited ingredients were not added intentionally, substances were unintentionally generated during manufacturing and storage and when certain substances can't be technologically eliminated completely. Therefore, MFDS set a maximum permissible limit on unintentionally generated substances which are prohibited for use and also prepared a separate standard for 'wet wipes' which were classified under cosmetics as of July 2015.

MFDS will continue to examine hazard incidents at home and abroad and risk assessment results to revise relevant cosmetics regulations and set maximum permissible limits on unintentionally generated substances prohibited for use.

B) Preparation of the Guidelines for the Cosmetics Good Manufacturing Practices (CGMP)

In order to enhance cosmetics manufacturers' understanding of the Cosmetics Good Manufacturing Practices (CGMP), MFDS prepared the 「Guidelines for the Cosmetics Good Manufacturing Practices (CGMP)」 in July 2013 based on its experiences and scientific facts and revised the Guidelines in December 2015. New information and technologies related to CGMP and future revisions of CGMP will be applied to the Guidelines and MFDS will continue to work on improving cosmetics manufactures' quality management practices.

3) Strengthening Safety Management of Cosmetics being Distributed

A) Monitoring Cosmetics

To establish a safety cosmetics manufacturing and distribution environment, MFDS sets up a basic direction of inspection every year and carried out a 'Master Plan for the Management of cosmetics Manufacturing and Distribution'.

In 2015, MFDS carried out a planned joint inspection of unregistered cosmetic product sellers, manufacturers manufacturing cosmetic products sold in stationary stores, sanitary wipe manufactures and manufacturers handling products that have caused a big social issue.

To establish a safety management system for cosmetic products, in 2016, MFDS will promote voluntary inspection of cosmetics manufacturers and sellers and, analyze and inspect children's

cosmetics and those cosmetic products that are potentially hazardous or are closely related to people's lives.

B) Inspection of Ads and Labeling

While cosmetics are everyday items that are most frequently and widely used, due to lack of exclusive personnel to monitor and inspect ads and labelling, there were no effective measures to manage them until recently.

But in 2015, to strengthen the inspection on various cosmetics advertisements on social networks, company websites and online shopping sites, MFDS carried out joint monitoring on cosmetics labeling and advertisement utilizing increased number (3→4) of exclusive personnel dedicated to this monitoring task.

In 2016, MFDS will continue to carry out inspection on cosmetics advertisements on TV shopping channels and online shopping sites all year-round and monitor false and exaggerated ads as well as those ads that falsely advertise cosmetic products as pharmaceutical products.

C) Collection and Testing of Cosmetics

To secure safety and quality of cosmetics, MFDS has been sampling and testing cosmetic products every year according to the 'Basic Plan for Quality Inspection' of the 'Basic Plan for the Management of Manufacturing and Distribution of Biopharmaceuticals, Herbal (Natural) Medicines, Cosmetics and Quasi-Drugs'. For special sampling and testing work, MFDS 246 million won budget. In addition, over 800 items are regularly collected and inspected annually after selecting the test items per product type, target number of items tested per local governments for regular quality inspection.

In 2016, MFDS will intensively collect and test personal cleansing wipes, especially baby and children's wipes which had been managed as 'industrial product' and 'social-concern items'.

B. Safety Management of Quasi-Drugs

1) Strengthening of Safety Management of Quasi-Drugs

A) Background

Like cosmetics, quasi-drugs are everyday items that are most frequently and widely used and deeply linked to people's lives. People are also very sensitive about quasi-drugs. Moreover,

false and exaggerated ads for quasi-drugs and the distribution of fraudulent and defective quasi-drugs can negatively influence the consumers to a great extent. MFDS will continue to improve relevant regulations and strengthen its collection and evaluation activities to manage and supply safe quasi-drugs.

B) Achievements

(1) Improving Quasi-Drug Regulations

MFDS strengthened the legal basis for safety management of quasi-drugs by implementing a policy for reexaminating the safety and efficacy of already approved and registered quasi-drugs based on latest scientific standards (Jul. 2015) and making it mandatory for the quasi-drug facilities to separate insecticide and rodenticide facility areas (Dec. 2015).

Also, MFDS created more job opportunities and reduced the companies' shortage in personnel by expanding the qualification requirements of manufacturing managers of quasi-drugs that are used for adding sanitary functions to sanitary pads and masks.

MFDS also added smoking habit reducing aids under the category of smoking cessation aids, newly included the substances used for getting rid of tongue and dental plaque as well as those substances used for cleaning and sterilizing removable appliances that people put inside their mouth as quasi-drugs. MFDS also added precautions that must be specified on the quasi-drug dental products (mouthwash, toothpaste, etc) that contain ethanol and fluoride to protect the consumers' rights to know and select.

MFDS enacted the 「Regulations on Classification Numbering of Quasi-Drugs」(MFDS Regulation) specifying classification numbers of quasi-drugs for the convenience of the public.

(2) Reevaluation of Quasi-Drugs

As the final action based on the insecticide safety reevaluation which have been carried out over 3 years (2012~2014), MFDS strengthened precautions for the products that contain 5 substances including D-phenothrin. For the products that contain 'Dipropylisocinchomeronate' in which there are not enough safety information about the substance, MFDS retrieved and suspended the sale of those products for preemptive safety. The quasi-drug reevaluation policy started in July 2015 and MFDS has been reevaluating the safety of 3 types of quasi-drugs (mosquito and mite repellents, electronic smoking craving suppressants that use tobacco oil, hair loss prevention products).

(3) Quasi-Drug Monitoring and Quality Management

With the expanded mandatory application of GMP regulation on quasi-drugs, MFDS worked on improving the safety and quality of quasi-drugs by intensively inspecting whether ointment and cataplasma product manufacturers are manufacturing and selling without acquiring GMP approval and whether the businesses that manufacture or import the items 'A' specified under the Section 7, Article 2 of the 「Pharmaceutical Affairs Act」 are manufacturing or selling differently from what they have been approved for.

After establishing a 3-year (2015~2016) collection and testing plan for all the distributable quasi-drugs, MFDS retrieved a total of 2,090 quasi-drug items in 2015 and tested 1,699 items. Among them 27 were found to be defective in terms of their quality. MFDS retrieved and disposed of those products and took administrative penalty actions accordingly.

(4) Public Campaign for the Safe Use of Quasi-Drugs

MFDS promoted the proper selection and safe use of masks for fine and yellow dust which have become worse in recent years, the proper use of smoking cessation products and precautions for using mosquito repellents and domestic insecticides.

C) Implementation Plan

In 2016, MFDS will strengthen the inspection of safety policy compliance for quasi-drugs, carry out planned inspection for preemptive and preventive safety management and carry out planned collection and inspection activities for sensory testing of quasi-drugs being distributed in the market.

MFDS will also require the industry to specify the names of preservatives and tar food coloring on the products. Also, MFDS will prepare standards on precautionary labeling for children, strengthen maximum allowed limits of preservatives in dental quasi-drug products (mouthwash, toothpaste) and improve relevant regulations. It will also carry out a pilot project with the bar code-based 'On-Site Sales Blocking System' which can be used for cutting off the sales of hazardous products (defective products, products subject to retrieval, products suspended for sale) to prevent consumers from getting injured from those products.

MFDS will also develop and distribute videos about 'safe and proper use of mosquito repellents' to prepare to resolve possible social health issues (MERS, Zika virus infection) and also develop/distribute promotional leaflets to prevent children's misuse and abuse of dental products (mouthwash, toothpaste). Also, MFDS will provide customized, day to day information

(precautions, safe use) about safe use of common quasi-drugs by season (summer, yellow and fine dust) and types of consumers (children, smoker, the elderly).

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4. Realizing the Creative Economy to Support Korean Biopharmaceutical Industry's Advancement into the Global Market

A. Background

Biotechnology creates various new industries by allowing convergence of the changes in pharmaceutical and medical industries and the technologies of other fields. Thus, to strengthen various technological capacities and improve convergence technologies, customized strategies need to be established. The Korean government selected the biotechnology industry as the new growth engine industry and has been increasing governmental support and R&D funding for the industry. MFDS is also actively working towards realizing a creative economy to strengthen the national competitiveness, create more jobs and take the leading position in the global market.

B. Achievements

The development of Korean vaccine for the swine influenza which broke out in 2009, development of the first stem-cell therapy approved for clinical use and the development of the world's first biosimilar monoclonal antibody (mAb) approved by the European Medicines Agency (EMA), all showed the potential and capacity of Korean biopharmaceutical industry and paved the way for the industry to advance into the global market.

MFDS established a safety management system for advanced biopharmaceuticals, expanded customized support to strengthen the competitiveness of Korean vaccines, provide support in acquiring WHO's Prequalification, provided regulatory information and consultation services and also established the 「Biopharmaceutical Strategies」. MFDS is also working hard to strengthen the cooperative relationships with WHO, APEC and various international regulatory

organizations to support Korean biopharmaceutical industry's global market entry.

MFDS also held the 'Global Bio Conference', having all the international, biopharmaceutical events organized by MFDS at one place and integrated the conference with other international events such as the international Pharmaceutical Regulators Forum (IPRF) and APEC Harmonization Center (AHC) workshops.

MFDS established the 'Implementation Plan for Supporting Global Vaccine Commercialization', supplied cell strains to support vaccine development, provided customized technical and regulatory support, provided support in acquiring WHO's PQ to invigorate vaccine export and strengthened cooperation with other international regulatory and pharmaceutical organizations. The 'Global Vaccine Commercialization Support Group' which consists of MFDS and experienced technical advisors, studies the problems that can appear during the product development stages, provides intensive support during the clinical trial period and provides customized consultation services to vaccine developers. The 'WHO Certification Support Group' supports the pharmaceutical companies that applies for WHO PQ Programme in terms of clinical trials, GMP and preparing technical documents. To serve as the control tower of all these support projects and monitor various issues and topic related to product development, MFDS also runs a public-private, 'biopharmaceutical industry development strategy planning group' called 'Dynamic BIO'.

MFDS continued on with the project for establishing a 'BIO IT Platform' which is a customized export support program MFDS has been carrying out since 2014. With this Platform, MFDS was able to provide regulatory and industry-related information to the biopharmaceutical industry and solve the issue of the lack of approval-related information which worked as a barrier for the industry's global market entry. In 2015, MFDS gathered and provided regulations and guidelines for GMOs, cell therapy products and gene therapy products of 9 countries including the US, EU, China, Japan, Brazil, India, Turkey, Mexico and Thailand.

C. Implementation Plan

The world's biopharmaceutical market is growing at a fast speed and many developing countries are focusing their resources and capacities into developing advanced pharmaceutical products and biosimilars. To support Korean biopharmaceutical industry's global market entry and strengthen the international competitiveness of the industry, the government's support needs to be expanded.

The sales share of biopharmaceuticals out of the top-selling pharmaceuticals is expected

to reach 50% by 2020. To obtain sufficient amount of information needed for the commercialization and export of Korean biopharmaceuticals, a well-structured system needs to be established and MFDS must continuously work on improving the outcomes and the efficiency of international joint projects.

To achieve this, MFDS plans to implement a global biopharmaceutical support policy and increase Korea's self-sufficiency of 18 biopharmaceutical items including 7 biosimilar products, 5 stem cell therapies, 1 gene therapy and vaccines by 2018.

Through a global commercialization support, development of the Bio IT Platform, provision of foreign regulatory and industry-related information and consultation services, the 'Pump-Priming Project for Biopharmaceuticals' and cooperation agreements with foreign regulatory authorities, MFDS will expand the Korean biosimilars' global market entry.

By running item-by-item public-private commercialization support groups and the preliminary evaluation system and implementing commercialization guidelines, MFDS will develop and revise relevant regulations, facilitate the pharmaceutical commercialization process and acquire 5 additional stem cell therapies for commercialization by 2017.

Through the public-private commercialization consultative groups, MFDS is currently providing consultation and review services from the product development stages and working hard to speed up the commercialization process. MFDS will also timely provide detailed guidelines that will help the commercialization of advanced biopharmaceuticals like stem cell medicines and, revise the current stem cell-related regulations to fix unnecessary parts and set necessary regulatory elements for successful and quick commercialization.

Also, to manage advanced biopharmaceuticals more efficiently and systematically, MFDS will work on developing a new law for advanced medical products including gene therapy products and cell therapy products which have similar characteristics. With the advancement of technologies, a bioartificial liver device (BAL) which is a combination of medical device and cell therapy and various other innovative, convergence materials and devices are expected to come out increasingly more but with the current evaluation system for convergence products, it is difficult to evaluate those advanced products effectively. So, MFDS will set up an exclusive organization for the approval, evaluation and management of convergence products and oversee the convergence product development from the early product development stage.

MFDS will promote the development of and supply of cell strains for vaccine development, operate a global vaccine commercialization support group and implement a vaccine self-sufficiency improvement strategy for the stable supply of the 28 essential vaccines administered in Korea. The vaccine self-sufficiency increased from 9 vaccines (32%) in 2014 to 11 vaccines (39%) in 2015 and, MFDS will increase this to 20 vaccines (71%) by 2020.

MFDS will also prepare standards and procedures that will allow the supply and use of vaccines and blood products which haven't been approved yet, during the outbreak of biological terrorism and serious epidemic and, set up the 'National Stable Pharmaceutical Supply Group' to establish a governmental master plan for the stable supply of pharmaceuticals. Also, by operating the 'BCG Vaccine Commercialization Support Team', MFDS will select and focus its developmental support into the vaccines that are expected to be undersupplied or that urgently needs to be produced and supplied locally.

By supplying cell strains which are essential for vaccine development to companies, MFDS will promote vaccine development and also, continue to operate the global vaccine commercialization support groups to provide technical and regulatory assistance in commercializing vaccine products. MFDS will also provide technical support in terms of GMP and customized one-on-one services to those that request to facilitate their successful WHO PQ certification and global market entry.

☆ WHO Prequalification (PQ) Programme: A programme implemented by WHO to evaluate quality, safety and efficacy of pharmaceuticals and for the provision of pharmaceuticals to developing countries. The pharmaceuticals approved by the programme acquires international recognition (currently, 15 products (packaging unit) of 10 types of pharmaceuticals of 4 companies have been approved).

MFDS will apply fast track evaluation process for those biopharmaceuticals with guaranteed safety and efficacy and speed up the commercialization and market entry of those biopharmaceuticals. MFDS will also clarify the requirements for the document submission for the approval of biopharmaceuticals to improve the predictability of the development and commercialization process of advanced biopharmaceuticals. To quickly provide treatment opportunities to the patients suffering from incurable diseases, MFDS will revise the regulations on approval and evaluation of biological products and prepare a plan for conditionally allowing the use of cell therapy medicines, anti-cancer drugs and other rare medicines for disease that have no known treatment.

In order to supply safe and high-quality biopharmaceuticals, MFDS will prepare necessary regulations to support pharmaceutical research, development and commercialization and the global market entry of those biopharmaceuticals. It will also work closely with other government ministries, the industry, academia and research institutions, prepare comprehensive support plans so that Korea's biopharmaceuticals can gain global competitiveness and lead the global pharmaceutical market.

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5. Establishment of an Advanced Approval and Evaluation System for Biopharmaceuticals

A. Strengthening Global Competitiveness of Korean Biopharmaceuticals through International Cooperation

1) Background

The world's biopharmaceutical market is expected to grow at a high annual growth rate. This can be attributed to the rapid growth of the gene therapeutic agents, stem cell therapies and biosimilar markets. To become one of the world's top 7 countries in the biopharmaceutical field, the Korean government prepared the 'Global Biopharmaceutical Support Plan' in August, 2013 and has been working on providing regulatory, technical, infrastructure and international cooperation support.

2) Achievements

A) Strengthening International Cooperation by Sharing Information and Working in International Committees with Major Regulatory Authorities Around the World

(1) World Health Organization (WHO)

As a Collaborating Centre for Standardization and Evaluation of Biologicals of WHO, MFDS participated in a joint research in January 2011. In 2015, MFDS participated in a joint research for establishing international quality standards for the blood coagulation factor VIII gene.

Also, in 2007, MFDS was designated as a center for WHO Global Learning Opportunities (GLO) and has been providing training on Good Manufacturing Practice (GMP) of vaccine. MFDS also signed a Memorandum

Of Understanding (MOU) with the Secretariat of Western Pacific Region of WHO in 2011 for cooperaton and started carrying out an Official Development Assistance (ODA) project in 2015. MFDS also signed a Donor Agreement with WHO's Regional Office for the Western Pacific (WPRO) and carried out a joint aid project.

(2) International Pharmaceutical Regulators Forum (IPRF)

MFDS was selected as the chair of 'BioSimilar Regulation Harmonization Working Group at the International Pharmaceutical Regulators Forum (IPRF) simultaneously held with the

International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use(ICH) held in November 2013 at Osaka, Japan and, participated in the development of biosimilar approval and review standards, identification of regulation status and differences around the world by region or by country, prevention of duplicate activities related to biosimilar among international organizations, and regulatory harmonization on drug monitoring. Also, recognizing the importance of scientific evaluation of the safety and efficacy of advanced pharmaceuticals and the need for regulatory harmonizations, Korea participated in IPCF's Gene Therapy and Cell Therapy working groups.

(3) Asia-Pacific Economic Cooperation (APEC)

At the APEC Senior Officials' Meeting (SOM) held in September 2011, Korea (MFDS) was selected as one of the 'Champion Nations' for establishing Biotherapeutic Products Roadmap and since 2009, it has been holding workshops organized by the APEC Harmonization Center (AHC).

(4) Strengthening International Cooperation among Advanced Regulatory Authorities

MFDS has participated in various international organizations and committees and made continuous efforts to cooperate with other nations around world. MFDS established a strong cooperative relationship with the Paul-Ehrlich-Institut(PEI), Germany in October, 2013 and, also established a cooperative relationship with the U.S. Food and Drug Administration (FDA) by signing a Confidentiality Commitment (CC). Moreover, MFDS signed a collaboration agreement with the Japanese Ministry of Health, Labour and Welfare (MHLW), a cooperation agreement for biopharmaceutical field with the Health Canada and an MOU with the Vietnamese Ministry of Health in 2015.

B) Establishment of an Experts' Network and Strengthening of Capacities

In January 2015, MFDS launched the 2nd MFDS Special Advisory Board which consists of 18 prestigious scholars and experts around the world in advanced biopharmaceutical field. The Special Advisory Board gives expert opinions and advice on biopharmaceutical policies and regulations, key issues and response strategies and the latest technologies and scientific trends. MFDS also held international fora and workshops to strengthen the capacities in advanced biopharmaceutical field. In June 2015, MFDS held the 「Global Bio Conference」 and approximately 2,100 people from the government organizations, industries, academia and media participated in the conference.

3) Implementation Plan

To become one of the world's seven major pharmaceutical nations by 2020, MFDS (Korea) will promote biopharmaceutical export and continue to carry out bilateral, multilateral and various international cooperation activities.

A) Becoming the Base of Multilateral Cooperation

(1) World Health Organization (WHO)

MFDS will continue to carry out the Official Development Assistance (ODA) project titled "Technical support to low and middle income countries in evaluation and licensing of biomedicines" for developing countries in the in the Western Pacific Region and provide technical support in herbal medicine field in 2016.

MFDS was designated as WHO Collaborating Centre for Standardization and Evaluation of Biologicals in January 2011. WHO reviewed the performance of MFDS over the 4 years and re-designated MFDS as WHO Collaborating Center, extending the term to January, 2019.

(2) International Pharmaceutical Regulators Forum (IPRF)

As the chair of 'BioSimilar Regulation Harmonization Working Group', Korea will hold 3 video conferences and 1 face-to-face meeting a year. Korea will also continuously share ideas with the Cell Therapy and Gene Therapy working groups.

(3) Asia-Pacific Economic Cooperation (APEC)

To harmonize biopharmaceutical regulations within the APEC regions, MFDS will analyze the regulatory differences studies over the previous workshops and designate biopharmaceutical training centers (Centers of Excellence, CoE).

B) Expansion of Bilateral Cooperation

MFDS will discuss field training and cooperation plans with the German Federal Institute for Vaccines and Biomedicines, Paul-Ehrlich-Institut (PEI) again in 2016 to strengthen the capacities of pharmaceutical evaluators. MFDS also signed a collaboration agreement with the Health Canada and it plans to cooperate with the National Institute for Biological Standards and Control (NIBSC), United States Pharmacopeia (USP) and WHO.

C) Strengthening Capacities for Regulatory Harmonization

From June 27 to July 1, to support Korean biopharmaceutical industry's advancement into

the global market, MFDS will invite experts from all around the world and hold the '2016 Global Bio Conference'. The Conference will consist of various international biopharmaceutical events, providing the participants the opportunity to cooperate and share knowledge with each other. The biopharmaceutical experts will share their knowledge and experience in the latest international trends and relevant regulatory topics.

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B. Improving the Review and Approval System for Biopharmaceuticals and Cosmetics and Leading the International Standards

1) Establishment of Future-Oriented Biopharmaceutical Review and Approval System

Considering the complexity of the structure and manufacturing process of biopharmaceuticals, there needs to be an effective evaluation system that can keep up with the advanced technological development in the biopharmaceutical industry. Also, evaluation standards for quickly and safely evaluating new, advanced biopharmaceuticals need to be established. To this end, MFDS implemented a set of guidelines and reviewer training programs, and strengthened the expertise and capacities of the reviewers. Also, biopharmaceutical experts were invited from advanced regulatory authorities, WHO, foreign regulatory organizations and the academia to share review criteria and directions for advanced biopharmaceuticals, safety management standards, regulatory trends and the latest biopharmaceutical development around the world.

2) Promotion of Vaccine Self-Sufficiency and Support for Advancement into the Global Market thorough Technical Commercialization Support

MFDS established a consultative body with Korean pharmaceutical companies to provide necessary technical support in establishing and moving vaccine manufacturing facilities and customized consultation services from vaccine development to approval process. The departmental meetings of the Biopharmaceutical Industry Development Strategy Planning Group (Dynamic BIO) launched in 2010, are used as communication channels by the biopharmaceutical industry for sharing opinions and ideas.

Currently, 11 out of the 28 vaccines that are approved in Korea, can be produced in Korea. MFDS aims to increase the number of vaccines that can be produced in Korea to 20 and enhance Korea's vaccine self-sufficiency.

3) Establishment of a Future-Oriented Review System for Advanced Biopharmaceuticals

The Korean government is continuously expanding investment in research and development to promote the biopharmaceutical industry as the country's future growth engine industry. Accordingly, MFDS has been developing relevant guidelines and improving the review and approval system for advanced biopharmaceuticals such as stem cell therapy and gene therapy. MFDS is also currently carrying out commercialization support projects for Korean researchers, providing training and consultation services according to their product development levels and stages.

[Table 2-2-1] Evaluation of Cell and Gene Therapy Products (2011~2015)

(as of Dec. 2015 , unit: case, Ref: Cell and Gene Therapy Products Division)

Statistics (original, amendment)		2011	2012	2013	2014	2015	Total
Cell Therapy Products	Product Review & Approval	7	9	11	18	17	62
	Approval of Clinical Trial Protocol	39	46	61	53	82	281
Gene Therapy Products	Approval of Clinical Trial Protocol	16	10	11	14	14	65

4) Establishment and Support of Korean Biosimilars' Global Competitiveness

Biosimilars are officially approved versions of original "innovator" products with guaranteed quality, safety and efficacy and the biosimilar industry is regarded as a new growth engine industry around the world. To support domestic biosimilar developers' global market entry, in 2009, MFDS established a legal basis by internationally harmonizing the definitions of biological products and review and approval standards in the 「Regulations on Approval and Evaluation of Biological Products」 and Etc. Then, after the operation of the 'Public-Private Biosimilar Working Group', in July 2012, the world's first antibody biosimilar called Remsima developed by Celltrion was approved in Korea. Based on the increased international recognition and credibility of Korea's biopharmaceutical industry, MFDS successfully became the chair of the 'Biosimilar Working Group' of the International Pharmaceutical Regulators Forum (IPRF)

in November 2013. In the years to come, MFDS will continue to provide internationally harmonized biosimilar evaluation standards, improve the predictability of the review and approval system, actively support the development of safe and effective biosimilars, cooperate with international organizations and foreign regulatory authorities, and lead regulatory harmonization in the biosimilar field.

5) Support of Korean Herbal Medicines' Global Market Entry

The US and European countries are working on their regulations and standards to be able to manage the traditional medicines made with natural substances as pharmaceuticals. Also, in Korea, various clinical trials are being conducted to develop herbal medicines and to introduce the developed medicines in the global pharmaceutical market.

To support Korean herbal medicines' global market entry, MFDS invited foreign regulatory authorities for a workshop and provided various information about approval systems and procedures around the world. MFDS is also currently planning to establish the revised 'Guidelines for Setting Chemical Profile of Herbal Medicine' to set quality standards according to the characteristics of herbal medicines and also establish the 'Guidelines for the DMF(Drug Master Files) of Herbal Medicine API' in response to the expanded designation of herbal medicine APIs.

6) Improvement of the Evaluation System for Quasi-Drugs and Cosmetics

A) Establishment of a Safe and Reliable Review System for Quasi-Drugs

Recognizing the need for an effective and reliable review system with the expanding scope and increasing number of quasi-drugs, MFDS has been developing review manuals by type and on standardizing the overall review system. To support the industry's product development, MFDS is currently expanding the quasi-drug manufacturing standards by type and has been developing efficacy evaluation methods by type as well. MFDS also improved the quality management and safety of quasi-drugs by improving the quasi-drug testing methods and enhanced the consistency and objectivity in review by establishing review manuals by type. Also, for quicker approval and review process and for the convenience the companies, MFDS established the manufacturing standards for deodorants and etc. In order to invigorate the industry, MFDS established the quasi-drug efficacy evaluation guidelines by type. MFDS will continue to strengthen the quasi-drug review system and develop efficacy evaluation and standard specification guidelines that can support the industry's product development. MFDS

is also aimed at revising the standards and testing methods for quasi-drugs. Moreover, to improve the consistency and efficiency of the approval and review system, MFDS will develop review manuals for rodenticides and continue to communicate with the industry by holding public seminars on the approval and review system.

B) Strengthening Product Competitiveness through Improvement of Cosmetics-Related Regulations

To promote consumers' safe cosmetics use and the development of high-quality, functional cosmetic products, the regulations related to the evaluation of functional cosmetic products need to be improved. Also, with the introduction of the cosmetics advertising substantiation policy, the ad substantiation evaluation method needs to be standardized to make objective substantiation possible. In response to the recent global movement towards banning animal testing, alternatives to animal testing need to be established to avoid using animals for testing cosmetics toxicity. MFDS will continue to add new product items to the standards and testing methods for functional cosmetics and improve the content testing method. MFDS will revised the regulations for evaluating functional cosmetic products according to the changing environment and also provide regulatory support to invigorate Korea's cosmetics industry and the industry's expansion into the global market. MFDS will working on improving cosmetics laws and regulations to promote safe cosmetics use, promote new products development by holding public seminars to improve the awareness and understanding of changed regulations and continue to promote safe cosmetics use to the public.

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Section 3

Medical Devices

1. Establishment of a Support System for Quick Commercialization of Medical Devices

A. 「Next-Generation Medical Devices 100 Project」(Customized Mentoring)

1) Background

Due to the remarkable advancement of IT·BT·NT-based infrastructure and development of ICT and wearable technologies, more advanced and easily usable medical devices are being developed in Korea. Also, with the introduction of 3D printing technology to the medical field, interest is rising in the development of custom-tailoring of a medical device to perfectly fit to the special needs of each patient's body.

As a result, the manufactures developing high-tech, convergence medical devices are in need of more professional and advanced technologies from various fields and the companies that develop medical devices through government-funded R&D projects also need clear guidelines on developing and commercializing new medical devices. To increase the rate of successful commercialization and to reduce the time it takes for the medical devices to enter the market, MFDS established a customized mentorship support system to provide technical and regulatory support throughout all stages from development of medical devices to approval.

2) Achievements

In 2015, a total of 478 mentors comprising of 138 mentors in research and development field, 192 mentors in clinical trial, 102 mentors in market authorization, l and 46 mentors in GMP, were appointed from universities and relevant institutions. A pilot project was carried out to examine the mentorship support method and operation before launching the actual mentorship support project.

To jointly improve the policies for medical devices among government agencies and to select the mentees to be supported by the customized mentorship project, MFDS set up the 'Convergence Healthcare Promotion Committee' comprising of MFDS and 5 government

organizations including the Ministry of Science, ICT and Future Planning, Ministry of Trade, Industry and Energy, Ministry of Health and Welfare and Small and Medium Business Administration. The Committee selected tasks for the mentees of the customized mentorship project.

3) Implementation Plan

After improving some areas and the weaknesses found in the pilot project, MFDS will strengthen the operation system of the customized mentorship support. 20 mentees will be selected and receive support in the whole period from product development to product release. MFDS will continue to recruit expert mentors to provide the best and in-depth technical and regulatory support to the mentees.

By coordinating mentorship support for the development of next-generation medical devices, MFDS aims to contribute to the invigoration of the domestic medical device industry and also provide support so these advanced local medical devices gain competitiveness in the global market and play a pivotal role in creating a creative economy.

B. Integrated Management of Medical Device Approval and New Medical Technology Evaluation

1) Background

To transform current medical device industry into a new growth engine for the economy, an environment which encourages industrial players to unlock their creativity needs to be established through relaxed regulations. Recognizing this, the Korean government is currently focused on improving and easing the regulations, which are outdated with the industrial development. On November 6, 2015, presided over by President Park Geun-hye, the government held its fourth ministerial meeting for regulatory reform and 'integrated management of medical device approval and new medical technology evaluation ('Integrated Management system')' was selected as one of the goals for the agenda, 'support for facilitating the market entry of new medical devices'.

The newly developed medical devices approved by MFDS cannot be used in medical institutions unless they are cleared with the new medical technology evaluation. However, some of the devices are having difficulties entering the market because they have the approval of MFDS but are not recognized as new medical technology. With the Integrated Management

system, a medical device can now go through market authorization process and National Evidence-based Healthcare Collaborating Agency (NECA)'s new medical technology evaluation together.

Also, for the medical devices to be release to the market, it took up to 470 days including the days for the approval process (MFDS, 80 days), for checking the eligibility for reimbursement (Health Insurance Review & Assessment Service, 30~110 days) and for the new medical technology evaluation (NECA, 280 days). But, to speed up this process, an Integrated Management system has been established so that MFDS's medical device approval and NECA's new medical technology evaluation are conducted simultaneously and for the two organizations to get the same results.

2) Achievements

For the integrated management system, 13 representatives from MFDS, Ministry of Health and Welfare and NECA formed the Integrated Management TF for Medical Device Approval and New Medical Technology Evaluation in November, 2015 and held six TF meetings to select the areas for integrated management and coordinate the approval and evaluation systems. Then, in January, 2016, the draft 「Guidelines on Integrated Management (pilot project) of Medical Device Approval and New Medical Technology Evaluation」 was prepared. The guidelines include the details of mutual cooperation and integrated management of the medical device approval (MFDS), confirmation of the eligibility for reimbursement (Health Insurance Review & Assessment Service) and new medical technology evaluation (NECA) and the details of the non-stop approval process specifying that the minister of MFDS must issue a final integrated permit within 120 days after the receipt of the application.

After holding a seminar (Jan. 28) with the relevant organizations (Korean Medical Association, Korean Hospital Association) as well as a public seminar (Feb. 3) with the medical device industry (manufacturers and importers) for explaining the guidelines and collecting opinions from the stakeholders, MFDS confirmed on the final guidelines and initiated a pilot project in February 22.

3) Implementation Plan

The legal grounds, detailed procedures and methods for the integrated management system, which will be implemented from July, 2016, will be introduced to MFDS' 「Enforcement Regulations of the Medical Device Act」 and the Ministry of Health and Welfare's 「Regulation

on Evaluation of New Medical Technologies」 and the revision of the two regulations will be completed by mid July. By implementing the integrated management system, the period it takes for the medical devices to be approved for release will be reduced by a maximum of 13 months (470 days → 120 days) and the medical devices will be able to enter the market more quickly as the medical institutions will be able to use the devices immediately after they are approved by the integrated evaluation process. It is expected that the additional cost (expenses for additional clinical trials and inventory management) created from delayed market entry will be saved as well.

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2. Advancement of Consumer-Centered Medical Device Safety Management System

A. Background

In Korea, the demand for medical devices is continuously rising with population aging and chronic diseases becoming a dominant health burden, and accordingly, the safety and quality management of medical devices and provision of accurate information on medical devices are becoming more important every day.

B. Achievements

For the safety management of medical devices, MFDS has been working to reinforce the quality management of marketed medical devices and medical device advertisement. First, MFDS started operating a preliminary review system on medical device advertisement since 2007 to promote safe use of medical devices and to prevent consumers from getting injured or harmed by false and deceptive ads, and reviewed a total of 22,143 cases in the past 9 years.

MFDS is also carrying out crackdown activities with the local governments, on medical device sellers that operate business in a form of ‘free trial or free experience centers’. MFDS is also conducting periodical monitoring activities with the dedicated monitoring personnel on major mass media such as internet and newspaper.

MFDS also conducts inspections on medical devices being distributed in the market for quality control and collected and inspected 607 types of products including those medical devices that are most closely and widely used by the public in 2015, and gave administrative penalties, order for recall and suspension of sales for 74 products that failed to meet relevant quality standards.

C. Implementation Plan

MFDS plans to provide accurate information on medical devices to help consumers make informed choices of products. MFDS will carry out periodic inspections on free-experience stores and medical device ads on the media and select products that produce the most consumer complaints as well as those everyday products that are most closely and widely used by consumers and continue to carry out post-market safety management on those products.

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3. Establishment of a Safety Evaluation System for Medical Devices

A. Background

Due to people's increasing pursuit of health and wellness and population aging, the medical device industry continues to expand and, with the relaxation of the Medical Device Act, the medical device management has become more important. Also, since more adverse events or incidents related to the improper use of medical devices are reported due to increased use of medical devices, the need for stricter post-market surveillance including the collection of safety information, is intensifying to secure safety of marketed medical devices.

B. Achievements

To promote adverse event reporting of medical institutions and to establish an advanced safety management system, MFDS has been carrying out the 'Medical Device Safety Information Monitoring Center' project since 2011. After analyzing and assessing the collected information

on adverse events, MFDS utilizes them to be included in instructions for use or order the medical device manufacturers to take corrective and preventive measures and ultimately to prevent the consumers from getting injured or harmed.

MFDS also re-evaluates approved or registered medical devices that need re-assessment on their safety and efficacy. From 2009 to 2013, a total of 10,105 products were re-evaluated and MFDS gave orders for clarification of precautions for use, methods of use and change the approval status on 1,222 products. MFDS also carries out re-evaluation seminars, publishes work manuals and provide various administrative services every year.

MFDS also made the medical device GMP regulations which requires the medical device manufacturers to follow international GMPs, mandatory along with the implementation of the 「Medical Device Act」 in May 30, 2004. And, by 2015, a total of 4,804 business entities including 2,396 manufacturers and 1,688 importers acquired GMP certification.

C. Implementation Plan

The number of adverse incident reports in Korea is very low compared to that in Japan and the US. To promote voluntary reports of adverse incidents, MFDS plans to expand 'Medical Device Safety Information Monitoring Centers' and carry out education programs and campaigns on adverse incident reporting for medical device manufacturers, importers and medical institutions.

MFDS will also reassess high-risk medical devices or devices that have caused a lot of adverse incidents in order to verify the safety and efficacy of marketed medical devices.

Moreover, MFDS will continue to develop and improve guidelines and training programs to improve the standards for GMPs of the medical device manufacturers. MFDS will also work on establishing mutual recognition agreements on medical device GMPs with the countries that signed FTAs with Korea to promote local medical device industry and global harmonization of our standards.

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4. Advancement of Medical Device Approval Review Process

A. Advancement of Medical Device Approval Review Process

1) Development of Guidelines for Approval Review Process for Medical Devices Manufactured Using 3D Printing

The recent increase in consumers' demands for personalized devices have led to increased interest in 3D printing technology and 3D printing is regarded as the new, innovative technology that will revolutionize the manufacturing industry. As of March, 2016, there is a total of 14 approved (registered) medical devices including the device for cranioplasty, which uses 3D printing technology.

Expecting that 3D printing will be widely used in medical devices, MFDS developed the 「Guidelines for Approval Review of the Medical Device being Manufactured Using 3D Printing」 specifying the type and formate of technical documents required when applying for the approval/evaluation of patient-customized medical devices manufactured using 3D printing.

MFDS plans to revise the guidelines expanding the scope and adding more items such as dental implants, orthopedic implants and other 3D printed items subject to the approval review process.

Also, MFDS plans to establish the 「Regulation on Quick Use of Patient-Customized Medical Devices (June, 2016)」 that will allow the medical practitioners and institutions to use patient-customized medial devices (prior to approval) made using 3D printer in emergency situations to those patients that have no other viable means of treatment

2) Clarification of the Purpose of Use, Methods for Use and Performance of Medical Devices

The detailed indications and areas of application were not included in the purpose of use the existing medical devices. So, to provide detailed and accurate information regarding purpose of use of the medical devices to the users, MFDS changed the instructions for writing a purpose of use section and now requires the applicants applying for medical device approval to submit documents supporting the purpose of use of the medical devices and to describe the purpose of use based on the submitted supporting documents.

To help the applicants prepare the purpose of use section, MFDS, with the cooperation of the medical device industry and experts, established the 'Guidelines for Approval Review of Purpose of Use of Medical Devices'. This allows the applicants to prepare and fill out the

purpose section more easily and clearly, reviewers to maintain transparency and consistency in the approval process and the consumers to get more accurate information about medical devices.

In 2016, MFDS plans to establish the 'Guidelines for Approval Review Process of the Home Healthcare Medical Devices' which includes the detailed precautions and methods for safe use of home healthcare medical devices and, also establish the 'Guidelines for Approval Review process of the High Intensity Focused Ultrasound (HIFU) Devices' which includes the features (output and purpose of use) of High Intensity Focused Ultrasound (HIFU) devices.

3) Preparation of Plans for Advancement of In Vitro Diagnostic (IVD) Medical Devices

After the implementation of the 'mandatory approval for in vitro diagnostic medical devices' (Jan. 1, 2015), MFDS prepared various plans for the advancement of the approval review system for IVD devices. MFDS developed a plan for efficient management of products that were changed from being a medicinal product to a medical device and also, to speed up the approval review process for advanced and next-generation IVD devices, MGDS prepared five guidelines including the guidelines for approval review of In vitro Companion Diagnostic Devices. Also, to provide information about the approval review process of IVD devices, MFDS published a guide on IVD devices and held a seminar as well.

In near future, utilizing medical big-data, MFDS will develop the guidelines for approval review process of disease prediction system, next-generation genome analysis technologies, Human Papillomavirus (HPV) diagnostic devices as well as TB and Nontuberculous mycobacteria diagnostic devices to advance the approval review process for IVD devices.

Also, since the evaluation of technical documents for Class II IVD devices will be conducted by commissioned private evaluators starting on Jan. 1, 2017, MFDS plans to prepare the evaluation guidelines and train the evaluators.

B. Support of Medical Device Commercialization and Provision of Safety Information

1) Quick Commercialization of New Convergence Medical Devices through a Pan-Governmental Cooperation

Currently, various government ministries including the Ministry of Science, ICT and Future

Planning, Ministry of Trade, Industry and Energy, Ministry of Health and Welfare and Small and Medium Business Administration are supporting research and development to promote the medical device industry but since the return on investment is too low, with less than 5% of the research projects being commercialized, MFDS has decided to initiate a project for quick commercializing new convergence medical devices.

MFDS signed MOUs with the key government research institutes and testing agencies and is currently support medical device commercialization. In 2016, MFDS will publish guidelines for evaluating the safety and performance of new medical devices and for evaluating the clinical trials plans and testing methods for the devices as well.

2) Supporting for the Invigorating of the u-Healthcare Medical Device Market

The development and approval of ICT-integrated u-healthcare medical devices[6] are increasing due to the advancement of medical device technologies and it is expected that the demand for clinical trials or a diagnostic support system for verifying the efficacy of these u-healthcare medical devices will increase as well. So, MFDS established a public-private cooperative group comprising relevant industry entities and the academy and prepared the 'Guidelines on Developing Clinical Trial Plan for the u-Healthcare Diagnostic Support System' which includes the details on preparing and designing clinical trial plans.

MFDS also carried out training programs for the u-healthcare medical device developers on the u-healthcare medical device approval system, patient information protection, recent trends in communications reliability technology, requirements for users and user environment and various areas that are required in the device approval process.

3) Training Professional Personnel for Supporting Medical Device Commercialization

As part of the support for commercializing medical devices through research and development and to invigorate the new growth engine of the country, MFDS initiated training programs to train professional workforce. MFDS carried out customized training programs with medical device research and development directors, approval and evaluation personnel and clinical trial investigators. MFDS carried out 23 training programs including the advanced clinical trial training program for 5 types of new medical devices, the R&D personnel's evaluation technology training program for quick commercialization, the training program on medical device testing methods and procedures and the program on medical device approval and

6) Healthcare Industry Trends, September, 2013, Vol.21. Korea Health Industry Development Institute

evaluation methods around the world as well as 5 online training programs which include a clinical trial training program.

In 2015, MFDS carried 79 sessions of training programs to a total of 1,737 participants and based on this training experience, MFDS plans to start a new customized training curriculum for experts in various fields such as medical device development, clinical trial design and medical device approval review.

4) Providing Relatable Safety Information about Everyday Medical Devices to the Public

The increasing interest in health and improvement in lifestyles have lead to increased use of medical devices but the number of consumer complaints and incidents related to everyday medical devices such as contact lenses and electric wheelchairs are continuously rising. Also, the medical devices used especially more by socially disadvantaged groups and adolescents need careful safety management so MFDS strengthened the provision of information on safe use of everyday medical devices. In 2015, MFDS provide safety information on the following 11 types of medical devices:

No.	Safety Information
1	Medical devices for New Year's gift for the elders (blood pressure gauge, personal warmer, medical vibrator)
2	Medical devices related to the Day of Persons with Disabilities (electric wheelchair, mobility scooter)
3	Medical devices used during summer vacation season (contact lens, prescription swimming goggles)
4	Medical devices related to the Pregnant Women's Day (pregnancy test kit)
5	Medical devices related to the Diabetes Day (personal blood glucose meter)
6	Guidelines on safe use of cosmetic fillers
7	Guidelines on safe use of breast implants

C. Strengthening International Cooperation and Communication

1) International Harmonization of Medical Device Regulations through the Participation in the Asian Harmonization Working Party (AHWP Working Towards Medical Device Harmonization in Asia)

MFDS was selected as the next chair (2015~2017) at the 19th Meeting of the Asian Harmonization Working Party (AHWP) held in Seoul in November, 2014. AHWP is comprised

of experts and representatives from the medical device regulatory authorities and the medical device industry in Asia and ten working groups which include working groups for medical device approval, quality control, clinical trial, standards and etc. AHWP also published international standard guidances such as software guidance.

To actively participate in the AHWP as the next chair and to strengthen the competitiveness of Korea and domestic medical device manufacturing industry, in February 2015, MFDS launched a public-private international cooperation team called, Mirror Committee comprising of 10 working groups and 120 experts from the medical device industry and relevant organizations. The Mirror Committee has developed international standard guidances, carried out surveys on regulations around the world and have been supporting the AHWP chair responsibilities. The Committee held quarterly meetings to share its activities.

In March and September, 2015, to cooperate with other international organizations around the world, MFDS participated in the International Medical Device Regulator Forum (IMDRF) which is comprised of advanced countries such as the US, EU and Canada, and shared MFDS' strategic goals and work implementation plans for the next 3 years as the chair of AHWP and also its intent to cooperate with the member states and organizations (IMDRF, WHO, APEC, PAHO). MFDS suggested that AHWP will actively participate in IMDRF's working group and also sent the AHWP representatives to IMDRF's workings groups for 「Adverse Event Terminologies and codes development」 and 「Approval Review Documents」.

As the chair, in November 2015, MFDS held the 20th AHWP annual meeting and the 19th AHWP Technical Committee (TC) Meeting in Thailand and a total of 300 people from 28 nations and 9 international organizations participated in the meetings. Mongolia and Kazakhstan have become the latest member economies to join the Asian Harmonization Working Party, making AHWP comprised of a total of 26 member states. AHWP also approved 12 international standard guidances and launched the Capacity Building Program for the developing nations among AHWP members and prepared detailed plans for cooperating with international organizations.

In 2016, MFDS will suggest international standard guidances for 'minor changes report' and 'approval review process of in vitro companion diagnostic devices' and introduce them to the annual meeting. MFDS will also hold AHWP Executive Meeting and Regulatory Authorities Meeting (April 2016, Seoul), the 21st AHWP Annual Meeting and the 20th AHWP Technical Committee (TC) workshop (November 2016, Thailand) and continue to strengthen its relationship with various international organizations (IMDRF, WHO, APEC, PAHO) to harmonize medical device regulations around the world.

2) Enhanced Consumer-Customized Communication Service

Korea's medical device industry is regarded as a key industry that will lead Korea's creative economy in the future. Thus, by developing a public-private communication system for preemptive consideration of various issues and agenda related to the approval review process of medical devices, the gap between technology and regulation needs to be reduced to respond and adapt to rapidly changing medical environment.

To establish a public-private communication system, MFDS has been running working committees in clinical areas and a total of 20 working committee were established in 2015. Also, to develop next-generation agenda in the medical device field, MFDS held the 1st International Medical Device Communication Forum (MDCF) in September and the 3rd Medical Device Communication Forum in November with the participation of 307 people. MFDS also published and promote the '2015 Medical Device Review Department's Communication Casebook' which includes the achievements of the communication channel operated in 2015.

In 2016, MFDS will continue to strengthen the public-private communication system. In the 2nd International Medical Device Communication Forum which will be held in June, MFDS will invite medical device regulatory authorities around the world and offer a place for global communication and cooperation for mutual, regulatory advancement and harmonization.

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2016 MFDS White Paper

Ministry of Food and Drug Safety

IV

Risk Prevention

Section 1

Establishment of a Basis for Consumer-Focused Preemptive Risk Prevention and Crisis Response System

1. Establishing a Basis for Preventing Safety Accident

The capacity to cope with crisis needs to be strengthened through systematic education and training as well as enactment and revisions of a crisis response manual to minimize the damage with a prompt and preemptive response in the occurrence of food or pharmaceutical safety accidents.

MFDS has established and has been operating a crisis response manual specifying actions to be taken against food and drug safety emergency situations. The crises response manual describes specific details of actions to be taken immediately at the time of crisis situation as well as a response system that can be actually utilized in the field with minimum formalities. In addition, MFDS has prepared and distributed the 'Guidelines on Risk Management in Food Business' to promote and facilitate prompt response of persons in charge of safety accidents in the field and also, set up and carried out a practical course on food and drug safety crisis response program and simulation training to reinforce crisis response ability of MFDS and public officials in local governments.

Meanwhile, to prepare for food and pharmaceutical safety emergency situations, MFDS has been carrying out a pan-governmental safety training called, 'Safety Korea Exercise (SKE)' every year and to share information about crisis response systems at home and abroad, MFDS has held the "1st International Food and Drug Crisis Response Symposium".

In 2016, to be able to execute the crisis manual in actual emergency situations, MFDS will revise and improve the manual and also, as the central risk managing organization, it will focus on training personnel capacities in first-arrival response to crisis. MFDS will develop risk management manuals for industries and local governments as well to enhance the overall risk management capacities for the food and drug safety.

2. Establishing a Food and Drug Safety Management System through Precautionary Safety Management

A. Precautionary Risk Management and Reduction of Toxic Substances

1) Preliminary Investigation of Hazards/Risk Factors

MFDS analyzed food hazard information which have been gathered at home and abroad since 2006, and carried out preliminary investigation on foods that are likely to include potentially hazardous substances and prepared safety measures after sampling and testing the foods. After the preliminary investigation, MFDS took corrective measures and administrative actions such as recall and disposal of the products that failed to comply with relevant food safety standards and specifications, and prepared provisional safety actions including hazard assessment and substance planning against the potentially hazardous products for which standards and specification are not yet specified.

For the 2015 preliminary investigation, MFDS directed its focus towards those potentially hazardous substances for which standards and specifications are not yet specified and, strengthened its work to eliminate any safety blind spot collecting and testing 970 cases of 9 food products. This was 21% increase in the number of inspected cases compared to the 801 cases which were investigated in the previous year. The investigation showed that acrylamide in roasted coffee, Bacillus cereus in raw fish, Staphylococcus aureus in dried meat(fish)/ice cream, residual pesticide in vegetables, Zeranol in chicken meat and Ethyl carbamate in alcoholics beverages were either not detected or were found at concentrations safely below the recommended levels. However, for the two alcoholic beverages that showed concentrations of preservatives (benzoic acid/sorbic acid), MFDS took safety measures (retrieve and disposal/cutoff distribution/administrative penality) on the beverages in question.

In 2016, MFDS will continue to collect and analyze hazard information at home and abroad, gather opinions from relevant organizations and departments and carry out preliminary investigation on about the same number of food items (900) to block and eliminate potential hazards in advance.

2) Reduction of Harmful Chemicals Unintentionally Created in the Process of Food Manufacturing and Processing

Since 2001, through a research project on reducing harmful chemicals (acrylamide, biogenic

amine, ethylcarbamate and benzopyrene) unintentionally generated in the course of food manufacturing or processing, MFDS has continuously carried out status investigation, risk assessments and development of harmful chemical reduction technology and, has successfully developed harmful chemical reduction technology for a number of chemicals.

With regard to acrylamide unintentionally generated in the course of manufacturing and processing of snacks using potatoes as raw material, MFDS has been providing a chemical reduction technology in the field since 2006 and now, safely, most products show only less than 1 ppm, the recommended value, of acrylamide concentration.

Acrylamide is one of the substances that are unintentionally created in the process of storage and maturing process of some foods (alcoholic beverage, etc.). MFDS organized and operated a reduction task force and worked with the National Tax Service, Korea Alcohol Liquor Industry Association, food industry and the academia since 2007 to reduce unintentional occurrence of acrylamide in foods. Also, MFDS developed the 'Manual for Reducing Acrylamide in Alcohol Beverages' (Apr. 2011) and by continuously providing the chemical reduction technology and carrying out monitoring activities, the acrylamide concentration in foods dropped safely below the recommended level (0.4 ppm).

Biogenic amine is created when the food containing protein is being decomposed by microorganisms. MFDS continuously worked on reducing biogenic amine in fermented food products and recommended (March, 2009) the industry and businesses to follow self-imposed guidelines for reducing biogenic amine to less than 500ppm, the goal of reduction of biogenic amine in fermented soy products. To further reduce biogenic amine in food products, MFDS also started providing technical field support to small-to-medium-sized companies that need support for reducing chemicals in food.

Moreover, after the 2012 incident where benzopyrene was detected in dried bonito which is a raw material of ramen soup, MFDS developed and distributed educational and campaign videos for chemical reduction and continued to provide customized technological and analysis field support for reducing hazardous chemicals during food manufacturing and processing to small-to-medium-sized companies (2004). After the field support in 2015, it was shown that benzopyrene in sesame oil has been safely reduced below the recommended level (foods with benzopyrene concentration exceeding the standard level of 2 ppb: less than 1%) and MFDS is still working very hard to reduce benzopyrene in perilla oil by providing field support to small-to-medium-sized companies.

MFDS plans to continuously push forward with the "Harmful Chemical Reduction Support Project" which supports customized technology (consultation service) and analysis (checking

reduction improvements) for small and medium-sized companies that can't afford harmful chemical reduction technology and start providing this support to catering/restaurant businesses as well.

3) Establishment of a Basis for Safety Management of Tobacco Products

Tobacco contains various harmful substances such as nicotine or tar but many countries including Korea have been lenient on tobacco control. So, WHO adopted the treaty, 「Framework Convention on Tobacco Control」[7] specifying price and no-price policy to reduce demand and supply of tobacco (May 2003) and 180 countries including Korea (May 2005) ratified it. The countries that ratified the treaty prepared and are currently implementing various kinds of policies related to comprehensive tobacco regulations including increase in tobacco price and public release of tobacco ingredients.

Under the 「National Health Promotion Law」, the Korean government has been designating increasingly more no-smoking areas and increasing the tobacco price to reduce smoking rate. The revised 「National Health Promotion Law」 (Sep. 2012) that makes MFDS in charge of the tobacco product safety control policy such as disclosure of tobacco ingredients and registration of tobacco products, has also been pre-announced. And, since 2013, to establish a basis for safety control of harmful ingredients in tobacco, MFDS has been carrying out research projects for analysis of harmful ingredients of tobacco and other tobacco safety areas.

As the National Assembly and the press media are demanding MFDS which has the independence and professionality in product safety management, to carry out safety management of tobacco, MFDS will actively try to secure a basis for safety control of tobacco products by disclosing tobacco contents and carrying out hazard analysis on tobacco and etc.

3. Strengthening Cooperation with Consumer-related Organizations and Groups

Recently, consumers have shown increasing interest in the whole process of manufacturing, distribution and sales, identifying and improving problems related to safety of consumers. The relationship between consumers and businesses producing products has also changed from

7) The first international health treaty unanimously adopted by WHO in May 2003. As of Jan. 2015, 180 countries ratified. It consists of price and non-price policy for reducing supply and demand of tobacco and various institutional policies.

the adversarial relationship in the past to a mutually developmental relationship working for consumers' safety. Thus, a cooperative system for consumers and relevant organizations and groups needs to be established so that consumers can actively participate even in the process of developing and executing food and drug safety policies.

MFDS has been working to protect consumers' safety, rights and interests by cooperating with consumer groups in the food and drug safety field. In 2007, MFDS signed a MOU for mutual cooperation with the Korea National Council of Consumer Organizations which represent 10 consumer organizations and has been sharing information about various risks to people's health, carrying out safety promotions and educational campaign related to safety and conducting research for improvement of food and drug safety. Moreover, in 2015, MFDS held a seminar with the representatives of 10 consumer organizations to share government policies and discuss social agenda related to food and drug safety and also, held joint workshops with various consumer groups and the industries to promote better communication.

In addition, MFDS signed an MOU with the Korea Consumer Agency in 2009 and started sharing information related to hazards and conducting joint investigation and research related to food and drug safety.

In 2015, MFDS renewed the MOU and established an advance consultation system for official announcements to prevent confusion from inaccuracy of or the difference in opinions towards the public release of information related to food and drug safety. MFDS and the Korean Consumer Agency also jointly investigated and announced social agenda related to food and drug safety and established a communication channel to strengthen the cooperative relationship between the two organizations.

In 2016, MFDS and the Korean Consumer Agency will continue to carry out joint investigations and research, advance consultation prior to any public announcement, working group meetings and joint workshops. MFDS will also commission consumer safety education to various consumer groups, collect consumer hazard information and hold periodical seminars with the consumer group representatives to understand consumers' interests and concerns and improve any consumer safety issue.

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Section 2 Promoting Food and Drug Safety Consensus by Strengthening On-site Communication

1. Promoting Communication with the Public

To gather opinions from all walks of life and to allow public's active participation in policies, MFDS established a two-way communication channel between the public and the government and has been providing food and drug information that can be helpful in everyday life through on-and offline.

To identify consumers' concerns and complaints regarding food and drug safety, MFDS analyzes consumer consultation cases, surveys and the media.

MFDS set up a management committee to choose key issues and agenda and to get feedbacks on important safety information. Through the committee, MFDS cooperated with relevant ministries and carried out guidance and investigation activities, surveys, improved relevant policies, gave improvement orders and provided life-related information to the public.

MFDS also held a consumer forum every year, invited the public to discuss and participate in food and drug safety issues. The consumer forum was held as the previous year, 4 times in 2015 to gather the opinions of various parties interested and to establish a social consensus on important topics.

MFDS offers people the opportunity to discuss and participate in not only food and drug policies but in various food and drug information that are closely related and useful to people's lives.

MFDS will continue to maintain an effective two-way communication channel to hear what people have to say and to establish a safety consensus and safe environment. MFDS will continue to provide age-specific and seasonal, food and drug safety information as well.

2. Establishing and Operating a Communication Network

To communicate with the government ministries effectively in the occurrence of food and drug safety issues, MFDS established the 'Public-Private Communication Committee for Food and Drug Hazards (9 ministries, 37 civilian members)'.

The Committee discussed plans for public communication on 'safety management of radiation contamination in domestic and imported food' on June 24, 2014 and, on November 25, the committee discussed plans for 'developing educational contents for national food and drug safety courses' and about developing educational materials for preventing allergic reactions to food. In 2015, the Committee discussed and shared experiential programs the government ministries can offer during the free semester period (Feb. 27), 'improving the function of the control tower for food safety management', 'direction of food safety management which the consumer expects' and various matters related to developing policies for safety management of foods such as foods sold nearby schools which are very closely connected to people's lives.

MFDS also operates the Communicators Advisory Committee comprised of consumer groups and experts in communication, promotion and various other fields. The Committee received advices from experts and homemakers on key topics such as 'preparing communication messages relevant to the public' (June 12) and 'unification of testing organizations and appropriateness of maintaining the perceived level of food safety' (September 1) and also received written advices for preparing public messages on HACCP policy promotion and aluminum consumption.

Also, to communicate effectively with the public in the occurrence of food and drug safety issues, MFDS carried out communication training with the food and drug safety departments, 6 regional offices of food and drug safety and local government officials on communication strategies, methods, preparing communication messages, analyzing communication and building the capacities for communication on food hazards. In 2015, the 'Public-Private Communication Committee for Food and Drug Hazards' will hold working group meetings to discuss effective response in the occurrence of food and drug safety hazards and continue to strengthen its communicative function and develop useful public messages by utilizing the Communication Advisory Committee.

3. Operating Public Experiential Programs

To strengthen the communication with the public and provide people the opportunity to experience food and drug policies, MFDS has been operating public experiential programs. MFDS opened up 'Consumer Food and Drug Safety Course' to provide useful information on safe use of food and drugs to homemakers and the elders. The course was held a total of 64 sessions in Seoul, Gyeonggi Province and Daejeon and a total of 3,133 people participated

in the course. The participants' satisfaction rate for the course was high at 92 points.

MFDS also launched a program called 'Food and Drug Safety Junior' and gave youth the opportunity to experience the actual food and drug safety works carried out by MFDS. A total of 3,072 middle school students participated in the program at 6 organizations including MFDS and regional offices of food and drug safety. In addition, MFDS started a youth (middle school and high school students) communication expert training program called 'Young Leaders' where the students become experts who share food and drug safety information voluntarily with people around them. In 2015, 57 teams, 209 people (22 middle school team, 35 high school team) were selected for a campaign called 'Know Your Health Functional Food'. The students selected throughout the country shared food and drug information with people online and offline for about 3 months based on the safety promotion proposals they submitted to MFDS. After the promotional campaign, their activities were evaluated and 12 teams with excellent performance received Ministerial award and prizes. The activities of the 'Young Leaders' were used to make excellent activity case book and this book was distributed to the Ministry of Education and consumer groups.

In addition, to spread safe and useful food and drug safety information, MFDS expanded and operated the 'Food and Drug Safety Monitor'. Currently, 200 people '7th Food and Drug Safety Monitor' program (Sep. 1 2014~Aug. 31, 2015) are active monitors and they not only share safety information through social networks and workshops but are given opportunities to work as policy monitors on education by region. The Food and Drug Monitors spread and shared about 70,000 cases of safety information and key safety policies of MFDS.

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Section 3

Enhancing Transparency, Sharing and Use of Food and Drug Safety Information

1. Collecting, Analyzing and Utilizing Food and Drug Safety Information

A. Enhancing Transparency, Sharing and Use of Food and Drug Safety Information

1) Background

Due to increase in trade volume with the expansion of FTA, more thorough safety control on food and drugs is needed. MFDS has established a structured system and is currently operating the system with various organizations to quickly and efficiently respond and take preventive actions based on domestic and foreign food and drug safety information collected and analyzed. Online and offline, food-related information are gathered by the National Food Safety Information Service and, the information about medical products are gathered by expert translators for each language region.

MFDS also maintains close relationship with the embassies and international organizations and gathers information on issues occurring overseas. MFDS also utilizes overseas Korean residents and the Overseas Information Reporters to get information regarding relevant regulatory policies and safety issues happening in foreign countries.

2) Achievements

A) Quick Collection and Analysis of Risk Information

Expeditious collection and delivery of food and drug safety information are critical for national safety. MFDS has been providing the collected information immediately to relevant government departments and industries to minimize risks to the public

From 2013 to 2015, MFDS collected a total of 97,710 pieces of information related to food and medical products and also collected and analyzed information about food risks and hazards related to the Japanese nuclear disaster that occurred in Fukushima.

In terms of the amount of collected food safety information online per country, top three countries were China, USA and Taiwan. The information collected from sources of the countries was mostly about chemicals, microorganisms and residual pesticides, respectively.

B) Utilizing Overseas Information Reporters

In 2015, the Overseas Information Reporters collected a total of 1,200 pieces of local information including 448 routine reports and 752 in-depth reports. These information were analyzed and used for developing policies. On the 'current status of labeling management and distribution of Halal-certified foods' and 'foreign mosquito repellents', relevant information was promptly supplied by the local information reporters and delivered to relevant departments.

The collected and analyzed information is being delivered to MFDS and its departments, 10 other government organizations (51 people), 16 public health and environment research institutes and to relevant public officers (278 officers) in 17 local governments to prevent food and drug-related safety accidents in advance.

C) Quick Processing of Risk Information Related to Food and Medical Products

All the risk information is collected simultaneously via online and offline. Online risk information related to medical products is collected by language-specific translators at the Risk Information Division of MFDS.

(1) Food

In 2015, in regards to the 23,709 risk information collected for 365 days by the National Food Safety Information Service through 276 websites in 52 countries over 6 language regions, MFDS took 134 safety actions such as strengthening inspection on imports of the items in question and collecting and analyzing the items being distributed in the market.

(2) Medical Products

MFDS' Risk Information Division daily monitors 148 websites in 21 countries for risk information related to medical products and by analyzing the information, MFDS takes preventive actions to prevent hazards related to medical products.

On June 8, 2015, one Japanese news article covered a story about Kaketsuken, a major manufacturer of blood products and vaccines, and its use of unauthorized additives and improper production processes and told that some of the shipment of the products have been suspended. Later on November 26, 2015, it was found that the same company has also been

manufacturing blood products and vaccines using unauthorized and illegal procedures for over 20 years. The vaccine products and vaccine solutions were being imported to domestic markets so MFDS immediately inspected the imports and strengthened testing and inspection for all the vaccine lots. This is an example of a preventive safety action that was executed through continuous monitoring and analysis of risk information on incidents that occurred overseas.

On November 24, 2015, the U.S. Food and Drug Administration (FDA) has issued a safety communication warning to physicians that hydrophilic and/or hydrophobic coatings on several types of intravascular medical devices could separate and cause serious injury or death to patients. The lubricious hydrophilic and/or hydrophobic coatings on these devices are intended to reduce friction between the surface of the device and the vascular lining during cerebrovascular or cardiovascular peripheral vascular operations. To prevent potential hazards, MFDS immediately notified this risk to the Korean Hospital Association and Korean Medical Association.

D) Utilization of Risk Information of Food and Medical Products

(1) Providing and Utilizing Customized Information

In the past, MFDS has prevented the sale of unwholesome or defective foreign foods and medical products which are not officially imported to Korea but can be purchased by consumers via online. MFDS currently provides information about hazards and risks related to purchasing goods from foreign online shopping sites through the 'Overseas Direct Purchase Hazard Information Room'. The Information Room provides information about foreign hazardous foods, Q&A section on overseas direct purchase, Korea's testing and inspection of defective products, cartoons about safe direct purchase and various public awareness videos.

To prevent foreign hazardous foods from flowing into the country and protect people's health, MFDS requested the Korea Customs Service to block potentially hazardous foods at customs and requested the Korea Communications Commission to block websites advertising and promoting hazardous foods.

Also, since the risk of exposure to foreign hazardous foods and medical products has increased due to the increased number of people traveling abroad, in July 2013, MFDS started notifying information about hazardous and defective foreign food and medical products through the electronic display boards near the duty-free shops and departure gates at Incheon International Airport.

(2) Strengthening the Competitiveness of Korean Exporters by Providing Useful Information

To strengthen the competitiveness of domestic exporters, MFDS provides information about foreign food standards, specifications and policies on a section called 'Export Food Information Room' on its food safety web portal (www.foodsafetykorea.go.kr). MFDS also analyzes and reviews the differences between foreign food standards and specifications, cases of exported domestic products that were found to be defective, allergy causing foods, and food-related policies and provides relevant information periodically to the industry to prevent defects from same causes.

3) Implementation Plan

To expand the scope of information collection, MFDS plans to enhance management of information sources and periodic analysis of information on major foreign websites, provide more systematic education and training to overseas information reporters to enhance their information collecting capacity, and add more personnel and target countries. To improve the quality of information collected by the overseas information reporters, MFDS will periodically revise and adjust requirements for reporters, the scope of information and the methods for evaluating the information. In addition, for prompt and accurate information exchange, MFDS will reinforce year-round information exchange system by setting up hot lines with main trading partners of Korea in Asia region.

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Section 4

Enhancing International Competitiveness through the Advancement of Testing and Inspection Agencies

1. Overview of Testing and Inspection Agencies

Testing and Inspection Agencies are categorized into two groups: testing organizations prescribed by the Ordinance of the Prime Minister (Prescribed agencies), and the ones designated by the Minister of Food and Drug Safety (Private agencies). They conduct testing and inspection by collecting test samples at the stage of import or distribution. Applicable regulations mandate manufacturers of foods or livestock products to perform self-quality control for their products, while allowing those who are not equipped with proper facilities and equipment for testing and inspection to entrust such task to a MFDS-designated testing and inspection agency. The Minister of Food and Drug Safety has recognized 59 testing organizations from 9 countries as Foreign Testing Laboratories (FTLs) to improve efficiency in testing and inspection of imported foods, etc.

2. Designation and Follow-up Management of Testing and Inspection Agencies

MFDS has designated and operated testing and inspection agencies by sector in order to ensure the safe management of foods, livestock products, and pharmaceutical drugs. Any testing organization seeking to be designated as a testing and inspection agency shall meet requirements for facilities, equipment, human resources, etc. necessary for testing and inspection, and file an application for designation with MFDS. Following the receipt of application, MFDS performs the application review and on-site audit to ascertain whether the applicant meets the requirements for designation. The testing organizations recognized as a testing and inspection Agency are subject to periodic inspection and supervision by MFDS.

3. Improved Reliability & Advanced Management System of Testing and Inspection Agencies

There was a need for MFDS to develop an advanced management system of testing and

inspection agencies to ensure the reliability of testing and inspection results produced. Since 2009, based on international standards on testing and inspection agencies, MFDS had established and implemented "an advanced testing and inspection agency management system" that fits Korea's circumstances. The system has been upgraded to "the Quality Assurance standards on Testing and Inspection Agencies" in 2014, allowing for greater reliability of test results and better compliance with international standards. The details of the standards are specified under the 「Regulation on Evaluation of Food and Drug Testing and Inspection Agencies」

A. Improvement of Relevant Regulations and Systems, including Stricter Requirements for Designation of Testing and Inspection Agencies

In July 2013, in order to manage and support food and drug testing·inspection agencies in a systematic and efficient manner, MFDS developed integrated regulations concerning testing and inspection agencies that had been scattered in 6 different laws of the 「Food Sanitation Act」, the 「Health Functional Foods Act」, the 「Livestock Products Sanitary Control Act」, the 「the Pharmaceutical Affairs Act」, the 「Cosmetics Act」 and the 「Medical Device Act」.

In an effort to harmonize domestic regulations with international standards and better support food and pharmaceutical industries, the 「Testing and Inspection of Food and Drugs Act」 (enacted on July 30, 2013, enforced on July 31, 2014), the enforcement decree and the enforcement rule of the same Act were enacted.

In the process of revising relevant sub-regulations, MFDS integrated 7 different regulations governing testing and inspection agencies into a single, unified 「Regulation on Evaluation of Food and Drug Testing and Inspection Agencies」 to improve administrative efficiency and enhance public convenience.

B. Reinforcing Periodic Inspection of Testing and Inspection Agencies

MFDS performs regular inspections of testing and inspection agencies to preemptively prevent poor testing practices and ensure their sustainable management. In 2015, regular and/or special inspections were conducted on testing and inspection agencies for Foods (80 organizations), livestock products (48), pharmaceuticals (11), cosmetics (12) and medial devices (15). The main purpose of the inspections were to see whether they had taken corrective measures required from the previous year, and whether they had violated certain regulations that might pose a risk to public health. In particular, the special inspections focused on the following: (1)

issuance of false test reports, (2) non-compliance with test methods and standards, and (3) unique identification of test materials.

C. World-class Support for the Development of Testing and Inspection Agencies

MFDS developed the Laboratory Information Management System (LIMS) in 2009 to advance the use and storage of data relating to testing activities. Since then, the system has been gradually adopted in public health and environment research institutes across cities and provinces, private food sanitation inspection agencies and drug testing and inspection agencies. Under the 「Testing and Inspection of Food and Drugs Act」, which was revised in December 2015, all testing and inspection agencies have been required to establish and use the LIMS, enabling MFDS to track every stage of testing procedures. In 2015, each testing and inspection agency was provided with tailored technical support on compliance with quality assurance standards, management of internal proficiency testing, maintaining traceability, and measurement uncertainty, etc. Also, evaluations on quality assurance were carried out for 24 testing and inspection agencies in the same year.

D. Establishment of National Reference Laboratories

With ever-changing dynamics of global trade, as evidenced by FTAs and TPPs, and an increase in international trade, it is expected that the demand for testing and inspection will grow to ensure food and drug safety. To improve the reliability of test and inspection results to global standards, MFDS is currently working on establishing National Reference Laboratories(NRLs).

MFDS plans to establish NRLs for 25 test items from 2016 until 2020. The selected items include the substances considered potentially harmful, or the ones with high levels of unsatisfactory results. The NRLs develop, provide and verify standard testing methods, offering scientific and technical support in testing and inspection. They also promote collaboration with international reference laboratories around the world. The legal basis for these laboratories will be prepared by revising the Act on Testing and Inspection of Food and Drugs in 2016. The NRLs testing 7 items, including Nitrofuran metabolites, will be set up this year.

E. Enhancing the capability of Testing and Inspection Agencies home and abroad

Proficiency testing is performed annually to improve the capability of testing and inspection agencies by providing reference materials whose property values are safe and sufficiently homogeneous. This is to evaluate testing competency of each organization, including the ability to produce accurate and precise test results. In 2015, a total of 200 testing and evaluation agencies conducted proficiency testing on 26 items including micro-quantity nutrients, and those who received "Questionable" or "Unsatisfactory" grade in a proficiency testing were required to conduct cause analysis and take corrective measures.

F. Facilitating Communication and Promoting Collaboration with Testing and Inspection Agencies

MFDS organizes an annual meeting with representatives of testing and inspection agencies to strengthen mutual cooperation. In 2012, the Korea Food Testing Laboratory Association was established not only for healthy development of and competition between testing and inspection agencies, but also for greater cooperation. An english web-site for foreign testing laboratories(FTLs) has been created to improve information-sharing, and e-Newsletters have been published in English to strengthen communication between MFDS and FTLs.

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2016 MFDS White Paper

Ministry of Food and Drug Safety

V

Research and Development for Food and Drug Safety

Section 1

Research and Development that are Directly Linked to Safe Life

1. Improvement of Food and Drug R&D

The strengthening of MFDS' responsibility and role is being strongly demanded as the public's interest in food and drug safety rises and with the government's strong will in securing national health and safety management. To meet these demands, MFDS established a mid-to-long-term master plan for research and development projects, carried out preliminary research based on laws to figure out the unmet demand in terms of food and drug safety and continuously strengthened its research and development functions to reduce the levels of public insecurity.

MFDS' key R&D budgets increased and were set to a total of 79.27 billion won in 2016, being managed over 6 areas; 'food safety management' (26.98 billion won), 'pharmaceutical safety management' (22.4 billion won), 'medical device safety management' (7.3 billion won), 'safety evaluation technology research and development' (14.55 billion won), 'advancement of safety technology' (3.84 billion won), 'livestock and marine product safety management' (4.2 billion won).

In 2015, MFDS established standards and specifications for safety management of food and drugs, continuously expanded the guidelines for the approval of medical devices and stem cell therapy medicines and the safety management of cosmetics. Also, MFDS strengthened expertise and made academic and commercialization achievements in food and drug safety.

MFDS' major achievements include, development of 50 authenticity testing methods for fake and unwholesome sesame oil, ginseng (red ginseng), Cynanchum wilfordii, Pleuropterus multiflorus, halal foods and fake pharmaceuticals, development of a method for testing unapproved GMOs and completion of 32 tests for the possibility of protein in GMOs to cause allergic reactions. MFDS also investigated tadalafil (Cialis) and other similar banned substances for the first time in the world and, developed and supplied the testing methods. MFDS also carried out risk assessment of raw substances (38) in household chemical products such as wet wipes and detergents, leading a pan-governmental safety assessment of products since the humidifier disinfectant incident.

In terms of international harmonization of regulations, MFDS prepared guidelines (11) for alternatives to animal testing which are harmonized with OECD's standards and shared

alternatives to animal testing, testing research management and current trends in the US and EU by holding a meeting for the International Cooperation of Alternative Test Methods (ICTAM). MFDS also developed ten animal disease models including 6 cancer and metabolic disease models, 3 circulatory and immune disease models and 1 drug metabolism model.

To strengthen the development of safety technologies that can make people feel safe, MFDS solved urgent safety issues by focusing investment in the safety management of food and drugs that are closely linked to people's lives. Also, through research of alcohol-related safety, studies in risk and toxicity assessment of tobacco products and research of narcotics safety technology advancement, MFDS is taking preemptive and preventive actions for the long-term national safety. To improve the efficiency in the R&D investment, planned preliminary research has been made mandatory and as last year, planned preliminary research will be conducted in 2016 as well. In 2016's preliminary research, research topics for 2017, mid-term funding plan for post-2018 and MFDS' R&D investment roadmap will be prepared. Also, MFDS will establish the 「Master Plan for Promoting Safety Technology for Food and Drugs」 and carry out R&D projects that are linked to the mid-term plan established through a systematic, top-down planning process.

Nam Bong-hyun, Director of Research Planning and Management Division
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2. Impartial Research Management and Provision of Services for Researchers

To establish transparency and impartiality in research projects, MFDS manages the selection, notification and evaluation of research projects through a research management system. MFDS also provides various services so that researchers can carry out projects fully understanding the laws and regulations for executing and managing MFDS' research funds which are general accounts.

In 2015, through 5 sessions of selection evaluation process, a total of 354 research projects have been selected. Among them, 118 MFDS' self research projects and 236 research service projects including 11 big and combined projects were carried out by the research project teams. In 2015, final end-of-year/continued next year on research or not assessment of the feasibility of research projects and the level and completion of research outcomes were carried

out over 14 sessions. The assessment results were used to improve the usability of research outcomes for developing policies.

In 2015, the number of and funds for research service projects increased compared to 2014 (202 projects → 235 projects, 47.8 billion won → 57.8 billion won) and 11 big and combined projects were carried out by the research project groups. In 2015, the sub-projects for the safety management of hazardous substances were combined with the sub-projects for the safety management of food and etc and, the number of sub-projects was reduced from 7 to 6.

To help the researchers in research service projects understand how to use, manage and balance research funds, MFDS published and distributed the 「Guidelines for Research Service Project Researchers」 and, held a seminar on 「2015 Research Service Project Fund Usage Report」. Every year, MFDS holds a seminar on 「New Research Service Projects」 to provide information on the status of selected research service projects. MFDS also introduced and implemented a commission policy through accounting firm for balance accounts of research funds to establish transparency and accuracy in the use of research funds.

MFDS plans to continuously revise and improve the 「Guidelines for Research Service Project Researchers」 to provide most up-to-date and accurate information on MFDS' research and development projects. MFDS will also hold the 「MFDS Outreach Research Fund Usage Seminar」 to promote proper use of research funds and establish a transparent and reliable environment for research fund management. By enhancing forward the Research Management System Project (http://rnd.mfds.go.kr) which MFDS initiated in 2015, MFDS will develop a user-friendly, research management system that will allow more flexible and efficiency information exchange.

Kim Mi-jung, Director of Research Management TF
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3. Outcome Management for Effective Research and Development Projects

MFDS' research and development outcomes are used as scientific data and basis for developing food and drug policies. MFDS manages research and development projects, from project planning to outcome evaluation, by setting outcomes goals and indicators for individual sub-projects.

To manage project outcomes, MFDS carries out follow-up evaluation for utilizing the

outcomes of completed projects and actively participates in the investigation, analysis and assessment carried out by the Ministry of Science, ICT and Future Planning to use project outcomes as the basic data for planning policies and future projects. The personnel information, research projects and outcomes of MFDS's research and development projects can be found on the National Science & Technology Information Service (NTIS).

The outcomes of MFDS' research and development projects are used mostly for developing policies and ultimately for improving the quality of life. There are five indicators of the project outcomes and they include the policy suggestion performance, the actual usage (%) of project outcomes in policies and etc and, the indicator scores are improving every year.

In 2015, mid-term evaluation on 4 of the 6 R&D sub-projects of MFDS were carried out and they received 'satisfactory' rating in the meta-evaluation carried out by the Ministry of Science, ICT and Future Planning and, the evaluation results were taken into account for planning next year's research and development budget and projects.

MFDS also carries out a follow-up evaluation every year to analyze the areas that need improvement. In 2015, MFDS investigated and analyzed the the outcomes and performance of the 6 sub-projects which include 'food safety management' (26.98 billion won), 'pharmaceutical safety management', 'medical device safety management', 'safety evaluation technology research and development', 'advancement of safety technology' and 'livestock and marine product safety management.'

To improve the efficiency and structure of R&D project management, MFDS worked on advancing the MFDS Research Management System and started running the system in March 2016. MFDS also plans to set up the 'Internal Evaluation Committee' to carry out in-depth and comprehensive outcome analysis and improve the reliability of the internal evaluation on 'project outcome indicators'. MFDS will set challenging yet reasonable goals that fits each project's implementation methods and also take into account the appropriateness of outcome indicators, the feasibility of evaluation methods, rationality of the project outcome goals and the appropriateness of weighted value set on project goals so that the outcomes can be qualitatively and quantitatively measured in detail.

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Section 2 Expanding Risk Assessment for Scientific Food Safety Management

1. Improvement of Risk Assessment System with Expanded National and International Cooperation

Risk assessment is very important in that it provides the scientific basis for deciding on risk management policies and for reducing the public's concern towards hazards. To protect people's health, MFDS develops safety standards on potentially hazards and harmful substances in food, establishes a risk assessment for preventive and follow-up safety management and, develops new assessment methods.

MFDS also established the Monitoring Information Management System (MIMS)/Monitoring Database and Assessment Program (MAP), established the Hazard Substance Database, set up Maximum Permissible Exposure limits for hazardous substances and food additives and established a method for analyzing hazardous substances in human biological specimens. Also, to introduce and spread new risk assessment technologies in Korea, MFDS developed and operated educational materials and training programs. To enhance the status of Korea's risk assessment, MFDS continuously cooperated with foreign risk assessment organizations and other relevant international organizations. Moreover, to expand the risk assessment infrastructure in Korea, MFDS is currently running customized risk assessment training programs.

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2. Advancement of the Risk Assessment System for Residual Substances in Agricultural, Livestock and Marine Products

A. Strengthening of the Basis for Safety Management through Establishment of Residual Substance Testing Methods and International Harmonization of Relevant Standards and Specifications

To expand the scope of imported products and to introduce the Positive List System (PLS)[8] which MFDS is currently working on, testing methods that can accurately and promptly check

the residue of animal drugs and pesticides that are not approved for use in Korea, must be prepared.

According to the verification process suggested by the CODEX Alimentarius Commission, MFDS has been developing testing methods for testing chemical residual pesticides and animal drugs in agricultural, marine and livestock products. MFDS also has been providing relevant information using the Pesticides and Veterinary Drugs Information website (http://www.foodnara.go.kr/residue) and will continue to work on strengthening residual substance safety management.

B. Improving Testing Methods in the Korean Food Standards Codex to Reduce Blind Spots of Food Safety Management

Research on food and alcoholic beverage standards, labelling standards and advancement of testing methods are being heavily demanded to minimize food safety blind spots that are expanding due to changes in the market from technological development and changes in consumers' food choices and purchasing patterns. MFDS carried out analysis on consumer reports and complaints, gathered opinions and suggestions from businesses, developed and improved testing methods for food and alcoholic beverage labeling and is currently planning to provide necessary support so that a scientific food labeling system is effectively implemented. Also, MFDS plans to prepare a regulatory instrument so that safer and healthier food products distributed in the market.

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3. Strengthening the Scientific Basis for Reducing Hazardous Pollutants in Food

Due to environmental pollution, abnormal climate changes and changes in eating habits, the likelihood of exposure (hazard level) to harmful pollutants (heavy metal, dioxine, mycotoxin, benzo[a]pyrene, etc.) has gradually increased over the years. In this regard, to reduce the

8) Positive List System (PLS): A system for applying a standardized limit (0.01ppm) to pesticides and animal drugs that don't have maximum residue limits established

amount of exposure to harmful pollutants, the current status of pollutant exposure must be examined in all stages including the consumption stage and, risk assessments must be carried out on those pollutants.

According to the 「Reevaluation of the Standards and Specifications on Unintentionally Generated Contaminants」, MFDS investigated harmful pollutants such as dioxin, mycotoxin and heavy metal in foodstuffs (31,20 items including agricultural products) and carried out risk assessment on the amount of pollutant exposure based on food intake data. The results of risk assessment on harmful pollutants in food (5 types of mycotoxins in food, 5 types of heavy metals in agricultural, livestock and marine products), were used as a basic data for determining the health risk through food intake and for preparing management standards for harmful pollutants.

MFDS will continue to carry out Government 3.0 project(jointresearch) to solve major social issues, especially to reduce arsenic in foods. In order to promote and spread risk assessment of hazardous pollutants and relevant technologies, MFDS will continue to carry out educational training programs and public campaigns. To reduce the total amount of exposure to harmful pollutants from food consumption, MFDS will continuously monitor harmful pollutants in foods and carry out risk assessment to prepare basic data for food safety management standards.

Kim Dong-sool, Director of Food Contaminants Division
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4. Research and Development of Expeditious and Precise Microbial Testing Methods

A. Study on Improving the Official Microbial Testing Methods

To increase the test efficiency and reliability through improvement of microbial testing methods, the official microbial testing method in the Korean Food Standards Codex and the official microbial testing method in the 'processing standards and ingredient specifications for livestock products' (hereinafter, 'Livestock Product Standards Codex'), have to be integrated and be compared with foreign microbial testing methods. Through a research for harmonizing official microbial testing methods, revisions for 6 testing methods (*Salmonella*, Enterohemorrhagic *E. coli*, *lactic acid bacteria*, bacterial growth testing, bacterial count, *E. coli*) were completed and revisions of testing methods for 5 food poisoning bacteria (*Listeria monocytogenes,*

Campylobacter jejuni/coli, Enterobacter sakazakii, Brucella, Brucellosis) and the sanitary indicative bacteria (E. coli·coliform (MPN)) were prepared. Also, MFDS established strategies for improving current microbial testing methods by comparing and analyzing official microbial testing methods used in the US and Japan.

To enhance the accuracy and reliability of the microbial testing methods that use advanced new technologies, MFDS will continue to compare and analyze testing methods of other countries and also carry out periodical training programs on the improved microbial testing methods.

B. Development of Technologies for Preventing and Quickly Responding to Food Poisoning

With continuous increase in large-scale food poisoning due to handling of unsuitable food and increase in group meal services, there is an increasing need to improve the detection technologies for early food poisoning detection and for preventing the spread of food poisoning.

For early food poisoning detection and to prevent food poisoning from spreading, MFDS developed a real-time gene detection method for 5 types of food poisoning bacteria (Staphylococcus aureus, Salmonella, Clostridium perfringens, Vibrio parahaemolyticus, Vibrio vulnificus), discovered natural antiviral substances such as lemongrass oil to Norovirus and developed sterilizing equipment and a quick food poisoning detection kit.

MFDS also developed a test kit that can simultaneously distinguish and analyze more than 45 key food poisoning bacteria genes and is planning to test a portable Norovirus test kit. Also, metagenome[9] and genomic information[10] of food poisoning bacteria in 'potentially hazardous foods that are very likely to cause food poisoning'[11] will be analyzed continuously and be stored in a database.

Chung Gyung-tae, Director of Microbiology Division
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9) Metagenome: 'A collection of all the genetic material present in an environmental sample, consisting of the genome of many individual organisms. Metagenomics is the study of genetic material recovered directly from environmental samples including many microorganisms which cannot be cultured in the laboratory.

10) Genomic information: It refers to the information about the genetic sequence of the microorganisms that exist in high-risk foods and this information can be useful for developing quick detection method and finding harmful gene in microorganisms (mutants of food poisoning bacteria)

11) High-risk foods: fish and shellfish (oyster, clam, gizzard), livestock (chicken, raw beef), agricultural products that are consumed raw (sprouts, cabbage, lettuce) and foods with high food poisoning risk

5. Strengthening Safety Management of Food Additives, Utensils, Containers and Packaging

Due to advancement of food processing technology and modernization of dietary life, the consumption of processed foods and packaged foods containing food additives and, the use of cooking utensils have greatly increased. And people's concerns on transferable substances which are derived from food additives, food utensils, containers and packaging, have also increased. In this regard, there has been calls for a continuous evaluation on the consumers' exposure level to those substances.

So in 2016, MFDS is carrying out risk assessment on food additives (16 items including bleaching agents, color fixing agents, anticaking agents) in foods and on transferable substances (12 substances including di-(2-ethylhexyl) phthalate, DEHP) in food utensils, containers and packing (Polyvinyl chloride, Polyvinylidene chloride, fluoroplastic). Improper uses of food additives in which standards and specifications for them are set, are continuously occurring and the food additives in which standards and specifications for them are not established, are continuously being detected in foods. Also, with regards to food utensils, containers and packaging, the management of the raw materials for which standards and specification are not established in Korea but are established in other countries, is being demanded. In this regard, to strengthen the safety management, MFSD carried out monitoring activities and developed testing methods for standards-established additives (6 additives including stabilizers), standards-unestablished additives (5 additives including brominated vegetable oil) and transferable substances (ultraviolet ray absorbent in polypropylene and polyethylene) in utensils, containers and packaging.

MFDS is also planning to carry out technical review regarding the use of raw materials of cleaning product, consider whether to recognize naturally derived food additives as food additives and investigate the content of naturally derived food additives in foods.

Kang Tae-seok, Director of Additives and Packages Division
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6. Establishing a Basis for Managing the Safety of Food Nutrition, Dietary Life and Functional Health Foods

People's interest in nutrition, dietary safety and health functional foods has risen due to societal aging and changes in dietary patterns. Therefore, in carrying out national nutrition and dietary safety management policies, MFDS need to carry out research for establishment of scientific evidence.

In this regard, MFDS continues to work on developing a risk assessment system for nutrients, and carrying out research on managing children's food to establish scientific basis for setting nutrition management and nutrition safety policies. MFDS also developed a method for testing nutrients and functional substances in milk formulas and contributed to the advancement of substance testing methods.

Koo Yong Eui, Team Chief of Nutrition and Functional Food Research Team
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7. Scientific Surveillance of Food Adulteration and Food Fraud

Recently, there has been an increase in incidents of manufacturing and distributing economically motivated adulteration (EMA) food, made with cheap ingredients or with illegal compounds. Also, for the first time in the world, MFDS developed an authenticity testing method which uses advanced physicochemical analysis, for sesame oil and ginseng (red ginseng). In addition, to strengthen the safety of imported food, MFDS analyzed 384 food items sold on foreign websites and requested the cease and customs clearance of 86 sexual performance enhancing products and dietary products that contain illegal compounds. Also, genetic analysis methods for animal and vegetable ingredients from 45 types of visually indistinguishable food such as whiteleg shrimp (*Litopenaesus vannamei*), banana prawn (*Fenneropenaesus merguiensis*) and fleshy prawn (*Fenneropenaeus chinensis*). MFDS also developed a method for testing substances that are likely to be mixed with food or have a history of being mixed with food. MFDS then established a database of the analysis on more than 1,500 foreign objects including metal and hair and, provided this data to local governments, relevant testing organizations and food manufacturers.

To eradicate distribution of EMA food, MFDS currently cooperates and shares relevant information with the Korea Customs Service, Supreme Public Prosecutors' Office and with

other relevant organizations and carries out inspections on imported food and foods that are being distributed.

Gwon Ki-sung, Director of New Hazardous Substances Team
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Section 3

Development of Safety Assessment Technologies for Supporting the Medicinal Products Safety Management System

1. Research on Advancement of Pharmaceutical Safety Management

In order to preemptively respond to the rapidly changing environment, MFDS conducts researches on pharmaceutical policies, systems and technologies to foster the advancement of pharmaceutical safety management. MFDS drafted revisions of standards and specifications for 183 items including Ramipril, carried out inspections and testing on 59 products, participated in the European Directorate for the Quality of Medicines and Healthcare (EDQM) Proficiency Testing Schemes (PTS) and recognized as conformant to the ISO17025 for the competence of testing and calibration laboratories. In addition, MFDS published and distributed braille/visual materials on the safe use of medicines for the visually/hearing impaired and provided the information in sign language videos.

Also, for multi-cultural families living in Korea, MFDS published and distributed a book entitled 'A Story about Medicine' containing information about diseases and safe use of pharmaceuticals (folate) in 5 languages - Korean, English, Chinese, Vietnamese, Russian and Cambodian. MFDS also carried out research projects for the advancement of pharmaceutical policies and published 8 on- and offline learning materials and case books about pharmaceutical quality control including testing methods. 48 reference standards were established and distributed additionally together with guide books. In the years to come, MFDS will continue to carry out research projects on pharmaceutical safety management, develop advanced policies and systems, review the overall standards and specifications for pharmaceuticals, establish new reference standards and respond strategically to international health agenda. Also, MFDS will conduct continued researches for the prevention and control of adverse effects through life-cycle analysis of pharmaceutical safety data and develop guidelines on the evaluation of pharmaceutical safety after they are opened. In order to strengthen the pharmaceutical testing abilities and technologies, MFDS are planning to expand the scope of the ISO 17025 accreditation to chemical and herbal (natural) medicine fields.

Dr Shin Won, Director of Pharmaceutical Research Division
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2. Research on Biopharmaceutical Safety Management

The global biopharmaceutical market is growing faster with the rapid development of biosimilars around the world. In Korea, in an strategic approach to promote the domestic biopharmaceutical industry as a 'new growth engine', 'Bio Health New Future Industry Development Strategy' was established in 2015 to expand government investments in pharmaceutical research and development. MFDS currently carries out various researches to develop science-based technologies for approval and evaluation of biopharmaceuticals such as stem cell medicines, gene therapy medicines, biosimilars and vaccines. Also, in order to respond efficiently to the rapid changes in global health environment due to scientific development and advanced technologies, MFDS is carrying out researches for the advancement of relevant policies and regulations, development and standardization of testing and evaluation methods for gene therapy products and other key biopharmaceuticals. MFDS currently has a total of 31 national reference standards for vaccines, plasma derivatives and GMO products, including the 3rd standard for Japanese encephalitis vaccine established in 2015. MFDS has upgraded the safety management system for national reference standards through introduction of control limit, development of international distribution procedures etc. MFDS also conducted studies on the safety and immunogenicity of vaccines to ensure the safety and quality of biopharmaceuticals, and develop standardized testing methods and standard sera in support of vaccine self-sufficiency project.

Dr Suh Soo-kyung, Director of Advanced Therapy Products Research Division
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Dr Kim Jae-ok, Director of Biologics Research Division
☎ 043.719.4703

3. Research on Herbal Medicine Safety Management and International Cooperation

MFDS, as a national regulatory authority responsible for ensuring the safety of herbal raw materials and herbal medicinal products, is working on the improvement of standards and specifications for items listed in the herbal medicine compendium and establishment of risk management system. The ministry is also operating the National Center for Herbal Medicine Resources and launched an ODA project for international cooperation to strengthen the safety management of herbal medicines. For more scientific and reasonable quality evaluation of

herbal medicines, MFDS secured necessary scientific data to develop and modify standards and specifications for herbal medicines. MFDS manufactured and re-evaluated the herbal reference standards used in quality control of herbal medicines. Currently, 114 Reference Materials of Medicinal Plant Materials and 57 Chemical Reference Standard of Herbal Medicine are distributed (as of May 2015). In order to prevent distribution of illegal medicinal herbs, MFDS is developing advanced authentication methods. As a result, an authentication method for 'Cynanchum wilfordii' has been registered in the Official Compendium. Since this new testing method requires expertise and proficiency of testers, MFDS provides training on purity testing of 'Cynanchum wilfordii' for testers. and published 'Guidance on Genetic Analysis of Cynanchum Wilfordii'. In addition, a research on risk assessment has been conducted to prevent new harmful substances as well as residual pollutants (heavy metal, residual pesticides, fungal toxin, residual sulfur dioxide, benzopyrene). The 'National Center for Herabl Medicine Resources' is operated by MFDS and currently archives 800 types of plant bioresources and around 3,000 medicinal herb samples listed in the Official Herbal Medicine Compendium. MFDS also established and is operating 'Forum on Harmonization of Herbal Medicines (FHH)' for the purpose of harmonizing regulations related to herbal medicines and contributes to the establishment of global level herbal reference standards by developing the 'Guideline on Establishment and Management of Reference Materials of Medicinal Plant Materials (RMPM) for FHH Members'. Moreover, in collaboration with the World Health Organization Regional Office for the Western Pacific Region, MFDS plans to implement 'Training on Regulatory Capacity Building for Quality Control of Traditional Medicines in the Developing Countries of the Western Pacific Region' to take a leading role in quality management of herbal medicines.

Dr Sim Yeong-hun, Director of Herbal Medicine Research Division
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4. Research on Standards, Specifications and Risk Assessment of Cosmetic and Quasi-Drug

Cosmetics are items used by consumers on a daily basis over their lifetime. Thus, the safety of these products must be guaranteed. With a full revision of the 「Cosmetics Act」(enforced on Feb. 5, 2012), the quality management system for cosmetic ingredients has been modified. In this new system, the use of harmful ingredients in cosmetics is controlled by the government,

and all other ingredients may be used by manufactures without restrictions. In order to ensure the safety and quality of cosmetic products, MFDS prohibits or limits ingredients that present health risks.

As quasi-drugs can be easily purchased but, contain bioactive ingredients or substances used in medicines, they are likely to be misused or contain new and potentially harmful substances, which raised public concerns over the safety of quasi-drugs. To address this issue, MFDS carried out a research project with aims to secure the safety of cosmetics and quasi-drugs, establish an efficient quality management system, and improve standards and specifications for cosmetics and quasi-drugs. In order to facilitate more efficient approval and evaluation of cosmetics and quasi-drugs, MFDS continued researches on standardized testing methods, standards and specifications and, drafted guidelines on Testing 'Methods for Substantiation of Cosmetics Advertising and Labeling Claims', 'Efficacy Evaluation Methods for Quasi-Drugs' and 'Analyzing Methods for Limited or Prohibited Cosmetic Ingredients' and, the revision of 'Specifications and Testing Methods in the Official Compendium'. In order to strengthen risk assessment for scientific safety management of cosmetics and quasi-drugs, and provide basic data in developing relevant policies, MFDS performed evaluation on the health hazards associated with substances of major public health concerns such as sterilizing preservatives in cosmetics as well as the safety of insecticides, and preservatives in dental products (toothpastes and mouthwash). Also, for the follow-up safety monitoring, MFDS performed tests on products released to the market to promptly respond to the safety issues related to cosmetics and quasi-drugs. Through the 'Cosmetics Risk Assessment Advancement Project', MFDS plans to establish a strategic plan for risk assessment of cosmetics after 2016, conduct risk assessment on 5 types of sterilizing preservatives and preservatives in dental products, and draft a revision of improved testing methods for items listed in the Cosmetic and Quasi-Drug Compendium, a roadmap for the improvement of the Korea Quasi-drug Codex, KCQ, and guidelines on standard efficacy evaluation. Based on the outcomes of 'Research on standards / specifications, and risk assessment of cosmetics and quasi-drugs', further support will be provided for the evaluation system and safety management policies for cosmetics and quasi-drugs, which is expected to contribute to strengthened quality and safety control of cosmetics.

Dr Kim Young-lim, Team Leader of Cosmetics Research Team
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5. Research on Prevention and Safety Management of Infectious Diseases

Due to the recent spreading of novel viruses such as MERS, the public concerns about health and safety are at the highest level. MFDS recognized the importance of developing effective technologies for approval and evaluation of vaccines and the need for vaccine self-sufficiency to quickly respond to and take appropriate actions in the occurrence of novel infectious diseases. In 2015, MFDS began 'Research on Safety Management Strategies for Future Novel Infectious Diseases' to establish a roadmap and action plans for evaluating vaccines for novel infectious diseases and develop strategies to establish a rapid approval system. MFDS developed testing methods for quality evaluation of BCG vaccines, manufactured a standard serum for evaluating the immunogenicity of vaccines, and established guidelines for the approval and evaluation of Pertussis vaccines.

Dr Kim Jae-ok, Senior Scientific Officer of Biologics Research Division
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6. Research on Medicinal Device Quality and Safety Management

Due to the rapid population aging, the focus of Medicinal care services is moving from acute diseases to chronic diseases, and the current physician centered system is being replaced with patient-centered care. and In accordance with the global trends in the lifecyle safety management of Medicinal devices from product development to commercialization and post-marketing surveillance, MFDS conducts researches on harmonization of safety regulations for an effective and prompt response to the regulatory changes in the global market. Also, for science-based review and evaluation of Medicinal devices, MFDS establishes advanced safety management system and regulatory science through developing specifications and guidance for review and approval including guidelines on testing methods and evaluation on the basis of scientific grounds to ensure the safety of Medicinal devices. MFDS will provide strong supports for the new Medicinal device industry and implement a long-term government roadmap through studies on development of Medicinal device evaluation technologies in responding to the rapidly transforming Medicinal environment.

Dr Park Chang-won, Director of Medical Device Research Division
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Section 4 Development of Safety Evaluation Technologies for Food and Drugs

1. Government Control of Toxic Substances and International Cooperation in Toxicity Testing Methods

Every year, new chemical substances are developed and found globally, people's interest in health and the quality of life is rising, more technologically advanced products are being developed and, as a result, expeditious safety management of these substances and products is being demanded. As in the Cynanchum auriculatum Royle ex Wight incident in which a number of Korean companies were found to be using Cynanchum auriculatum royle, a herb unauthorized for medical use, instead of Cynanchum wilfordii, a medical herb proven to be helpful in relieving menopausal symptoms, the probability of harmful substances being mixed to food and drugs is rising and there is a need to strengthen the scientific safety management of food and drugs. To prevent adverse events from the misuse of natural substances and to establish a scientific basis for the safety management food and drugs, since 2002, MFDS has developed toxicity test data on a total of 44 natural substances. Also, seeing the increased demand of health functional foods, MFDS has selected 10 most consumed medicinal herbs that need toxicity test among raw materials (116 types of medicinal herbs) of food and drugs. MFDS also participated in OECD's Working Group of the National Coordinators of the Test Guidelines Programme (WNT) representing Korea and worked on developing OECD toxicity test guidelines. Also, to establish a basis for safety testing nano products, MFDS participated in OECD's Working Party on Nanotechnology (WPN) and successfully developed a joint research report for the Colony Forming Efficiency (CFE) assay. To provide safety-related information to the public, MFDS established a toxicity information providing system called, 'Tox-info', developed a readily searchable toxicity information DB, the Poisoning Information DB which provides treatment information of emergency patients with poisoning and the Product Information DB which provides information about various products that contain poisoning-inducing substances. MFDS is planning to expand preemptive toxicity assessment on public-concern food and drug products that are associated with safety issues and establish an advance response system for reducing public's safety concerns. Moreover, MFDS will cooperate with OECD and other international organizations in joint toxicity research, establish

a basis for the safety management of potentially harmful substances, and work to quickly provide the most accurate information through 'Tox-Info'.

Jung Ja-young, Director of Toxicological Research Division
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2. Development of Alternatives to Animal Testing and Advancement of Non-Clinical Tests

The EU and many countries around the world have prohibited animal testing and, alternatives to animal testing and ways to test cosmetics and drugs without using living animals are increasingly demanded globally. In 2016, Korea revised the 「Cosmetics Act (No. 14027, Feb. 3, 2016)」 and banned the sale and distribution of animal tested cosmetic products. The MFDS established the Korean Center for the Validation of Alternative Methods (KoCVAM, 2009), signed a Memorandum of Cooperation (MoC) for the International Cooperation on Alternative Test Methods (ICATM) with the EU, US, Japan, Canada and have actively participated in developing international alternatives to animal testing. For 3 years from 2012, the MFDS had run the 'Research Group for the Development of Alternative (Non-Animal) Methods for Testing Safety of Cosmetics' and developed 8 alternative test methods including the 'Eye Irritation Alternative Testing using Human Corneal Model'. MFDS also studied the 'Local Lymph Node Assay using the Flow Cytometric Method' and submitted a proposal for the guidelines on skin sensitation test to the OECD. Also, the MFDS adopted OECD's alternative test guidelines on 'Eye Irritation Test' and 'Single Dose Acute Toxicity Testing', to use them for testing toxicity in cosmetics. By using KoCVAM's advanced operating system, the MFDS will continue to work to make Korea's test method the international guidelines for test methods and also continue to adopt globally-approved alternative (non-animal) testing guidelines.

The pharmaceutical market is growing and the production of reliable, non-clinical data that are based on OECD's Good Laboratory Practices (GLP) is becoming more important. Recently, with the revision of the 「Medical Device Act」 and application of GLP to medical devices, there was a need to train personnel for non-clinical tests. Since 2008, the MFDS has been carrying out non-clinical personnel training programs with new pharmaceutical developers and personnel working in the non-clinical testing field. And in 2015, the MFDS conducted 10 sessions of the training programs and held international workshops. Also, in order to

internationally harmonize the 「Standards on Toxicity Testing of Pharmaceuticals (MFDS Notification No. 2015-82)」, a working group comprising experts from industry, academia and research institutes, analyzed the latest ICH and OECD guidelines on genotoxicity and revised the standards. The MFDS will continue to carry out training programs and support Korean pharmaceutical industry's global market entry.

Sohn Soo-jung, Director of Toxicological Screening and Testing Division
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3. Research on Predictability of Drugs and Assessment of Pharmaceutical Dependence

Due to societal aging, increase in chronic diseases and people's increased interest in health, drugs and health functional foods are often consumed together so MFDS has been investigating the effect of mixed use of drugs and health functional foods as well as the drug interaction when multiple drugs are taken. In regards to narcotics, with the increase in online transactions, increasingly more new narcotic drugs are flowing into the country. The situation called for a government level action and accordingly, MFDS is currently working on revising and improving policies and regulations for scientifically managing and distinguishing narcotic drugs from non-narcotics drugs. Also, MFDS is carrying out a risk assessment on 'temporarily designated narcotics' and a development research on a technology for quick prediction and evaluation of the dependency to novel narcotic drugs. MFDS also participated in narcotics-related international conferences, developed standard substances, established standard guidelines for testing narcotics drugs and held research groups meetings to share information about narcotics at home and abroad and to strengthen the cooperation between narcotic control offices and ministries.

Kim Hyung-soo, Director of Pharmacological Research Division
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4. Securing Public Health and Safety through Advancement of Clinical Evaluation and Reduction of Adverse Events

The paradigm of pharmaceutical usage is changing with the rapidly emerging customized pharmaceutical treatment. The number of pharmaceuticals that come with pharmacogenetic information is increasing in the US and, the Korean government has also included 'customized medicine development technology' and 'genome information utilization technology' in the 5 key technology research areas and is focused on developing genomic biomarkers and preliminary clinical research. Also, by introducing innovative clinical trial methods and strengthening the protection of clinical trial participants, MFDS has been improving the competitiveness and ethical standards of clinical trials in Korea. In order to find out the relationship between genetic information and adverse pharmaceutical reactions, MFDS established scientific basis and developed regulatory and instrumental foundation for introducing personalized medicines. Moreover, MFDS is carrying out research on providing and utilizing pharmacogenetic information for the safety management of pharmaceuticals.

To improve international competitiveness and level of clinical trials in Korea, MFDS has prepared 382 cases of pharmaceutial clinical trial manuals and established a clinical trial information DB that provides a total of 2,327 items of information about effects of pharmaceuticals which can be used for designing and evaluating clinical trials. and clinical test guideline for advanced medical device. In addition, MFDS secured a base data for improving the regulations for efficient implementation of the clinical trail subject protection program (HRPP). Also, to consolidate and manage pharmaceutical genetic information, MFDS has established a DB by collecting 50,432 items of information about pharmaceutical genes, genetic polymorphism, Koreans' genetic information and genetic variation on drug response as well as publications.

The importance of an ethical basis for clinical trials and environment is and has always been emphasized around the world. To project the clinical trial participants as well as the trial itself, MFDS is planning to establish guidelines for clinical trial participants and procedures. Also, it will develop a plan for improving the safety management of pharmaceuticals for the elders, young children, women and all other disadvantaged groups. MFDS is also planning to utilize pharmacogenomic technologies to study and collect information about pharmaceuticals that cause severe cutaneous adverse reactions (SCARs) and other adverse reactions.

Choi Seung-eun, Director of Clinical Research Division
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5. Preventing Adulterated Food and Drugs through an Advanced Analysis System

On behalf of the government agenda for eradicating adulterated food, the National Institute of Food and Drug Safety Evaluation (NIFDS) of MFDS is currently developing testing and evaluation methods for illegal food and drugs. The Advanced Analysis Team of NIFDS provided analysis on a total of 502 samples requested by the Criminal Investigation Office and the Bureau of Food Integrity in 2015. For the first time in the world, MFDS elucidated 'trans-Bisprehomotadalafil' which is a novel substance similar to tadalafil, a drug used to treat erectile dysfunction and, published 17 research papers on prominent academic journals (SCI, Science Citation Index). Also, to establish the reliability and accuracy in test and analysis results on harmful constituents in tobacco products, MFDS additionally acquired the ISO/IEC 17025 certificate in the scope of nicotine and tar in cigarette smoke from the Korea Laboratory Accreditation Scheme (KOLAS).

Baek Sun-young, Director of Advanced Analysis Team
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6. Establishment of a System for Development, Preservation and Utilization of Laboratory Animal Bio Resources (BIOREIN: Bio Resources Initiative)

Laboratory animals are essential bio resources in studying and developing new drugs as well as in evaluating the safety and efficacy of food and drugs. However, the laboratory animals used in Korea are entirely imports from other nations. Also, since the biological samples such as blood and urine of the laboratory animals which have been administered with rare substances or administered with drugs for a long period, are very important research resources, there needs to be a system to fully utilize those resources. So, to establish a system for procuring and utilizing laboratory animals needed for the safety management of food and drugs and ultimately strengthen the national R&D capacities and 'resource sovereignty', MFDS is currently working on the BIOREIN(Laboratory Animal Bio Resources Initiative) project.

In 2015, MFDS acquired the Korean strain (Korl[12]:ICR, C57BL/6NKorl) to ICR and C57BL/6

12) Korl: Korea Laboratory Animal

mice which account for 60% of the mice used for experiments in Korea. Also, MFDS' 「Center for Mouse Models of Human Diseases」 developed 10 kinds of disease model mouse including cancer, diabetes and drug metabolic deficiency, to use for drug development research. In addition, MFDS currently working on establishing an 'Laboratory Animal Resource Bank' that can procure and utilize the laboratory animal bio resources that are valuable for research. MFDS also operated the 'Bio Resource Base Institutions' to collect valuable laboratory animal bio resources.

In the years to come, MFDS will supply Korean mouse strain to laboratory animal breeders so that Korean researchers can use them for their research. MFDS will develop 60 kinds of disease model mouse for metabolic diseases, circulatory diseases, immune system diseases by 2018 to meet the demands of the Korean pharmaceutical development research. Also by establishing the 'Laboratory Animal Resource Bank', MFDS will efficiently procure and utilize laboratory animal bio resources and establish the sovereignty over bio resources.

Chung Myeon-Woo, Director of Laboratory Animal Resources Division
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Section 5 Advancement and Strengthening of Expertise in the National Lot Release System

1. Current Status of the National Lot Release System and Regulatory Improvements

The National Lot Release System for re-evaluating the quality of biological products such as vaccines and blood products, is currently being operated and the system is managed by MFDS' National Institute of Food and Drug Safety Evaluation

As of Dec. 31 2015, there was a total of 196 items and 67 products that are subject to the National Lot Release System. In 2015, a total of 2,341 lots which is 41 lots less than the previous year, were approved by the National Lot Release System (Table 4-5-1). The lot release requests will likely increase with the increase of domestic vaccines' share of the market and increase in the number of blood product manufacturing facilities in the years to come.

[Table 4-5-1] National Lot Release Statistics in the Last 5 Years

(Ref: 2014 Annual Report on National Lot Releases, unit; lot, as of Dec. 31, 2015)

Category \ Year	2011	2012	2013	2014	2015
Bacterial vaccines	384	301	329	245	189
Virus vaccines	559	601	671	683	673
Botulinum toxin (BoNT) products	92	152	242	475	537
Blood products	739	953	1,019	975	940
Other	2	5	2	4	2
Total	1,776	2,012	2,263	2,382	2,341

Also, on April 1, 2016, MFDS started taking actions to improve the National Lot Release System for biological products based on risk analysis. MFDS enacted and revised the 「Regulation on the Designation, Approval Procedure, and Method of Biological Products Subject to National Lot Release」 and relevant manual of policies and procedures (MAPPs).

Prior to the implementation of the improved National Lot Release System, MFDS examined the overall information related to risk assessment, prepared an evaluation report and set up

a risk assessment committee. At the committee, various relevant department in MFDS discussed and verified the risk assessment and inquired the companies for their opinions. Then, the risk ratings of the final evaluation report which was decided at the 2nd committee meeting was notified to the companies. The efficient and standardized, Laboratory Information Management System (LIMS) which was established by taking into account of the users' opinions, was launched in March, 2016. MFDS will enact and revise four MAPPs related to the National Lot Release System and, expand the scope of test items of the Test Records which are used by the testing institutions for testing the materials, equipment and procedures, to all tests by 2016. As described above, MFDS will continue to work on improving the efficiency and reliability of the National Lot Release System.

2. Strengthening Cooperation and Communication through the Operation of Public-Private Consultative Group

MFDS has set up a public-private consultative group to internationally harmonize and improve the efficiency of quality management by promoting information share and technical exchanges among laboratories.

Currently, 10 manufacturers and 2 quality testing organizations are participating in the 「Vaccine Quality Management Laboratory Network (Lab-Net)」. In 2015, the Network carried out a joint research on quality testing methods and national standard quality under 6 topics. Through these research, MFDS was able to manufacture and calculate content/potency of candidate substances of the national standard products, examine proficiency in testing endotoxin and standardize the methods for testing polysaccharide content in flu vaccines. Also, MFDS held 「Biological Product Quality Management Laboratory Network (Lab-Net)」 workshops for the internal and outside personnel and experts in vaccine and blood products.

MFDS is currently operating the 「Private-Public Forum on Blood Product Quality Study」 which is participated by 8 manufacturers and importers, and 3 blood banks. MFDS carried out joint research on MFDS' internal research project with the blood product manufacturers, invited guest speakers to seminars and had field trips to the manufacturing facilities.

In 2016, MFD plans to provide continued technical support and strengthen the cooperative network of the 「Private-Public Forum on Blood Product Quality Study」 and also hold end-of-year workshops with the members of the forum.

3. International Cooperation Activities

MFDS currently cooperates with foreign national regulation agency such as the World Health Organization (WHO), European Directorate for the Quality of Medicines and Healthcare (European Directorate for the Quality of Medicines & HealthCare, EDQM), Paul Ehrlich Institute (PEI) to strengthen its capacities for the safety management biological products and to exchange and discuss relevant ideas and information.

In 2006, MFDS signed a Technical Service Agreement (TSA) with WHO and has been commissioned to test WHO's vaccines. In 2015, MFDS carried out a potency test, a thermal stability test and an endotoxin test on Japanese encephalitis chimeric virus vaccine.

In addition, after being designated as WHO's Collaborating Center, MFDS started running an international vaccine test training program. In 2015, MFDS carried out the '4th International Vaccine Verification Training Program' on 8 public officials in charge of vaccine quality from 7 countries in Asia and South America. This training program was also a part of the process for being selected as a training center for Global Learning Opportunities for Vaccine Quality (GLO/VQ). WHO's GLO personnel evaluated the training program and MFDS contributed to promoting Korea's strict and advanced national lot release system by getting a positive evaluation.

In order to promote developmental exchanges between national control laboratories in Asia, MFDS established a new national control laboratory network (Asia Lab-Net) in 2015. MFDS also invited seven control laboratory experts from 6 countries including Japan and Australia. The experts shared their countries' national lot release system and discussed plans for joint research for the development of the standard Asian region products.

MFDS participated in WHO's international technical advisory group and expert meetings for the development of guidelines, the 2nd Global Vaccine and Immunization Research Forum (GVIRF) and the 16th International Conference of Drug Regulatory Authorities (ICDRA).

MFDS also signed a cooperation agreement with the Paul Ehrlich Institut (PEI) and participated in PEI's vaccine and blood product training program. MFDS acquired data and information on national lot release systems in Europe, learned the Monocyte Activation Test (MAT) and carried out an internal research project based on that training experience.

Also, before implementing the risk analysis-based national lot release system, to make sure the system work stably, MFDS visited national lot release department in Canada and European countries, collected relevant data and established areas for improvement in Korea's national lot release system.

In 2016, MFDS will run training program as a training center for WHO Global Learning Opportunities for Vaccine Quality (GLO/VQ) for 10 days starting on Oct. 31 with the trainees from Asia, Latin America and Africa. MFDS will also carry out the Korea International Cooperation Agency (KOICA) global training program on 'strengthening capacities for national biopharmaceutical lot release' with the health authorities from the developing countries that have been supplied with WHO's vaccines since May 2015. Also, MFDS has been commissioned by WHO to test live attenuated Japanese encephalitis vaccine. The Bacterial Testing TF of MFDS will participate in WHO's 2016 joint research and work on developing an international standard product of Encephalitis vaccine.

4. Strengthening the Quality Management Function in National Testing and Operation of Proficiency Program

To establish traceability and international credibility and traceability in the test results, MFDS developed a systematic, quality management and quality assurance system in its testing and analysis work and became a certified international testing institute in Dec. 2014, satisfying the general requirements of ISO/IEC 17025. Also, to secure objectivity and reliability in its testing proficiency, MFDS continuously participates in various international proficiency schemes and also carries out its own proficiency program to evaluate quality management performance of domestic manufacturers.

To maintain its accreditation as a certified international testing institute, MFDS carries out an internal audit every year and in October 2014, KOLAS (Korea Laboratory Accreditation Scheme) carried out a periodical field follow-up inspection on MFDS. Also, MFDS participated in the Nucleic Acid Amplification Techniques (NAT) testing for HCV among EDQM's International Proficiency Testing Programs and was recognized for its international-level, quality testing capacities.

MFDS plans to continuously expand the testing items recognized by the International Organization for Standardization and carry out new/continued training of personnel in charge of lot release approval tests in certified international testing agencies (ISO/IEC 17025). In 2016, MFDS carried out proficiency testing program, aiming to get 5 testing items in blood product area certified. In May, MFDS will apply for the expansion of the scope of certification. In 2016, MFDS will participate in 3 of EDQM's Proficiency Testing Scheme (PTS) including the 'Chromogenic Substrate Testing Method for Measuring Low Molecular Weight Heparin (LMWH)

Dose' MFDS will strengthen its proficiency in testing and analysis of vaccine and blood products, and strive to become an advanced, international-level research and testing institution that is globally trusted and recognized.

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Ahn Chi-young, Director of Blood Products Division
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VI

Appendix

1. Changes in the Number of staff

May. 19, 2016	- Reflected the required number for 2016 (12 persons) - 1 Division established (Integrated Food Information Service Division)〈April.26, 2018 temporarily〉 - Increased 12 persons * HQ: Integrated Food Information Service Division(2persons), Cyber security(1person), Strengthening safety management of imported food(2persons), Safety and traceability of drug(1person), Traceability of medical device(1person) * NIFDS: R&D management(1person), Biosimilar approval process(1person) * Regional FDA: Food traceability(1person), Archives management(2persons)
Feb. 5, 2016	- Adjustment in positions in 2016: ±15 persons (two grade-3·4 officers, six grade-4·5 officers, two grade-5 officers, 5 senior officers)
Dec. 30, 2015.	- Reduced total number of personnel: 16 persons (5 persons from the Headquarters, 3 persons from the National Institute of Food and Drug Safety Evaluation, 8 persons from regional offices of food and drug safety) - Management Operations Personnel switched to General Staff: ±5 (±4 from the Headquarters, ±1 from a regional office of food and drug safety) - Open Position : Director General of Food Nutrition and Dietary Safety Bureau is newly designated for open position. Post of Director General of Medical Device Evaluation Department is no longer subject to open position.
Dec. 4, 2015.	- Increased the number of personnel for cyber security: 1 person (Headquarters) - Import Food Analysis Division in Gwangju Regional Office of Food and Drug Safety abolished (△ 4)→ Import Food Analysis Division newly established in Seoul Regional Office of Food and Drug Safety (+4) - 'Open Position' newly established: Chief of Consumer Risk Prevention Bureau - National Institute of Food and Drug Safety's internal personnel adjustment: Orthopedic and Restorative Devices Division (△2) → Advanced Medical Devices Division (+2)
May 29, 2015	- Reflected the required number for 2015 (14 persons) • Newly established 1 division(Pharmaceutical Safety Evaluation Division) 〈17.5.31.temporarily〉 • Increased 14 persons * HQ: Food Radiation(2persons), Archives/Personal Information(1person) * NIFDS: Food Radiation(1person) * Regional FDA: Pharmaceutical Safety Evaluation Division(3persons), human tissue(2 persons), Integrated network(1person), Food Traceability(2persons), Archives/Personal Information(2persons) • Adjusted ranks : ±22 persons(class 3·4 -2, class 4·5 -5, class 5-15) - Follow-up measures for audit on prescribed number for 204 • National Qualification Center of NIFDS → vaccine division, blood products division • Inspection analysis center of Busan·Gyeonggin regional FDA → 2nd affiliated agency

Jan. 9, 2015	- Reflected organization diagnosis of 2014 : +9 persons(class 5 -2, class 6- 3, class 7-3, class 8 -1) • HQ : △ 21 person * (transfer·abolition) Health Functional Food Standard Division abolished, new material food division → transferred to NIFDS, abolished medical device quality division, (created) Health Functional Food Policy Division, Medical Device Safety Evaluation Division • NIFDS : +14 persons * (transfer·abolition) radiation safety division → abolished, (created) new material food division(transfer from HQ), external diagnosis division, (renamed) medicine specification research division → medicine research division • Regional FDA : +16 persons * (established) Incheon port/Yongin imported food inspection center(temporary inspection center, normal organization) - Transferred management operation position to general position : ±28(HQ ±3, NIFDS ±21, Regional FDA ±4) - Reduced total number : △16 persons(HQ 5, NIFDS 4, Regional FDA 7)
Aug. 27, 2014	- Reflected required number for 2014(12 persons) • 1 division established(Quasi-drug Policy Division) • 12 persons increased * safety management of quasi-drug reinforced(3 persons[HQ], 1 person[NIFDS]), test inspection quality management reinforced(2 persons), integrated food safety information network constructed and operated(3 persons), plasma safety management reinforced(2 persons[HQ], 1 person[NIFDS]) - Resolve disagreement between job and ranks(1 person) : public health operation assistant secretary→office operation secretary
Feb. 20, 2014	- Vice minister in special service, transferred to general position according to revision of 「National Government Organization Act(Dec. 24, 2013)」 - Adjusted number of employee to transfer the successful candidate of administration position test to other job type(3 persons)
Dec. 18, 2013	- Adjusted the number of employee according to reorganization of job type(Dec. 12, 2013) • Technical post(94 persons) → General post(94 persons) • Contract post(11 open type positions*) → transferred to term-based public officials * Director level : Director of Food Standard Planning Office, Biophamaceutical Inspection Office, Medical Device Inspection * Manager level : Spokesperson, managers of International Cooperation Office, Information Management and Statistics Office, Audit and Inspection Office, Herbal Medicine Policy, Bioequivalence Evaluation Division of NIFDS, Radiation Safety Division, Clinical Research Division • Special post(2persons)* → general post(term-based secretary, administrative official) * Emergency and Security Office, facility·equipment class 5 - Reduced 17 persons according to operation plan of integrated number of officials of Ministry of Public Administration and Security(June 2013)* * HQ(△6 persons), NIFDS(△3 persons), Regional FDA(△8 persons)
Nov. 5, 2013.	- established Gamcheon port import food inspection center for stable performance of Japanese imported fishery product inspection - Adjusted disagreement between current number and prescribed number and other function posts : ±17 persons

Oct. 4, 2013	Reflected required number for 2013 and increased personnel for national policy project - 2division established : Alcoholic Beverages Safety Management and Planning Division(temporary), Pharmaceutical Approval and Patent Management Division - Increased 15 persons • Required numebr for 2013 : 12 persons • Dedicated for eradiation of adulterated food : 5 persons • Transfer radiation safety control personnel(radiation safety division) to ministry of welfare(△3 persons) - Others • Adjusted open type position(3 director level, 8 manager level) • Changed name and location of Gyeongin FDA* * Incheon metropolitan city → Gyeonggido, Gwangyang import inspection center(Yeosu → Gwangyang)
Mar. 23, 2013	Established Ministry of Food and Drug Safety - Transferred safety policy function of food and drugs of Ministry of Health and Welfare, and agro-livestock fishery product sanitation and safety of Ministry of Ministry for Food, Agriculture, Forestry and Fisheries to MFDS according to revision of 「National Government Organization Act(Mar. 23, 2013)」 - Personnel : 1483 persons → 1760 persons(+277 persons) • Transfer of Ministry of Agriculture and Forestry* : 260 persons * livestock area(1 bureau, 8 divisions, 171 person), fishery area(1 bureau, 87 persons), area of agriculture(1 person) • Transfer of Ministry of Welfare* : 10 persons * food area(1 division, 6 persons), medicine area(2 persons), common area(2 persons) • Increase(+12 persons), decrease(△5 persons)
Nov. 18, 2012	- Established separate quota for filling up vacancy due to maternity leave for MFDS and agencies(a total of 64 persons) - Added open type position of bioequivalence manager - Changed competent department of medical device inspection division(advanced medical device division) - established regulation for job division of imported foods of Regional FDA
July 30, 2012	- Increased persons due to reinforcement of safety management of raw materials and introduction of national lot release approval system • 19 persons(class 5-3, class 6-2, class 7-3, senior officers-3, researchers-8) - Rearranged jurisdiction with Uiwang inspection center through creation of Gwangju imported food inspection center in Gyeonggin office - Abolished function class 10 according to revision of Government Officials Act • Changed 33 persons of functional class 10→ functional class 9 in lump sum
Feb. 3, 2012	- Established biopharmaceutical and medical device approval inspection division and created personnel • Established advanced medical device division and cell gene medicine division - Discarded manufacturing quality research team of NIFDS and established biopharmaceutical quality management division in charge of quality management function of biopharmaceuticals - Renamed the division and reorganized review division for each clinical trial area of medical device • Biopharmaceutical inspection division : advanced product division → gene recombination medicine division • Medical device inspection division : diagnosis device division → cardiovascular device division, treatment device division → orthopedics and rehabilitation device division, material product division → oral digestion device division

July 29, 2011	- Installed emergency planning office at Director General for Planning and Coordination
Jan. 4, 2011	- Discarded side effects monitoring team of NIFDS and established medicine safety information team in charge of collection and evaluation of side effect information of medicine at Administration
Apr. 30, 2009	Reorganized organization (reduced 6 divisions with application of project system) - Administration 1 office 5 bureau(1team·4 bureau) 65 divisions→ 1office 5bureau (1 team·4 bureau) 48 divisions • Established Criminal Investigation Office, Overseas Investigation Office • Reorganized harmful substance management office to risk prevention policy bureau • Reorganized Biopharmaceutical Bureau to Biopharmaceuticals and Herbal Medicine Bureau • Reorganized nutrition functional food bureau to nutrition policy office • Reorganize 4 evaluation bureau to 4 inspection bureau(food standard bureau, medicine inspection bureau, biopharmaceutical inspection bureau, medical device inspection bureau) - National Toxicity Science Institute → National Institute of Food and Drug Safety Evaluation(3 bureau 18 divisions → 3 bureaus 29 divisions) • reinforce function of food and medical device safety support, organize connection with Administration, food risk evaluation bureau, medical device research bureau, and toxicity evaluation research bureau) - 6 Regional FDA • Reorganized General Services Division to customer support division, medicine division to medical product safety division, test analysis division to harmful substance analysis division, food and drug analysis division to imported foo analysis • Transfers 101 personnel and simple tasks of instruction and guidance according to arrangement plan of special provincial administrative agency of food and drug to cities and provinces
Mar. 6, 2008	Reorganized to bureau and division(office) system - Create Spokesperson under administrator, Regulatory Reform and Legal Affairs Office in Director General for Planning and Coordination, respectively - Reorganized performance management team under vice minister to performance management team under Director General for Planning and Coordination, inspection and examination management team to inspection management team of harmful substance management center of food and safety bureau - Abolished innovation planning office, policy promotion team - Adjusted name of some division creatively and transferred the team based system to division based system according to government reorganization policy
Sep. 20, 2007	- Create performance management team under vice minister team, food poisoning prevention management team under Food HQ, medicine quality team under Medicine HQ, medicine quality bureau under Medicine HQ, quality equivalence evaluation team under medicine quality bureau, medical device approval inspection team under medical device HQ, and research support team in National Toxicity Science Institute, respectively - Reorganized medicine equivalence team of Medicine HQ to bioequivalence evaluation team - Reorganized National Toxicity Science Institute to National Toxicity Science Institute, biotechnology support team to the team under pharmaceutical research bureau, endocrine disorder substance team under toxicity study bureau to endocrine disorder evaluation team of risk evaluation research bureau, respectively

Aug. 25, 2006	- Create inspection and examination management team under vice minister, information support team and total counseling center under Policy promotion management HQ, new material food team under nutrition functional food HQ, clinical management team and herbal medicine team under Medicine HQ, cosmetic evaluation team under medicine evaluation division of medicine HQ, herbal medicine evaluation team under medicinal herb evaluation division of medicine HQ, biopharmaceutical management team under biopharmaceutical HQ, medical device quality team under medical device HQ, respectively - abolished inspection management team of harmful substance management center of Food HQ - Reorganized biopharmaceutical team of Biopharmaceutical HQ to biopharmaceutical safety team, medicine evaluation division of Medicine HQ to medicine evaluation bureau to quasi-drug team, respectively
June 30, 2006	- Introduced position of high-ranking officials(22 positions)
Jan. 24, 2006	- established harmful substance management team in food HQ(risk management team, risk standard team, inspection management team), abolished food specification team - Expanded and reorganized test analysis team of Busan, Gyeonggin Regional FDA to test analysis center (test analysis team, harmful substance analysis team), established new port imported food inspection center at Busan Regional FDA and Pyeongtaek imported food inspection center at Gyeongin Regional FDA
Sep. 30, 2005	Reorganized organization to Korean type center system(HQ system) and team system - HQ : reorganized 2 offices, 2 bureaus, 6 divisions to 6 headquarters and 4 divisions, and introduced team system in all departments • 6HQ : policy promotion management HQ, food HQ, nutrition function food HQ, medicine HQ, biopharmaceutical HQ, medical device HQ • 4 evaluation bureau : food evaluation, medicine evaluation, medicinal herb evaluation, medical device evaluation bureau - Reorganized effectiveness research division - risk research division of Toxicology Institute to Pharmaceutical bureau· Risk evaluation bureau - Reorganized food monitoring division of 6 Regional FDAs to food safety management team - Create food safety standard team and risk information management team under food HQ, gene medicine team and tissue engineering team under Biological Medicine HQ, separated legal trade officer to administrative legal affair team and trade cooperation team - established exposure evaluation team, applied application team under National Institute of Toxicological Research - established operation support team at Daegu, Gwangju, Daejeon Regional FDA, respectively
Apr. 26, 2005	- Changed planning office to policy promotion office, planning budget office to finance planning office, promotion office to policy promotion office
Dec. 31, 2004	- Changed renovation officer to renovation planning officer, abolished test analysis officer of safety evaluation office, established research and planning coordinator
May 24, 2004	- Separated medical device division of Pharmaceutical Safety Bureau to medical device safety division and Medical Device Management Division - established biotechnology support division under Effectiveness Research Bureau of National Institute of Toxicological Research

Jan. 9, 2004	- Reorganized food evaluation division and food additive evaluation division under safety evaluation office to food specification evaluation division and food safety division - Transfer function and personnel for medicine safety, effectiveness and equivalence evaluation tasks performed by National Institute of Toxicological Research, to Medicine Evaluation Division of Administration - Reorganized general toxicity, special toxicity and pharmacology division of National Institute of Toxicological Research to toxicity research division, efficiency research division and risk division
July 25, 2003	- established biological medicine specification division under Biological medicine evaluation bureau, and functional food evaluation division under Food evaluation bureau, and functional food division under food safety bureau - established Yangsan imported food inspection center at Busan Regional FDA
May 27, 2002	- Renamed National Toxicity Laboratory to National Institute of Toxicological Research - established Audit and Inspection Office and Medicine Bioqeuivalence Evaluation Division, Chemical Division of National Institute of Toxicological Research
Sep. 29, 2001	- established Central Enforcement Team of Adulterated and Unhealthy Food at biopharmaceutical division and food safety division of Pharmaceutical Safety Bureau
Mar. 27, 2001	- established imported food inspection center of Incheon international airport at Gyeongin Regional FDA
May 10, 2000	- established endocrine toxicity in National Toxicity Laboratory
Feb. 28, 1998	Opened Food and Drug Administration - Transferred the tasks of food policy division, chemical division and medical device division of Transferred the execution asks of food policy bureau, and medical device of Ministry of Health and Welfare • Some tasks such as enactment and revision of laws and determination of policy remained at Ministry of Health and Welfare - Installed National Toxicity Laboratory and 6 Regional FDAs
Apr. 6, 1996	established food and drug safety administration and 6 Regional FDA as affiliated agencies of Ministry of Public Health and Welfare - Carried out some tasks of food division Ministry of Health and Welfare → Transfer safety administration to Regional FDA • Safety HQ : 2 bureaus(6 divisions) 5 offices(22 divisions) - 4 divisions of National Institute of Health(sanitation, chemical, herbal medicine, radiation standard division) → reorganized as 5 safety evaluation division(food, food additive, cosmetics, biological products, medical device) - National Institute of Health and Safety → Toxicity Laboratory reorganized

2. Ministers/Commissioners/Vice Ministers in MFDS

1) Ministers

Name	Terms of Office
Sohn Mun Gi	Mar. 28, 2016 ~
Kim Seong Hee	Apr. 7, 2015 ~ Mar. 12, 2016
Jeong Seong	Mar. 23, 2013 ~ Mar. 12, 2015

2) Commissioners

Name	Terms of Office
Jeong Seung	2013. 3.15. ~ 2013. 3.22.
Lee Heeseong	2011.12.30. ~ 2013. 3.14.
No Yeonhong	2010. 4. 2. ~ 2011.12.11.
Yun Yeopo	2008. 3. 8. ~ 2010. 4. 1.
Kim Myeonghyeon	2007. 6.21. ~ 2008. 3. 7.
Mun Changjin	2006. 2. 1. ~ 2007. 6.20.
Kim Jeongsook	2004. 9. 3. ~ 2006. 1.31.
Sim Changgu	2003. 3. 3. ~ 2004. 9. 2.
Lee Youngsook	2002. 3.20. ~ 2003. 3. 2.
Yang Gyuwhan	2000. 8.11. ~ 2002. 3.19.
Heo Geun	1999. 1.29. ~ 2000. 8.10.
Park Jongsae	1998. 3. 9. ~ 1999. 1.28.

3) Vice Ministers

Name	Terms of Office
Yoo Moo Young	2016. 5.11. ~
Sohn Mun Gi	2015.10.21. ~ 2016. 3.27.
Jang Giyun	2014.12. 8. ~ 2015.10.20.
Jang Byeongwon	2013. 4.19. ~ 2014.11.20.
Kim Seonghee	2011.12.30. ~ 2013. 4.18.
Lee Heeseong	2010. 5.20. ~ 2011.12.29.

Name	Terms of Office
Lee Sangyong	2008. 3.31. ~ 2010. 4.18.
Mun Byeongwoo	2007. 7.24. ~ 2008. 2.25.
Kim Myeonghyeon	2005. 9. 7. ~ 2007. 6.20.
Beon Cheolsik	2004.10.19. ~ 2005. 9. 6.
Jeong Yeonchan	2003. 5. 1. ~ 2004. 9.30.
Lee Hyeongju	2002. 4.18. ~ 2003. 4.10.
Park Jeonggu	1999. 6.26. ~ 2002. 4. 7.
Kim Heeseong	1998. 3.25. ~ 1999. 6.25.

3. The Roles and Responsibilities(HQ)

Department		Main Functions
Spokesperson		Promote the measures and performance of MFDS
Planning and Coordination Bureau	Planning and Finance Office	Direct and coordinate various kinds of middle and long-term policy and plans, direct and coordinate data required by the National Assembly, organize budget, coordinate and settle execution, coordinate and direct R&D project
	Organization and Management Innovation Office	Manage organization and quota, establish and inspect performance management plan, direct and coordinate improvement of government 3.0, administration system and organization culture
	Regulatory Reform and Legal Affairs Office	Draft and review legislation·administrative rule plan, direct regulatory reform, support cabinet· vice-minister meeting, support legislation of National Assembly, direct administrative appeal and litigation affairs
	International Cooperation Office	Direct and coordinate international cooperation and international trading of food and drugs, manage resident officers of diplomatic offices
	ICT Management and Statistics Office	Establish and evaluate middle/long term information plan of food and drugs, operate, maintain and repair information system, direct policy statistics
	Customer Support Office	Establish and execute comprehensive plans for improvement of customer satisfaction, develop customer support policy, direct and coordinate civil complaints and operate total counseling center
	Emergency Planning and Safety Office	Control and coordinate overall plan and training to cope with national emergency, manage mobilization resources for emergency(supplies, companies)
Audit and Inspection Office		Audit MFDS, its agencies and groups under MFDS, and handle audit results
Criminal Investigation Office		Investigate criminals of food and drugs, discover and investigate habitual and intentional criminal of food and drugs
Affairs Division		Documents, general affairs, personnel, use, accounting, facility work
Consumer Risk Prevention Bureau	Customer Risk Prevention Bureau	Develop consumer policy for improvement of protection of consumer right and interest for food and drugs, develop policy for prevention of risk of food and drugs
	Communication and Cooperation Division	Establish and execute total communication plans for food and drugs Communicate with people for improvement of safety awareness of food and drugs
	Risk Information Division	Collect risk information of food and drugs at home and abroad, construct risk information collection and analysis system and develop technique
	Integrated Food Information Service Division	Establish and operate integrated food safety information network and provide integrated food safety service

Department			Main Functions
	Laboratory Audit and Policy Division		Direct and coordinate system improvement, enactment and revision of laws and regulations related to inspection and examination of food and drugs, establish result quality enhancement and total development plan of inspection and examination agency
Food Safety Policy Bureau	Food Policy Coordination Division		Establish sanitation and safety management policy of utensil, container or packaging, food additive, health functional food and food
	General Food Management Division		Establish total plan on direction and control of business of foods, etc, establish and manage collection and inspection plan of foods
	Food Consumption Safety Division		Operate labeling standard of foods, labeling and advertisement deliberation standards of food for weight loss, establish and coordinate total plan on intensive management standard of hazard, and operate the food traceability
	Food Import Policy Division		Establish and operate follow-up measures of new material foods, enactment and revision of notice and regulations, safety management, system improvement, and establish total safety management plan of imported foods
	Alcoholic Beverages Safety Management and Planning Division		Establish and coordinate total plan for alcoholic beverage safety management policy, improve regulations and system, education and promotion, administrative measures
	Food Standard Planning Office	Food Standard Division	Establish and execute total plan for improving food standard and specification
		Livestock Products Standard Division	Establish and execute total plans for improving standad and specification of livestock
		Food Additives Standard Division	Establish and execute total plan on operation and establishment of standard and specification for sterilizer and disinfectant of utensil, etc., utensil, container and package and food additives
Food Nutrition and Dietary Safety Bureau	Nutrition Safety Policy Division		Develop policy on food nutrition safety, improve system, establish and direct total plan and policy on safety of food nutrition, direct policy of nutrition labeling
	Health Functional Food Policy Division		Develop policy on health functional food, establish and direct safety control total plan, direct sales approval and report of health functional food
	Dietary Life Safety Division		Establish and execute total plan of dietary life safety management of children, matters on nutrition and safety policy of favorite food of children and dietary safety management of children

Department		Main Functions
	Foodborne Disease Prevention and Surveillance Division	Establish and execute comprehensive plans for prevention of food poisoning, operate pan-governmental food poisoning responding council, educate, promote and evaluate food poisoning prevention
Agro-Livestock and Fishery Products Safety Bureau	Agro-Livestock and Fishery Products Policy Division	Operate livestock sanitation and safety management system, establish measures, matters on operation, enactment and revision of labelling of livestock
	Livestock Products Sanitation Division	Investigate safety of livestock product, collect, inspect, establish and execute guidance and control plan
	Agro-Fishery Products Safety Division	Establish and operate safety management plan of agro-fishery product, direct and coordinate tasks on risk evaluation of agro product cultivation environment
	Foreign Inspection Division	Establish and coordinate sanitation and safety management policy of imported fishery product, imported and exported livestock product
Pharmaceutical Safety Bureau	Pharmaceutical Policy Division	Develop policy on safety management of medicine, enact and revise notice and laws on medicine, operate medicine approval system and develop policy
	Pharmaceutical Management Division	Establish and coordinate pharmacist monitoring plan, operate labeling and advertisement system of medicine, designate and manage medicine likely to be abused or misused
	Narcotics Policy Division	Establish and coordinate policy development and total plan of narcotics and substance materials, enact and revise related laws and notice, establish and coordinate distribution and monitoring framework plan
	Pharmaceutical Quality Division	Establish plan related to manufacturing and quality management standard of medicine, operate system, establish education plan and international cooperation
	Clinical Trials Management Division	Direct coordination and establishment of policy related to clinical trial, approval and management of clinical trial plan of medicine
	Pharmaceutical Approval and Patent Management Division	Operate registration, management and related system of patent list of medicine, enact and revise regulation
	Pharmaceutical Safety Evaluation Division	Collect, manage and evaluate side effects information of medicine and quasi-drug, operate medicine damage relief system
Biopharmaceuticals and Herbal Medicine Bureau	Biopharmaceutical Policy Division	Establish and coordinate policy related to biological product, gene recombination medicine, gene medicine, cell medicine, tissue-engineering medicine, human tissue and plasma safety
	Biopharmaceutical Quality Management Division	Establish manufacturing and quality management standard of biopharmaceuticals, manage and operate change, establish and coordinate monitoring plan of human tissue transplants
	Herbal Medicine Policy	Establish and coordinate safety related policy of herbal medicine and medicinal herb products, enact and revise related laws and regulations.

Department		Main Functions
	Cosmetics Policy Division	Establish and coordinate cosmetics related policy, enact and revise related laws and regulations, establish total plan of cosmetics manufacturing and quality management standards
	Quasi-drug Policy Division	Establish and coordinate policy related to quasi-drug, enact and revise related laws and regulations, establish and coordinate monitoring plan of quasi-drugs
Medical Device Safety Bureau	Medical Device Policy Division	Establish and coordinate distribution policy of medical device, operate approval system, classification and designation of medical device, and develop policy.
	Medical Device Management Division	Establish and coordinate monitoring plan of medical device, establish and coordinate instruction and enforcement plan of medical device handler, matters on preliminary deliberation of advertisement of medical device
	Medical Device Safety Evaluation Division	Management of side effects of medical device, management of safety information of medical device, matters on re-evaluation and review of medical device

4. Number of Staff

1) Prescribed Number

As of May 19, 2016 (Unit : persons)

Position / Agency, Division	Total	State	General Posit											Management Operation Post
		Minister	General·Research high ranking	3·4	Class 4	4·5	Class 5	6	7	8	9	Senior officer	Researcher	
Total	1,774	1	23	12	46	32	203	302	306	139	53	158	464	35
HQ	584	1	10	10	33	21	115	122	111	6	8	36	91	20
Agency	1,190		13	2	13	11	88	180	195	133	45	122	373	15
NIFDS	408		7		5	1	29	13	11	19	5	107	208	3
Regional FDA	782		6	2	8	10	59	167	184	114	40	15	165	12
Seoul Regional Office	122		1	1	1	2	9	28	28	11	7	5	23	5
Busan Regional Office	206		1	1	4		17	42	50	42	7	2	38	2
Gyeongin Regional Office	260		1		3	2	17	56	51	32	13	5	76	4
Daegu Regional Office	51		1			2	4	10	14	9	3	1	7	
Gwangju Regional Office	71		1			2	7	14	20	11	5	1	9	1
Daejeon Regional Office	72		1			2	5	17	20	9	5	1	12	

2) History of Change in Prescribed Numbers

May. 19, 2016 1,744 persons (12 persons increased)

- required person for 2016: 12 persons
- personal for Integrated Food Information Service Division: 2 persons
- personal for cyber security: 1 person
- personal for strengthening safety management of imported food: 2 persons
- personal for safety and traceability of drug and medical device management: 2 persons
- personal for R&D management and biosimilar approval process: 2 persons
- personal for food traceability and archive management: 3 persons

Dec. 30, 2015 1,762 persons (reduced by 16)

► Cutback 16 people according the Integrated Personnel Management Plan (June 2013) of the Ministry of Security and Public Administration ('13.6)

- Headquarters: △5
- National Institute of Food and Drug Safety Evaluation: △3
- Regional Offices of Food and Drug Safety: △8

Dec. 4, 2015. 1,778 persons (increased by 1)

- Added a new staff for cyber security (1)

May 29, 2015 1777 persons(14 persons increased)

► required person for 2015 : 14 persons

- personnel for Pharmaceutical Safety Evaluation Division : 3 persons
- personnel for human tissue : 2 persons
- personnel for operation of integrated food safety information network : 1 person
- personnel for food traceability : 2 persons
- personnel for management of food radiation : 3 persons
- personnel in charge of records and personal information : 3 persons

Jan. 9, 2015 1763 persons(7 persons decreased)

► Frequent position of 2014 : 9 persons

► 16 persons reduced according to integrated operation plan of MOPAS(June 203)

- HQ : △5 persons

- NIFDS : △4 persons
- Regional FDA : △7 persons

Aug. 27, 2014 1770 persons(12 persons increased)

► required person for 2014 : 12 persons
- personnel for quasi-drug safety management : 4 persons
- personnel for test and inspection quality management : 2 persons
- personnel for operation and construction of integrated food safety information network : 3 persons
- personnel for plasma safety management : 3 persons

Dec. 18, 2013 1758 persons(17 persons decreased)

► reduced 17 persons according to integrated operation plan of MOPAS(June 13)
- HQ : △6 persons
- NIFDS : △3 persons
- Regional FDA : △8 persons

Oct. 4, 2013 1775 persons(15 persons increased)

► Frequent position of 2013 : 6 persons

► Increase personnel in charge of eradication of adulterated food : 5 persons
- increase personnel of Government 3.0 : 1 person

► required number for 2013 : 12 persons
- personnel for management of alcoholic beverage : 2 persons
- personnel for medicine approval and patent : 4 persons
- personnel for follow-up management of cosmetics : 3 persons
- personnel for local inspection of medical device GMP : 2 persons
- personnel for protection of personal information : 1 person

► transfer of personnel of radiation safety management from Ministry of Welfare : △3 persons

Mar. 23, 2013 MFDS established, 1760 persons(277 persons increased)

► Personnel transferred from Ministry of Agriculture and Forestry : 260 persons

► Personnel transferred from the Ministry of Welfare : 10 persons

► Increased imported food inspection staff : 12 persons

► Common division : △5 persons

5. Laws and Regulations under the Ministry of Food and Drug Safety

Name of Law(15)	Enforcement Ordinance(16)	Enforcement Rule (Ordinance of Prime Minister)(20)
Framework Act on Food Safety	Enforcement Decree of Framework Act on Food Safety	
Food Sanitation Act	Enforcement Decree of Food Sanitation Act	Enforcement Rule of Food Sanitation Act
		Rule on Health Examination of Employee in Food and Sanitation Area
Special Act on Imported Food Safety Management	Enforcement Decree of the Special Act on Safety Management of Imported Foods	Enforcement Regulations of the Special Act on Safety Management of Imported Foods
Act on the Establishment and Operation of the Korea Institute For Food Safety Management Accreditation		
Health Functional Foods Act	Enforcement Decree of Health Functional Foods Act	Enforcement Rule of Health Functional Foods Act
Special Act on Safety Control of Children's Dietary Life	Enforcement Decree of Special Act on Safety Control of Children's Dietary Life	Enforcement Rule of Special Act on Safety Control of Children's Dietary Life
Livestock Products Sanitary Control Act	Enforcement Decree of Livestock Products Sanitary Control Act	Enforcement Rule of Livestock Products Sanitary Control Act
Agricultural and Fishery Products Quality Control Act	Enforcement Decree of Agricultural and Fishery Products Quality Control Act	Rule on Labeling of Genetically Modified Agro-Fishery Products and Safety Examination of Agro-Fishery Products
Pharmaceutical Affairs Act	Enforcement Decree of Pharmaceutical Affairs Act	Rule on Safety of Medicine, etc
	Regulation on Damage Relief of Side-Effect of Medicine	Enforcement Rule of Regulation on Damage Relief of Side-Effect of Medicine
	Decree on Facility of Manufacturer and Importer of Medicine, etc.	Enforcement Rule of Decree on Facility of Manufacturer and Importer of Medicine, etc.
		Rule on Manufacturing, Sales Management of Biological Products
Act on the Control of Narcotics, ETC.	Enforcement Decree of Act on the Control of Narcotics, ETC.	Enforcement Rule of Act on the Control of Narcotics, ETC.
Cosmetics Act	Enforcement Decree of Cosmetics Act	Enforcement Rule of Cosmetics Act
Medical Devices Act	Enforcement Decree of Medical Devices Act	Enforcement Rule of Medical Devices Act
Laboratory Animal Act	Enforcement Decree of Laboratory Animal Act	Enforcement Rule of Laboratory Animal Act
Safety, Management, etc. of Human Tissue Act	Enforcement Decree of Safety, Management, etc. of Human Tissue Act	Rule on Safety of Human Tissue
	Ministry of Food and Drug Safety and its Organizations	Enforcement Rule of Ministry of Food and Drug Safety and its Organizations
		Rule on Establishment and Supervision of Non-Profit Corporation under MFDS
		Enforcement Rule of Emergency Resource Management Act under MFDS
Food and Drug Examination and Inspection Act	Enforcement Decree of Food and Drug Examination and Inspection Act	Enforcement Rule of Food and Drug Examination and Inspection Act
		Rule on Inspection and Examination Request of MFDS and its Organizations
Food and Drugs Safety Technology Promotion Act	Enforcement Decree of the Act on Promotion of Safety Technology for Food and Drugs	Enforcement Regulations of the Act on Promotion of Safety Technology for Food and Drugs

6. Contributors

Contents	Division / Director	Contributors
A Message from the Minister	ICT Management and Statistics Office/ Moon Kwang-kyu	Choi Jeong Soon
		Jang Minhee
		Seong, Yeon Ju
Contents	ICT Management and Statistics Office/ Moon Kwang-kyu	Choi Jeong Soon
		Jang Minhee
		Seong, Yeon Ju
I. Outline		
1. Vision, Objectives, and Core Strategies	Planning and Finance/ Kang Baeg-won	Choi Ji-woon
		Han Gyu-hong
2. Organization·Affiliated Organizations	Organization and Management Innovation Office/ Cho Dae Sung	Jang Su Yong
		Im Chang Geun
		Lim Rock Joung
3. History	Organization and Management Innovation Office/ Cho Dae Sung	Jang Su Yong
		Im Chang Geun
		Lim Rock Joung
II. Food		
Chapter 1. Strengthening of the Food Safety Management System		
1. Cooperation between Government Bodies to Eradicate Unwholesome Food	Unwholesome Food Eradication Team/ Kang Daejin	Shin Yongjoo
		Jeong Mihee
		Jang Yunseok
2. Strengthening of Food Production and Manufacturing Safety		
1) Establishment of a Basis for Food Manufacturing Safety	Food Consumption Safety Division/ Kang Seog-youn	Kim Se-hwan
		Baek Nam-i
		Jeon Dae-hoon
		Lee Jung-wook
	General Food Management Division/ Han Sang Bae	Kim Sung Il
		Sun Nam Kyu
2) Safety Management of the Production and Distribution of Agricultural, Livestock and Marine Products	Agro-Fishery Products Safety Division/ Park Il-kyu	Baek Gil-tae
		Seo Sam-seok
	Livestock Products Sanitation Division/ Choi Soon Gon	Song Sung Ok
		Lee Kyoung A
		Lee Mun Hong
3. Improving the Level of Safety Management for Foods Being Distributed and Consumed	General Food Management Division/ Han Sang Bae	Kim Sung Il
		Sun Nam Kyu
	Food Consumption Safety Division/ Kang Seog-youn	Park Sang-eun
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		Bae Sung-myung
		Jeong Jin-mock

Contents	Division / Director	Contributors
4. Strengthening Safety Management of Imported Foods		
1) Strengthening Inspection and Management of Imported Foods	Food Import Policy Division/ Jeon, Jong Min	Oh, Jae Joon Kim, Myung Hee
2) Strengthening of On-Site Inspection in Exporting Countries for Precautionary Safety Management	Inspection and Audit Division/ Lee Soo-doo	Jun Se-hee Park Su-jeong
3) Reinforcing Safety Management of Novel Foods including Genetically Modified (GM) Foods	Novel Food Division Kang Yun-sook	Lee Woo Young Chung Hyung Wook Shin Ji-eun
	Food Import Policy Division/ Jeon Jong-min	Kim, Kwang Soo Ahn, Jung Ha
5. Establishment of an Alcoholic Beverage Safety Management System	Alcoholic Beverages Safety Management and Planning Division/ Park Hee ok	Kim Seong geun Yoo Sun young
Chapter 2. Internationalization of Scientific Food Standards and Specifications		
1. Improving Food Safety Standards and Specifications	Food Standard Division/ Yoon Hye-jeong	Park Jong-seok Jung Yong-hyun
	Livestock Products Standard Division/ Son Seong Wan	Byun Seong Keun Yun So Mi
2. Improving and Reinforcing Standards and Specifications on Food Additives, Equipment, Containers and Packaging	Food Additives Standard Division/ Chang-Hee Lee	Sung-Kug Park Hyun-Joo Ahn
Chapter 3. Expansion of Healthy Dietary Environment		
1. Strengthening Food Safety Management		
1) Expansion of the Management of Meal Service Sanitation and Nutrition	Life Safety Division/ Na Ahn-hee	Hwang Sun-soon Choi Woo-Jeong Lee Sung-Hak
2) Strengthening Safety Management of Children's Food	Life Safety Division/ Na Ahn-hee	Kim Seong-Hee Lim Ji-Yeoun Lee Sung-Hak
2. Reduction of Food Poisoning through Development of a Safe Eat-out and Meal Service Environment	Foodborn Disease Prevention& Surveillance Division/ Kim Il	Jeong jeong-soon Jo jung-ok
3. Improving the Regulation of Health Functional Foods and Invigoration of the Market	Health Functional Food Policy Division/ Kim Sol	Oh Un Hwan Jang Mi Ran
4. Strengthening of Safety Management of National Nutrition		
1) Efforts to Reduce the Nutrients including Sodium which are liked with increased rates in chronic disease If consumed in excess of recommeded guidelines	Nutrition Safety Policy Division/ Jung Jinee	Lee Hye Young Lee Soon Ho Ryu Seung Ho Lee Si Young

Contents	Division / Director	Contributors
Ⅲ. Medicinal Products		
Chapter 1. Medicine		
1. Introduction and Stabilization of GMP that is in Harmony with International Standards	Pharmaceutical Quality Division/ Kim Myoeng Ho	Lee Ha Young Lee Jae Hyoen
2. Internationalization of Medicine Approval and Evaluation System		
1) Establishment of a Globally Competent Medicine Approval and Evaluation System	Drug Review Management Division/ Choi Young ju	Kim Hee sung Song Ju kyoung
2) Invigoration of Cooperation with Foreign Regulatory Authorities	Pharmaceutical Policy Division/ Sang-Bong Kim	Pan-soon Kim Sun-im Park
3) Modernization of Pre- and Post-Management of Clinical Trials	Clinical Trials Management Division/ Kim Myung-jung	Lee sung-doo Nam Tae-kyun Jeong ho Lee Cheol-seung
3. Strengthening Safety Management of Approved Pharmaceuticals		
1) Cutting Off Distribution of Illegal and Unwholesome Medicine and Activation of a Monitoring Network	Pharmaceutical Management Division/ Kim Chun-Rae	Song Hyun-sue Lee Sun-Hee Lee Won-im
2) Pharmaceutical Damage and Side Effect Relief Policy	Pharmaceutical Safety Evaluation Division/ Lee Su jung	Kim Sang hyun Han Song yi
3) Collection, Evaluation, Production and Supply of Safety Information about Released Drug Products	Pharmaceutical Safety Evaluation Division/ Lee Su jung	Lim Sang woo Kim Mi Young
4. Strengthening the Competitiveness of the Pharmaceutical Industry by Stable Operation the Patent-Regulatory Approval Linkage System	Pharmaceutical License and Patent Division/ Lee Nam-hee	Park Hyun jung Kim Min jo Heo Kyung moo
5. Establishment of a Management System for Preventing Abuse and Misuse of Narcotic Drugs	Narcotics Policy Division/ Kim Sungjin	Kim Kwang-jin Choi Hee-jung Seong Dong-cheon Eun Kyung, Han Kim Jiseon Shin Myung-in
Chapter 2. Biopharmaceuticals and Cosmetics		
1. Safety Management and Quality Improvement of Biopharmaceuticals (Human Tissues)	Biopharmaceutical Quality Management Division/ Kim Kiman	Go Jihun Kim Kiwan Kim Hyungseok
2. Safety Management of Herbal and Natural Medicine	Herbal Medicine Policy Division/ Park Ki-sook	Hwang Sun-yi Seo Dong-hoon Hwang Jae-yang

Contents	Division / Director	Contributors
3. Consumer-Centered Safety Management of Cosmetics and Quasi-Drugs	Cosmetics Policy Division/ Kwon Oh Sang	Lee Sung Min
		Lee Jung Hwa
	Quasi-Drug Policy Division/ Ahn young jin	Choi geong sik
		Kim sun hee
4. Realizing a Creative Economy to Support Korean Biopharmaceutical Industry's Advancement into the Global Market	Biopharmaceutical Policy Division/ Kim Young-ok	Kim Namsoo
		Kang min ho
		Chae Jooyoung
		Yeo sung gu
5. Establishment of an Advanced Approval and Evaluation System for Biopharmaceutials		
1) Strengthening Global Competitiveness of Korean Biopharmaceuticals through International Cooperation	Biopharmaceutical Policy Division/ Kim Young-ok	Lee Yoo-kyoung
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		Park Eun-soon
		Yeo sung gu
2) Improving for the Review and Approval System Biopharmaceuticals and Cosmetics and Leading the International Standards	Biologics Division/ Hyejoo Chung	Seung-Wan Jee
		JiSuk Seo

Chapter 3. Medical Devices

1. Establishment of a Support System for Quick Commercialization of Medical Devices	Medical Devise Policy Division/ Shin Joon-Su	Ki Yong-Ki
		Hwang Hye-Jin
		Jang Moo-Young
2. Advancement of Consumer-Centered Medical Device Safety Management System	Medical Devise Management Division/ Ju Seon-tae	Han Mi-sung
		Lee Jae-won
		Cho Ji-youn
3. Establishment of a Safety Evaluation System for Medical Devices	Medical Devise Safety Evaluation Division/ Hwang In-jin	Park Joo-hwan
		Kim Se-jung
4. Advancement of Medical Device Approval Review Process	High-Tech Medical Device Division/ Cho Yangha	Jeong Jinbaek
		Kang Youngkyu
		Yang Wonsun
		Son Seungho

IV. Risk Prevention

Chapter 1. Establishment of a Basis for Consumer-Focused Preemptive Risk Prevention and Crisis Response System

1. Establishing a Basis for Preventing Safety Accident	Customer Risk Prevention Policy Division/ Jang Min-su	Jang In-seong
		Kim Jae-seon
		Hwang Su Jin
		Kang Yun-sook
2. Establishing a Food and Drug Safety Management System through Precautionary Safety Management	Customer Risk Prevention Policy Division/ Jang Min-su	Oh, Jae-ho
		Kim Bang-hyun
3. Strengthening Cooperation with Consumer-related Organizations and Groups	Customer Risk Prevention Policy Division/ Jang Min-su	Choi Hyun-cheol
		Ko Seong Hwan

Contents	Division / Director	Contributors
Chapter 2. Promoting Food and Drug Safety Consensus by Strengthening On-site Communication		
1. Promoting Communication with the Public	Communication and Cooperation Division/ Lee Hyo-min	Park Nam-Su
		Lee Ju-Kyung
2. Establishing and Operating a Communication Network	Communication and Cooperation Division/ Lee Hyo-min	Lee Mi-Soon
		Lee Hai-Eun
3. Operating Public Experiential Programs	Communication and Cooperation Division/ Lee Hyo-min	Kim Hyun-Kyung
		Park Na-Young
Chapter 3. Enhancing Transparency, Sharing and Use of Food and Drug Safety Information		
1. Collecting, Analyzing and Utilizing Food and Drug Safety Information	Risk Information Division/ Lee, Ym-Shik	Choi, Gye-Sun
		Kim, Hyeon-Jeong
		Pack, Soung-Yeoul
Chapter 4. Enhancing International Competitiveness through the Advancement of Testing and Inspection Agencies		
1. Overview of Testing and Inspection Agencies	Laboratory Audit and Policy Division/ Rhee Seong-do	Lee Hyeon-hee
		Ahn Yong-sun
2. Designation and Follow-up Management of Testing and Inspection Agencies	Laboratory Audit and Policy Division/ Rhee Seong-do	Lee Hyeon-hee
		Ahn Yong-sun
3. Improved Reliability & Advanced Management System of Testing and Inspection Agencies	Laboratory Audit and Policy Division/ Rhee Seong-do	Lee Hyeon-hee
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V. Research and Development for Food and Drug Safety		
Chapter 1. Research and Development that are Directly Linked to Safe Life		
1. Improvement of Food and Drug R&D	Research Planning and Management Division/ Nam BongHyun	Mun Chun-sun
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2. Impartial Research Management and Provision of Services for Researchers	Research Management TF/ Kim Mi-jeong	Lee Seon-hwa
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3. Outcome Management for Effective Research and Development Projects	Research Management TF/ Kim Mi-jeong	Roh Hye-won
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		Kim Dae-uk
Chapter 2. Expanding Risk Assessment for Scientific Food Safety Management		
1. Improvement of Risk Assessment System with Expanded National and International Cooperation	Food Safety Risk Assessment Division/ Hwang In Gyun	Moon Guiim
		Cho Yoon Jae
		Suh Jinhyang
2. Advancement of the Risk Assessment System for Residual Substances in Agricultural, Livestock and Marine Products	Pesticide and Veterinary Drug Residues Division/ Lee Gyuseek	Chang Moon-Ik
		Lee Sang-Mok

Contents	Division / Director	Contributors
3. Strengthening the Scientific Basis for Reducing Hazardous Pollutants in Food	Food Contaminants Division/ Kim Dong Sul	Kim Sheen Hee Paek Ock Jin
4. Research and Development of Expeditious and Precise Microbial Testing Methods	Food Microbiology Division/ Chung Gyung Tae	Kim Soon-Han Heo Eun Jeong
5. Strengthening Safety Management of Food Additives, Utensils, Containers and Packaging	Food Additives and Packages Division/ TaeSeok Kang	Jae Chon Choi Ho Soo Lim
6. Establishing a Basis for Managing the Safety of Food Nutrition, Dietary Life and Functional Health Foods	Nutrition and Functional Food Research Team/ Koo Yong Eui	Lee Hwa Jung Kang Yoon-Jung
7. Scientific Surveillance of Food Adulteration and Food Fraud	New Hazardous Substances Team/ Kwon Kisung	Lee Jin-Ha Kang Tae Sun
Chapter 3. Development of Safety Assessment Technologies for Supporting the Medicinal Products Safety Management System		
1. Research on Advancement of Pharmaceutical Safety Management	Drug Research Division/ Shin Won	Lee Kwang-moon Byun Jung-ah
2. Research on Biopharmaceutical Safety Management	Biologics Research Division/ Kim Jaeok	Kim Byung Guk Kang Hyunkyung
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6. Research on Medicinal Device Quality and Safety Management	Medical Device Research Division/ Park Chang won	Yoo Si hyung Lee Chang-hyung Lee Seung-ro Kim San
Chapter 4. Development of Safety Evaluation Technologies for Food and Drugs		
1. Government Control of Toxic Substances and International Cooperation in Toxicity Testing Methods	Toxicological Research Division/ Jeong Ja young	Cho Soo yeul Seok Ji hyeon
2. Development of Alternatives to Animal Testing and Advancement of Non-Clinical Tests	Toxicological Screening and Testing Division/ Soo Jung Sohn	Joo Hwan Kim Il Young Ahn Tae Sung Kim Jung-Sun Yi Kyungyuk Ko

Contents	Division / Director	Contributors
3. Research on Predictability of Drugs and Assessment of Pharmaceutical Dependence	Pharmacological Research Division/ Kim Hyung Soo	Kim Young-Hoon
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5. Preventing Adulterated Food and Drugs through an Advanced Analysis System	Advanced Analysis Team/ Baek Sunyoung	Cho Sooyeul
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6. Establishment of a System for Development, Preservation and Utilization of Laboratory Animal Bio Resources (BIOREIN: Bio Resources Initiative)	Laboratory Animal Resources Division/ Chung Myeon Woo	Lee Su Hae
		Kim Hae Deun
Chapter 5. Advancement and Strengthening of Expertise in the National Lot Release System		
1. Current Status of the National Lot Release System and Regulatory Improvements	Vaccines Division/ Ban Sang Ja	Lee Chulhyun
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2. Strengthening Cooperation and Communication through the Operation of Public-Private Consultative Group	Vaccines Division/ Ban Sang Ja	Lee Chulhyun
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3. The Roles and Responsibilities(HQ)	Organization and Management Innovation Division/ Cho Dae Sung	Jang Su Yong
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Contents	Division / Director	Contributors
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