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2017
Ministry of Food and Drug Safety
White Paper

Ministry of
Food and Drug Safety

Foreword

Under our vision of *"safe food and drug, healthy people, and well-being society"*, all staff of the Ministry of Food and Drug Safety (MFDS) are dedicated to ensure the safety of foods, drugs, and medical devices.

2016 was the year when the Special Act on Imported Food Safety Management was enacted to ensure safe and systemic control of imported food from farm to fork. Not only that, HACCP, once had been implemented only to processed food, was introduced to agriculture, livestock, and fishery products to strengthen overall food safety control system.

Furthermore, in terms of ensuring the safety of medical products, we revised the Relief Scheme for Adverse Drug Reactions to ensure drug safety and provide relief for victims of adverse drug reactions. Also, we modernized medical device management system to make sure necessary medical products can be supplied in a timely and safe manner.

Changes around the world such as climate change, low birth rate, and aging population require us to respond to these challenges effectively and proactively. On top of that, we are facing the fourth industrial revolution and emerging technologies such as CRIPSR-Cas9 system are being rapidly introduced to food and drug industries. Against this backdrop, we need to come up with new and better measures to ensure food and drug safety.

To proactively keep up with the changes in industries and regulatory landscape around the world, we monitor new technology trends to make sure such changes are applied and reflected in relevant laws and regulations. Also, we are committed ourselves to provide the public with necessary information in a timely way.

The 2017 White Paper is a compilation of our policies and achievements over the last year. We hope this white paper will help readers to better understand our policies and contribute to the development of food and drug industries.

June 2017

Minister of Food and Drug Safety

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·Pesticide and Verterinary Drug Residues Division
·Food Contaminants Division
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·Nutrition and Functional Food Research Team
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History

2017.03 Renewed the Food Nutrition and Dietary Safety Bureau as Food and Consumer Safety Bureau
Renewed the Agro-Livestock and Fishery Products Safety Bureau as Imported Food Safety Policy Bureau

2017.02 Establishment of the Division of Alcoholic Beverages Safety Management and Plannining, Narcotics Management(Headquarters)
Establishment of the Division of Biologics Division(National Institute of Food and Drug Safety Evaluation)

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)

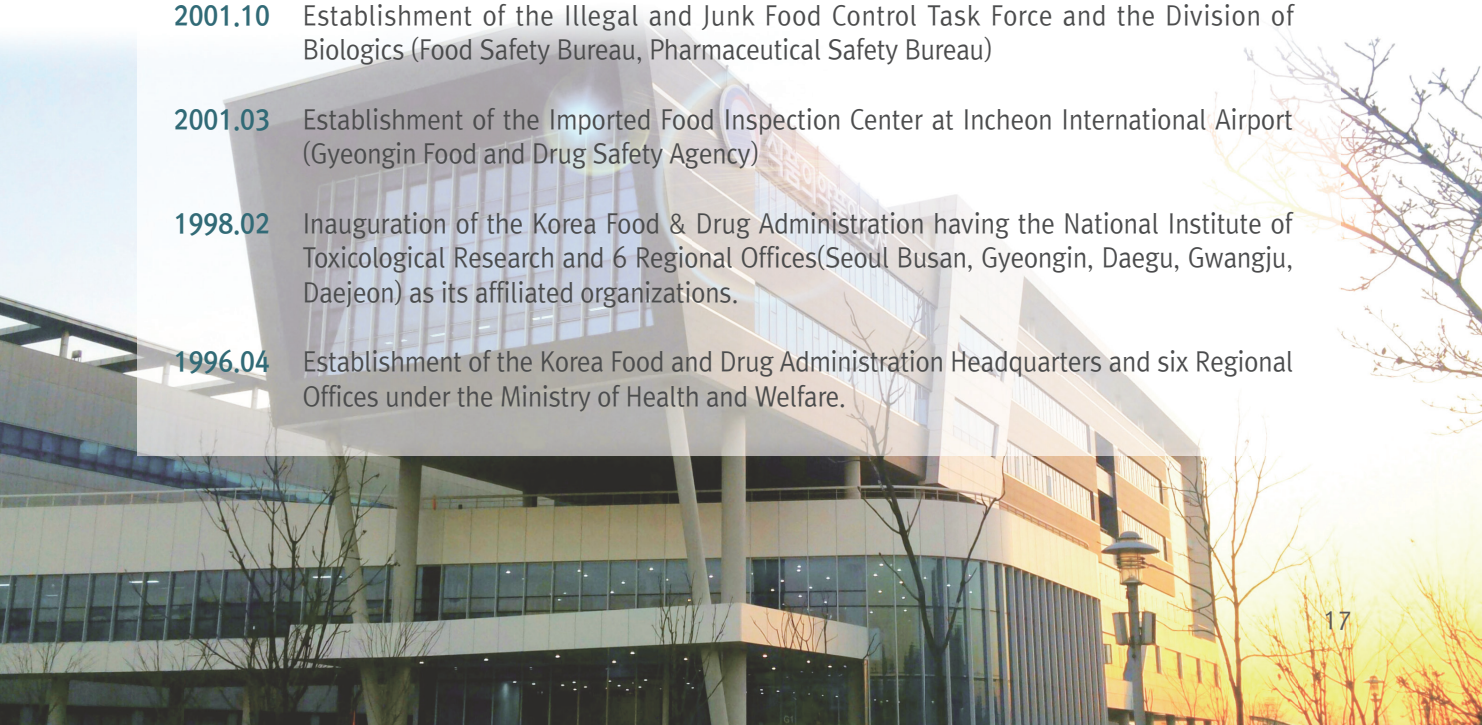
2002.06 Establishment of the Audit and Inspection Office (Headquarters)
Renaming of the National Center of Toxicological Research to the National institute of Toxicological Research

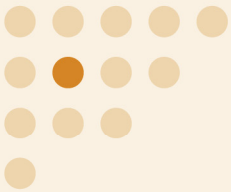
2001.10 Establishment of the Illegal and Junk Food Control Task Force and the Division of Biologics (Food Safety Bureau, Pharmaceutical Safety Bureau)

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.





2017 MFDS White Paper

Ministry of Food and Drug Safety

II

Food

Section 1

Strengthening 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

Recognizing that food safety issues people encounter everyday have important values in safeguarding people's lives and protecting their right to pursue happiness, the government has designated the food safety as a core governmental task.

Against this backdrop, the government defined unwholesome food* as one of 'four major social evils' that must be eradicated and designated the Ministry of Food and Drug Safety (MFDS) as the pan-governmental control tower for food safety to carry out intensive unwholesome food eradication measures.

☆ 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 including hazardous and defective foods that fail to meet legal standards were defined as 'unwholesome food' to help people easily understand what they are.

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

In an effort to effectively carry out unwholesome food eradication measures, the government established the 「Pan-governmental Council for Eradication of Unwholesome Food」 consisting of 29 government offices including the Ministry of Agriculture, Food and Rural Affairs, Ministry of Oceans and Fisheries, Korea Customs Service, and Korean National Police Agency (April 2013) and came up with a 'Pan-governmental comprehensive plan for eradicating unwholesome food' (May 2013). Among 46 detailed tasks of this plan, 8 tasks were completed and 18 extra tasks were added. Based on these 56 tasks, the council carried out its policies in 2016.

☆ Pan-governmental council for eradication of unwholesome food: Office for Government Policy Coordination, Ministry of Food and Drug Safety, Ministry of Education, Ministry of Justice, Ministry of Culture, Sports, and Tourism, Ministry of Agriculture, Food and Rural Affairs, Ministry of Oceans and Fisheries, Anti-Corruption & Civil Rights Commission, Ministry of Public Safety and Security, Korea Customs Service, Supreme Prosecutor's Office, Korean National Police Agency, and 17 cities and provinces.

B. Main Objectives of Pan-governmental Policies for Eradicating Unwholesome Food

1) Implementation of Pan-governmental Joint Monitoring System

Unlike the routine surveillance monitoring that have been conducted sporadically by each ministry, the Pan-governmental Council for Eradication of Unwholesome Food has implemented systematic crackdowns on each type of business from production to consumption stages in areas with high prevalence rate of key unwholesome food by cooperating with other governmental bodies. It has also improved the system to find and eradicate the root cause of unwholesome food at the same time.

From 2013 to 2016, the council has inspected a total of 57,787 businesses/establishments, found 4,095 businesses that violated the food safety-related regulations and arrested 78,000 people 'who deliberately manipulate products to make people buy'. Also, it has analyzed the cause of unwholesome food in various ways to find 47 tasks for system improvement.

These systematic pan-governmental joint planned monitoring activities have created synergic effect as governmental bodies cooperated and concentrated their crackdown capabilities on these activities, contributing to reduction of food safety blind spots that the authorities have lacked control over so far.

2) Integrated Management and Sharing of Food Safety Information

The Task Force for Eradicating Unwholesome Food has provided 'Unwholesome Food Information Analysis Report' (monthly, yearly) to 42 institutions including government offices associated with the council and consumer groups. The report contains pan-governmental food safety information archived in Integrated Food Safety Information including administrative information (performance of food safety crackdown activities and non-compliant products), consumer complaints (1399 reports, national public reports), information from media at home and abroad, and food consumption trends.

In addition, MFDS set up a hotline for governmental bodies to ensure non-stop communication with people and signed an MOU with investigative agencies like the Supreme Prosecutor's Office and Korean National Police Agency to have prior consultation before news releases on arrests of criminals related to food safety, preventing consumer confusion, amplification of issues and spreading of rumors.

3) Special Management of Those Repeatedly Violating Food Safety Regulations on Purpose

Considering that getting rid of defective products does not necessarily lead to eradication of unwholesome foods, MFDS shifted its work paradigm from product-oriented to people-oriented one. In December 2016, 'Management System for Business Operators with Problems' was newly added to the Integrated Food Safety Information to track those who produce, distribute, and sell unwholesome foods until they are caught and to impose harsh penalties on them to weed them out of the market.

With this system, it will be able to root out those who exploit loopholes in our legal system as it automatically identifies business operators who repeatedly deceive consumers to help strengthen special control and monitoring on those identified operators.

4) Education and Campaigns for Spreading a Safe Food Culture

In order to spread nationwide safe food culture, the Task Force for Eradicating Unwholesome Food has conducted cooperative public campaigns with other governmental bodies including MFDS, Ministry of Culture, Sports, and Tourism, and Korean National Police Agency by making video clips such as 'Eradicating Unwholesome Food', broadcasting them through various media such as TV, buses, subways, and major supermarkets, and producing and distributing related promotional materials like leaflets.

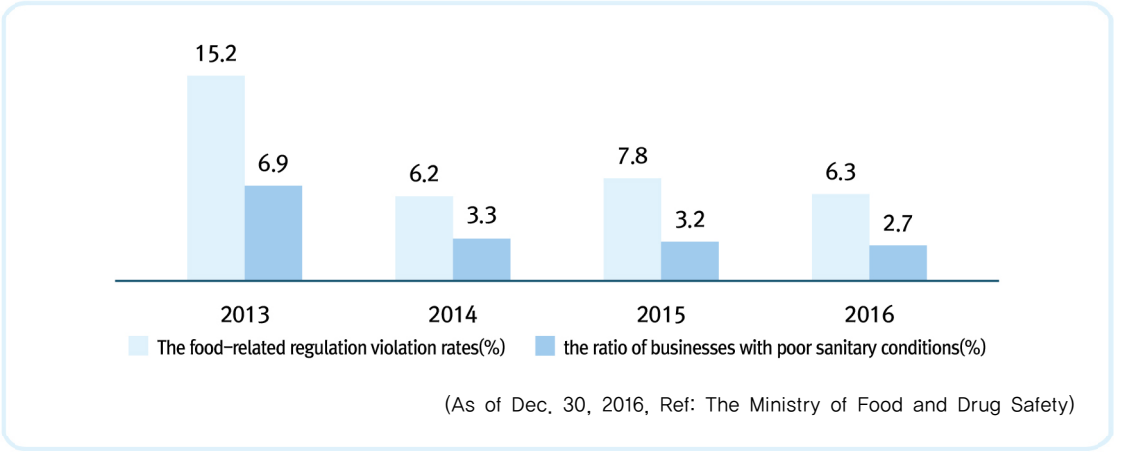
Also, under the slogan of 'Let's not make or buy unwholesome foods', it has carried out customized education programs on eradication of unwholesome food. From 2013 to 2016, 17 manufacturers and customer groups, or 122,775 people, have participated in these programs that mainly focused on how to control sanitary condition (for manufacturers) and how to identify and report unwholesome foods (for consumers).

C. Achievements of Pan-governmental Eradication on Unwholesome Food and Remaining Tasks

1) Achievements and Effects

The Pan-governmental Council for Eradication of Unwholesome Food which was launched in 2013 as a governmental-wide initiative has conducted intensive cooperative crackdowns on most commonly consumed foods and snacks that are popular as 'national snacks'. As a result, the food safety rule violation rates have decreased and the hygiene index has been greatly improved as the number of businesses with poor sanitary conditions that violates the expiration date and manages foods at unsanitary environments has decreased.

In addition, the council has contributed to establish a virtuous circle in food safety management system by analyzing the causes of unwholesome food through crackdowns and communication with those in the field and finding and suggesting policies and systems that need to be improved to solve these problems.



[Image 2-1-1] The food-related regulation violation rates and the ratio of businesses with poor sanitary conditions (from 2013 to 2016)

2) Remaining Tasks

Although the government has continued its effort to strengthen the safety management through the pre-import registration, on-site inspection of overseas manufacturers and more intensified import clearance inspection, trust of people on imported foods has not significantly improved. This may be because Illegal activities such as manipulation· change of the country of origin and fake expiration dates of imported products are still prevalent. Keeping this in mind, in 2017, MFDS will come up with realistic measures on imported food to fundamentally

root out these products and distribution routes that these *illegal activities frequently occur.

☆ Illegal distribution of ingredients not for dietary uses, increasing volumes of fishery products illegally, manipulation of expiration dates, fake country of origin.

Also, 'One-Strike Out System' for businesses and operators that intentionally and significantly violate food safety-related regulations would be strengthened from January 2017. To effectively carry out this system, MFDS will frequently conduct intensive investigation on the applicable illegal activities of those who fake the expiry dates or use unhealthy water, and strictly apply the rules in order to weed them out of the market and create a safe environment where people can believe the food they buy is safe.

On top of that, for effective crackdowns, it will use and analyze data in the Integrated Food Safety Information such as crackdown history and non-compliant products, etc. to identify businesses that are highly likely to violate food safety regulations and to enhance crackdowns on those operators.

Kang Daejin, Director of Food Integrity Bureau
☎ 043.719.1903

2. Strengthening Safety in 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 (HACCP) is a systematic preventive approach to food safety which was first developed by the National Aeronautics and Space Administration (NASA) to ensure food safety for the first manned space missions. The HACCP system developed into a food safety management system that monitors, analyzes and controls hazards that can be adulterated with food during the all stages of a food chain, from food production to distribution.

The mandatory HACCP was first introduced in Korea based on the 2002 「Food Sanitation Act」, and 6 items including fish paste products were designated as the 'mandatory HACCP-applied items'[1](Kimchi cabbage was added in Dec. 2006) in August 2003. In October 2005, 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 4,358 in 2016 but the number of HACCP certified businesses are small compared to the total number of food manufacturing companies (27,607).

[Table 2-1-1] HACCP Certification Status

(Dec. 31, 2016. unit: business entity (cumulative), Ref.: Food Consumption Safety Division)

Category	2011	2012	2013	2014	2015	2016
Total	1,163	1,809	2,408	3,029	3,734	4,358
Mandatory Application	703	1,130	1,417	2,056	2,450	2,885
Voluntary Application	618	1,008	1,397	1,500	1,995	2,321

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

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

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

In spite of MFDS carried out numerous campaigns to promote the effectiveness and excellence of the HACCP system, approximately 50% of Korean consumers were understanding HACCP system.

Therefore, MFDS not only carried television campaigns on the network and cable television but also actively utilized both consumer groups and food-related organizations to promote the HACCP system to the public.

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

(Dec. 31, 2016. unit: %, Ref.: Food Consumption Safety Division)

Category	2008	2009	2010	2011	2012	2014	2016
Ratio (%)	18.1	25.6	30	40.2	48.3	51.6	64.7

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 and the topic of sanitation has been issued. Also, 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% of grade 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%~70% 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 Agency of HACCP Accreditation and Services established in February 2017.

Jwa Jungho, Director of Food Safety Labelling and Certification Division
☎ 043.719.2851

2) Management of Foreign Substances in Food

A) Background

With accidents in relation to hazardous foreign objects in food occurred in 2008 when a mouse head was found in a pack of shrimp snack and a knife blade in a tuna can, the government amended the 「Food Sanitary Law」 on February 6, 2009 that businesses shall be obliged to report to the Ministry of Food and Drug Safety and to the Si/Gun/Gu office having jurisdiction over the area where they are located upon receipt of reports on foreign substances detected in their food in order to promptly take measures necessary to investigate and deal with consumer complaints regarding foreign objects and to resolve disputes and distrust between food businesses and consumers.

B) Achievements

The number of reports on foreign matters found in food was 5,332 in 2016, decreased by 45% comparing to that reported in 2010 when the mandatory report system was implemented for the first time. Foreign matters reported last year were insects (34.3%), molds (10.3%), metals (8.2%), and plastic (5.8%), and etc. and the causes of foreign objects in food were: those introduced during manufacturing process (473 cases) and those introduced during consumption and distribution processes (1,082 cases), false reports from those who confused raw materials with foreign matters (536 cases), and items that cannot be investigated due to loss of foreign objects or refusal of inspection by consumers, etc. (1,660 cases)

Also, to effectively improve the reporting and inspecting processes regarding foreign substances detected in food, the category of foreign objects was adjusted to those that people hate and can be easily introduced during manufacturing process. the relevant regulation was amended to delete 'consumption process' from the causes of foreign matters in food in order to prevent ungrounded, subjective and speculative conclusion of public officials inspecting cases and improve consumer confidence in food.

C) Implementation Plan

As food businesses have been improved their capabilities in managing foreign substances, in 2017, MFDS will focus on controlling more harmful and hated foreign objects in food and encourage food businesses to make individual efforts to better manage their sanitary condition in relation to foreign objects by promoting 'cooperative Network for foreign Object Control' consisting of mentors and mentees between large corporations and SMEs.

Kim Myeong-Ho, Director of Food Safety Management Division
☎ 043.719.2051

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

1) Background

As there are only limited number of ways to reduce or eliminate hazardous elements associated with agricultural, livestock, and fishery products during the distribution stage, preventive safety management during the production stage is very important and safety inspection on lands, water, and materials should be conducted in a systematic way.

2) Achievements

A) Safety Management of Agricultural Products

In 2016, MFDS conducted safety inspections on agricultural products that were commonly consumed but frequently found to be not compliant especially in the public wholesale markets where about 60% of domestic agricultural products are distributed and prevent them from being sold in advance.

With increased anxieties regarding nuclear disaster occurred in Fukushima, Japan, it has inspected radiation level of imported goods and found and withdrew· disposed of 1 item of dried neungi mushroom showed excessive level of cesium. Information on agricultural products with a trace of radiation below the standard level are also released on the MFDS website.

Meanwhile, the safety inspection during the production stage, which was commissioned to the Ministry of Agricultural, Food and Rural Affairs by MFDS, has been continuously conducted to detect residual pesticides, heavy metals, and fungal toxins. Based on the results, necessary measures such as shipment delay, change of use or disposal have been taken for those found to be not compliant and improvement measures for relevant production. And information on agricultural products unfit for human consumption are shared with the National Agricultural Products Quality Management Service and National Agricultural Cooperative Federation.

B) Safety Management of Livestock Products

The safety inspections·investigations on livestock products were carried out for a total of 390,000 items including those at slaughterhouse (meat) and dairy farms (raw milk) during the production stage.

The residual substance tests on meat were also carried out by 17 cities(Si) and provincial(Do) livestock sanitation testing agencies for a total of 151,162 livestocks to check toxic substances including 41 types of antibiotics, 51 synthetic antibacterial products, 2 hormone drugs, other medicinal products, and 43 types of agricultural pesticides. Also eggs from 4,636 farms (including overlapped farms) were collected and inspected for antibiotics and synthetic antibacterial products and as a result, quinolones were detected in 3 cases. Accordingly, the shipment of these eggs in question were postponed for further tests. Microorganism tests were also conducted at slaughterhouse, meat packaging facilities and meat shops and 126 (0.1%) cases were found to have microorganism exceeding the permitted limit. On-site inspections were carried out on those shops and facilities to analyze the cause and technical guidance were also given.

C) Safety Management of Fishery Products

In 2016, fishery products including the most commonly consumed products, marine products having a history of being non-compliant with safety regulations, regional·seasonal marine products, and each item of marine products were tested for animal medicine, heavy metals, shellfish toxin, Vibrio parahaemolycius, and Norovirus. As a result, 173 cases were found to

exceed the permitted limit and measures such as restriction·delay of shipment, withdrawal·disposal of those products and administrative actions were taken on those items.

In order to enhance safety management during the distribution and sales stages, especially for radiation, MFDS selected products that are commonly consumed and identified as having safety concerns and tested them for radiation to found that those products were all safe.

Also, it carried out quick on-site screening of water quality in water tanks and collected products being distributed in sushi restaurants to prevent *Vibrio parahaemolyticus* from being distributed. Moreover, in an effort to protect people from food poisoning, it created·sent promotional video clips (to about 750 institutions including National Federation of Fisheries Cooperatives) and raised awareness of how to prevent Vibrio and how to eat fish safely.

Meanwhile, MFDS has commissioned the safety inspection during the production stage to the Ministry of Maritime Affairs and Fisheries. Flatfish, eels, blue mussels, sharks, catfish and etc were tested and 141 cases were detected, disposed of or banned for shipment (or fishing).

[Table 2-1-3] Agricultural, Livestock, and Fishery Products Safety Inspection·Investigations carried out in 2016

(As of Dec. 31, 2016. Unit: case)

	Total		Agricultural products		Livestock products		Fishery products	
	No. of cases	Unfit for consumption	No. of cases	Unfit for consumption	No. of cases	Unfit for consumption	No. of cases	Unfit for consumption
Total	567,987	4,053 (0.7%)	133,526	1,853 (1.4%)	390,947	2,601 (0.66%)	27,482	173 (0.6%)
Production stage	478,150	3,023 (0.6%)	77,515	1,182 (1.5%)	366,504	2,446 (0.66%)	13,187	141 (1.1%)
Distribution, consumption stages	89,837	1,030 (1.2%)	56,011	671 (1.2%)	24,443	155 (0.63%)	14,295	32 (0.2%)

3) Implementation Plan

A) Safety Management of Agricultural Products

In 2017, MFDS will strengthen safety management on hazardous·concerned·vulnerable agricultural products to carry out safety inspections on 120,500 products of agricultural products.

The most commonly consumed products and top 15 items with repetitive history of being unfit for human consumption will be designated as subjects for special management, so they will be collected and tested every month to inspect a total of 45,000 products. Also, for safety

management of radiation, which is a major concern of the public, MFDS will conduct radiation test on 1,900 products of 43 items of agricultural products being distributed in Korea.

Also, it will investigate the status of agricultural products processing facilities that handle simple processing of products such as peeling, cutting, heating, drying, freezing, packaging, etc., give guidance to them and examine their products after collecting products. It will produce and distribute a Sanitation Manual to improve sanitation and enhance preemptive safety management to prevent agricultural products unfit for consumption from being distributed or sold by inspecting the public wholesale markets. Moreover, guidance and inspection on herbalists and wholesalers of medicinal herbs in top 5 herb medicine markets in Korea will be intensified and online distributers·shops will be also monitored to prevent illegal distribution of non-edible agricultural products and ingredients for limited use.

Meanwhile, the safety inspection during the production stage carried out by the Ministry of Agriculture, Food and Rural Affairs (National Agricultural Products Quality Management Service) will be conducted on a total of 75,500 cases including 9,150 agricultural products produced in areas that could be contaminated, 100 items with records of being non-compliant, 11,000 products that will be managed during vulnerable periods, and 500 cases for radiation tests.

B) Safety Management of Livestock

Regarding safety inspection of livestock products, MFDS collaborates with several institutions including MAFRA, Regional Korea Food & Drug Administrations, and city and provincial testing & inspection centers re-evaluate livestock through consultation and reflect the results in the safety inspection plan of livestock products for the following year. Also, rather than simply increasing the number of test cases or items, efforts have been made to raise the efficiency of monitoring and tests on the most commonly consumed medicinal products for animals in Korea by focusing on the items that have been detected many times. Meanwhile, when it comes to regulatory inspections on meats with high possibility of violating the permissible limit of residual substances, MFDS increased the number of the inspection cases from 29,000 to 29,300 taking the violence rates into account.

In addition to the regular product collections·inspections, special monitoring for false advertisements and hypes on the internet and mass inspections for storage·transportation businesses have been carried out in order to prevent hazardous accidents in advance.

C) Safety Management of Fishery Products

For fishery products safety management in 2017, MFDS will strengthen safety inspection on fish farms with a history of being detected for safety issues and increase education and training on safety management. Also, it will inspect 21,000 products including heavy metal testing for sharks, etc. as they have been detected for having heavy metals many times and make efforts to guarantee sustainable management of the safety of fishery products which could be managed in poor sanitary conditions.

In addition, among marine products during the distribution·sales stage, samples of a total 8,500 products will be collected for inspections after designating 17 domestic and 33 imported products with repetitive records of being unfit for consumption as subjects for priority management, and 39 products such as pollack, squid, and short-neck calm as the most commonly consumed products.

Meanwhile, the safety inspection during the production stage carried out by the Ministry of Maritime Affairs and Fisheries(National Fishery Products Quality Management Service) will be conducted on a total of 12,500 products including 16 items for special management, 5,600 products of 60 items that are the most commonly consumed, 980 products of domestic fishery products from near and deep sea for radiation tests, 5,050 certified marine products, and 270 products of 10 items for hazardous microorganism management.

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3. Enhancing the Safety Management of Foods Being Distributed·Consumed

A. Nationwide Joint Crackdown

In order to prevent food-related incidents in advance and ensure food safety, MFDS conducts joint crackdowns every year with the relevant organizations including local governments on foods that are at the center of controversy and those with repetitive history of being detected as unfit for consumption, and businesses that have repeatedly violated safety rules on purpose, according to the periodical or seasonal necessities.

In 2016, 31,492 joint crackdowns were carried out on winter·summer holiday foods, school

cafeterias preparing for a new semester, and youth training centers and 780 businesses (violation rates: 2.5%)were found to have poorly managed sanitation, to which corrective and improvement measures were applied.

B. Reinforcing Collection·Inspection of Foods Being Distributed

MFDS, local food&drug safety administrations, cities and provinces (Si/Gun/Gu) maintain food safety by collecting and inspecting foods being distributed in domestic market. In particular, the efficiency of these collection·inspections has been improved as relevant tasks are shared among them: MFDS establishes and handles comprehensive plans, local food & drug safety administrations collect and test foods for planned inspections, and cities and provinces (Si/Gun/Gu) establishes detailed plans according to the comprehensive plans of MFDS.

Last year, 190,000 items of agricultural·livestock·fishery products were collected and inspected and 1,176 cases that were not in compliance with food safety standards and regulations were seized or disposed. The rate of non-compliance was 0.6.

In 2017, MFDS will make an endeavor to manage food safety more efficiently, for example, by giving weighted values to the factors affecting safety of each food type and focusing on collection·inspection of food types selected considering weighted values.

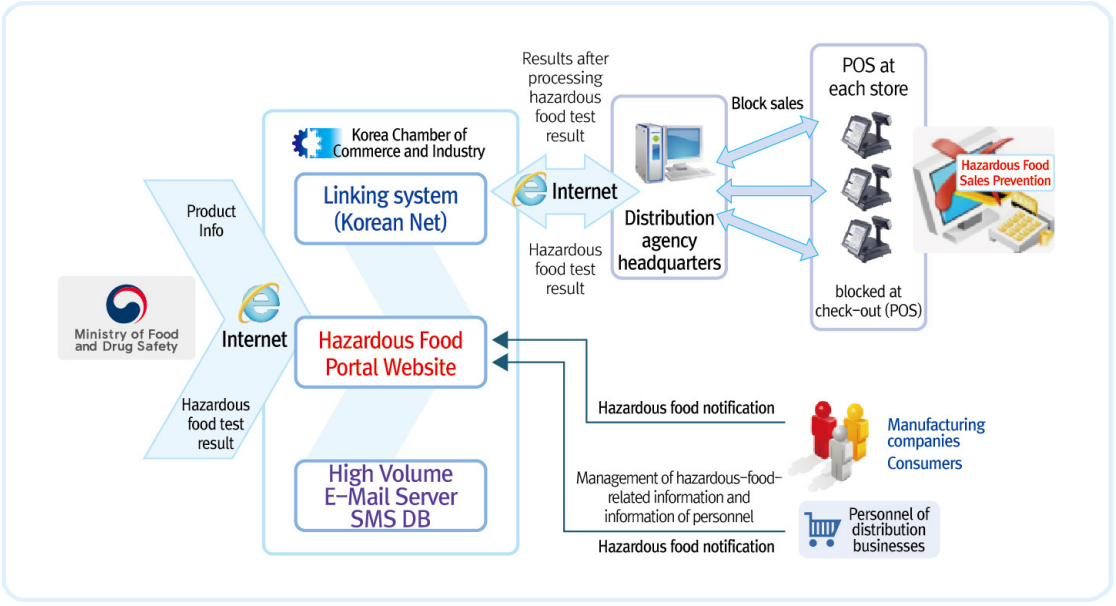
C. Harmful Food Sales Prohibition System

The quality and safety of foods being distributed in domestic market are confirmed by the collection·inspections carried out by governmental organizations such as MFDS and periodical self-quality tests performed on their own products by food manufacturing businesses.

After these tests and inspections, all the information on non-compliance products are reported to MFDS in real-time, and with the 'Harmful Food Sales Prohibition System' established and managed by MFDS, those reported real-time information are sent to counters in convenience stores or supermarkets in order to protect consumers from buying those hazardous products.

As of 2016, the 'Harmful Food Sales Prohibition System' has been used in a total of 78,151 stores nationwide related to food distribution and sales, including major supermarkets, department stores, small and medium-sized distributors, convenience stores, Nadeul store (small-sized supermarket), stores for TV shopping channels (including online shopping stores), and food suppliers. Thanks to this, about 26 million people, approximately 98% of the

economically active population in Korea, are able to safely purchase food products at stores with this system every day.



[Image 2-1-2] Flow Chart of Harmful Product (Food) Sales Prohibition System

* Increase in the number of stores (total) : 8,771 stores (in 2009)→ 52,966 (in 2014) → 64,060 (in 2015) → 78,151 (in 2016)
* Daily average beneficiaries of the system: 5.07 million people (in 2009) → 21.68 million (in 2014) → 23.83 million (in 2015) → 25.74 million (in 2016)

MFDS will continue its efforts to install this system in more stores, even small and medium-sized shops, to effectively prevent sales of hazardous food products by quickly recalling or banning distribution and sales of those products.

D. Food Traceability

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 Traceability 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 Traceability 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 Traceability System. Currently the 3nd phase (Dec. 2016) 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 (Food Traceability system for foods and health functional food products) to be investigated and assessed every 2~3 years.

B) Promotion of the Food Traceability System

In 2016, to promote mandatory and voluntary application of the Food Traceability System System, information meetings (seminars) were held 36 times for businesses, 76 sessions of training were carried out at a place exclusively established for the training was carried out for a total 998 persons. MFDS also offer field consultations to 3,618 establishments, operated campaign booths, carried out public campaigns (6 times) and as of 2015, 2,614 food-related businesses were registered to the Food Traceability System.

C) Linking the Food Traceability System

In order to establish plans for linking and applying the Food Traceability 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 3 working-level meetings were carried out. In the council meetings, the council members discussed carrying out research projects for laying the groundwork for linking the Food Traceability System, revising the Framework Act on Food Safety, sharing the information gathered from the Food Traceability System, plans for pan-governmental promotion activities and etc.

3) Implementation Plan

A) Phased Mandatory Application of the Food Traceability System and Increased Application

The year 2017 will be the 4rd phase of the mandatory application of the Food Traceability System. The mandatory system will be applied to businesses that import, manufacture or process infant and baby foods or health functional food products. MFDS is currently newly enforcing (2016~2018) a phased mandatory registration of milk formulas producessing operators.

B) Support for Business Operators Getting Registered in the Food Traceability System

The mandatory is being applied by phases to businesses that import, manufacture or process infant and baby foods, health functional food products, milk formulas and 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 and customized educational program and by improving the Food Traceability System, MFDS will enhance the System and make it more user-oriented and accessible to businesses.

MFDS will also improve the Food Traceability 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 Traceability 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 Food Traceability System from production to sale. Also, a Food Traceability council including outside experts, will be formed and have in-depth discussions of plans for linking the Food Traceability System from production(Agriculture, Livestock, Aquatic products) to sale.

E. Establishing Hazardous Food Recalling System and Sharing More Information with Consumers

In order to reduce consumer damages caused by hazardous foods, such as food safety incidents, measures to promptly recall and cut off the distribution·sales of such foods are

required. For this, MFDS has been provided information regarding hazardous foods in real-time with relevant organizations, distributors, and consumers by opening its web-sites and sharing portal sites for food safety information.

With Integrated Food Safety Administrative System (Integrated network), MFDS notifies information on foods that do not meet the safety standards and prevents the sales of those products to promptly recall hazardous foods and enhance information sharing with consumers, and since 2016, it has also shared the items for recall and results of recall on the MFDS website. And the 'Hazardous Food Sales Prevention System', which sends information on hazardous foods to the counters of distributors and stores to automatically cut off the sales of the food in question, has been be installed in 10,000 stores every year and 78,151 stores and shops are now using the system as of 2016.

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

1) Background

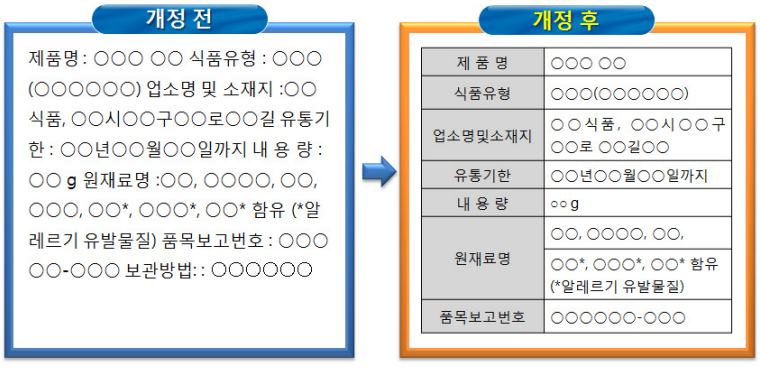
In order to provide accurate information on foods, food additives, utensils, and containers·packaging through labels, MFDS establishes and implements 「Food Labeling Standards」. As the social environment changes and consumers' demand for foods increases accordingly, it is the time to improve and come up with more consumer-oriented food labeling system.

2) Achievements

MFDS introduced a labeling system for food utensils in phases to help consumers to ensure that the food containers or utensils they use are safely manufactured according to the standards defined in the Food Sanitation Act. In 2016, this labeling system was fully implemented on rubber products, so that consumers could check the 'For Food' marks on the rubber gloves, etc. before purchase. MFDS has also promoted this system on TV or in movie theaters for this system to be established earlier than planned and understood by many people.

[Image 2-1-3] Labeling System for Food Utensils

Although it is mandatory to attach labels on food packaging containing information on name of ingredients, expiry date, name of business, and instructions for consumers, labels were difficult to read because of small and different-sized fonts. In June 13, 2016, the relevant regulation is amended to require that information should be written in over 10 pt font in a chart or paragraphs, rather than simply listing them.



[Image 2-1-4] New labels containing information in a Chart /Paragraphs with Increased Font Size

Since 2015, MFDS has carried out nationwide campaigns on allergies every year to raise awareness on allergy, through food labelling, of elementary school students, parents and school nurses in efforts to prevent food allergy of children. In 2016, a total of 83 campaigns were implemented for 3,829 participants.

3) Implementation Plan

MFDS plans to improve the food labelling system to provide more accurate and necessary information to consumers. n 2017, the system is implemented on products in synthetic resin, helping consumers to purchase and use safe disposable plastic gloves or plastic cruets with 'For Food' marks. Also, with more allergens labeling and prevention campaigns for food allergy, MFDS will do its best to contribute to improving the quality of life of patients with food allergies.

G. Monitoring of False Advertisements and Hypes

As more and more people are interested in the quality of life, false·hype advertisements that indicate or promote therapeutic effect of some kinds of food or that can make people confuse them with pharmaceutical products are also increased. Therfore, MFDS have implemented systematic monitoring and inspections on those advertisements.

As a results, MFDS caught 540 false and exaggerated advertisements through monitoring and those related to these advertising received administrative penalties or were prosecuted. It also requested the Korea Communications Standards Commission to block access to illegal overseas websites with false advertising in an effort to prevent consumer damages from those advertisements. Moreover, MFDS added a section called 'Information sharing on false and exaggerated food advertisement (www.foodsafetykorea.go.kr)' in its web portal to provide consumers information on the scope of false·hype advertising and violation cases.

With these monitoring system for false·hype advertising, more prevention campaigns on food advertisement will be carried out for people operating portal sites, online shopping sites, or in advertisement industry to prevent consumer damages. Monitoring of advertising of those who sell foods online will be reinforced as MFDS designated them as business operators pursuant to the Food Sanitation Act.

H. Operation of 'Consumer Food Sanitation Supervisor' System

In order to encourage consumers' active participation in food sanitation monitoring activities

and to ensure fairness·reliability·transparency in these activities by working with experts such as those in consumer groups, MFDS has operated 'Consumer Food Sanitation Supervisor' system.

In 2016 alone, 9,307 people were newly appointed as 'Consumer Food Sanitation Supervisor' and a total of 122,935 inspectors have participated in monitoring activities, inspecting sanitation condition of 606,120 food service businesses including restaurants and cafeterias providing food services.

MFDS will actively support the 'Consumer Food Sanitation Supervisor' system, encouraging consumers to take part in monitoring activities on food sanitation conditions and increasing their trust in food sanitation administration.

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4. Strengthening the Safety Management Systems of Imported Foods

A. Strengthening Inspection and Management of Imported Foods

1) Background

Korea's food self-sufficiency rate rose from 49.7% in 2014 to 50.2% in 2015. Also, because of globalization impacts on the world economy including the Korea-Europe Free Trade Agreement (July, 2011) and the Korea-U.S. Free Trade Agreement (March, 2012), the number and volume of imports increased 31.7% and 9% to 625,448 imports and 17,261 tons in 2016 from those of 2012.

However, a survey on the level of perceived food safety shows that 5 out of 10 people (58.7%) feel unsafe towards imported foods indicating the urgent national needs to enhance safety management of imported foods.

2) Achievements

A) Enhanced Preliminary Management of Imported Foods

MFDS took steps to establish sub-regulations, following the enactment of the Special Act

on Safety Management of Imported Foods (Feb. 2015) designed to begin on-site food safety management in exporting countries by requiring their manufacturers for pre-registration with the aim of preventing imported food hazards that increase each year. MFDS also further ensured the safety and sanitation of imported foods by setting up the Foreign Manufacturer Online Registration System (Dec.2015), and hygiene standards & evaluation procedures for livestock product exporters (Dec.2015).

B) Reinforced Customs Inspection on Imported Foods

While imported foods account for a growing portion of Korea's food safety, there are ever-present concerns of hazards cutting across borders and their proliferation as we have seen from the Chinese melamine milk scandal in 2008 and the Japanese nuclear disaster in 2011. Accordingly, strengthening field inspection on manufacturers with a history of handling defective and unwholesome products, or a high import volume, MFDS established a preliminary prediction import inspection system called OPERA in order to classify the ratings of imported foods by analyzing the past records and inspection results of manufacturers and importers.

After analyzing the hazard records by country, item and substance, MFDS differentiated random sample rates based on the hazard levels and selected the items subject to in-depth inspection to apply the 'selection and focus' principle to the inspection. For random sample testing, the Ministry utilized and improved the preliminary prediction import inspection system (OPERA) designed for in-depth inspection on potentially hazardous imported foods.

In order to safely manage Japanese imports after the Fukushima nuclear disaster (March, 2011), MFDS temporarily suspended the import of 27 items from 13 prefectures subject to the Japanese government's distribution prohibition action. Also, the Ministry made it mandatory to attach the Japanese government's official certificate to Japanese food imports and conduct an inspection on each import for double inspection. The import of Japanese food is basically suspended even when a small amount of radiation is detected through radiation inspection by certificate requirements for inspection on radioactive nuclides such as strontium, plutonium, etc. In order to let people know the status of radiation safety management, MFDS posts the updated information on radiation inspection and detection of Japanese imported foods on its website. MFDS also distributes radiation-related news and information to over 600 organizations including the media, consumer groups, etc. to further improve the nationwide awareness of food safety and accessibility to safety information.

C) Strengthened Importers' Responsibility for Imported Food

With the aim of securing the effectiveness of the food safety education order policy, MFDS improved the policy by allowing hygiene education personnel as well as business operators for education, and provided a total of 796 people with 23 training sessions. MFDS also offered a capacity building program to new food hygiene personnel (1 session, 20 people) in order to enhance the capacities of public officials in charge of food imports while offering a program on imported food inspection systems (10 sessions, 201 people. online course) in order to promote the understanding of the systems.

3) Implementation Plan

A) Enhancing On-Site Food Safety Management Prior to Import

Under 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, MFDS will implement pre-registration of foreign manufacturers overseas, strengthen local safety management in export countries, apply differential inspection levels through the analysis of past records of importers and their goods, and establish a system for tracking the history of imported foods.

Aiming at securing objectivity, transparency and efficiency of on-sight inspection, MFDS will invest more in sensory inspection tools and intensively control potentially hazardous foods based on the preliminary prediction import inspection system (OPERA) by scoring hazard levels through the analysis of information about inspection history, hazards, importers, manufacturers, low-priced products, etc.

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

In addition to the currently implemented inspection order, MFDS will apply an import level inspection order policy to imported foods with high defect rates to enhance business operators' sense of responsibility, implement the expanded education order policy to prevent the recurrence of defects, increase the scope of education recipients to ensure the effectiveness of the policy, and set up a highly-accessible, online education course.

After implementing the inspection order policy for imported foods (Mar. 29, 2012), MFDS applied the Regulation on Foods Subject to Inspection Order prepared by improving the weaknesses in the policy to 3 cases (Indonesia, snacks etc.) starting from Feb. 29, 2016. MFDS

will also provide real-time information on defective products and manufacturers for all the importers to help them prevent the imports of problematic products and further 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), the number and weight of food imports have continuously risen and the standard and specification inspection at the customs is insufficient to cover and secure the safety of processed food and agricultural products which take up 31.7% (weight 9.0%) and the largest share of the total food imports.

Hence, by establishing and enforcing 「Special Act on Imported Food Safety Management」, on-site inspection of foreign food facilities are considered important than ever.

B) Achievements

MFDS carried out on-site inspections of foreign food facilities that export large amount of products to KOREA commerce or that show a history of defective products. Also, MFDS held information meetings on Korea food standards&specifications for stakeholder and relevant organizations in exporting countries.

MFDS also promoted 「Good Importer Registration System」 that makes importers responsible for safety of their import food by themselves.

C) Implementation Plan

MFDS will continuously carry out on-site inspections on foreign food facilities that have a history of manufacturing defective products or make 'children's favorite foods'.

Also, by implementing the 「Good Importer Registration System」 and holding information

meetings on precautionary safety management system, MFDS will increase the number of good importers and is planning on offering incentives to those importers. Also, MFDS will follow-up on those Good importers regularly to maintain stable and safe environment for importing excellent products.

2) On-Site Survey of Workplace in Livestock Product Exporting Countries

A) Background

The number and weight of food imports have continuously risen 4.7%(weight) during the last five years and 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 workplace and the production/manufacturing processes of manufacturing businesses in exporting countries.

B) Achievements

For pre-import safety management, MFDS carries out 8 steps of inspections including the exporting countries' livestock disease and sanitation tests and on-site surveys on facilities that have equal sanitation level as those in Korea in have and allows the imports of the products that have only been registered and approved(made mandatory in 1993) by MFDS and ensure safety. MFDS has carried out sanitary inspections on 71 overseas facilities in 9 countries including the US, China, Frace, Italy, etc.

Especially, by implementing livestock sanitary test and overseas facility registration system (February 4, 2016) according to 「Special Act on Imported Food Safety Management」and sanitary management according to disease quarantine of BSE and food-and-mouth disease when allowing import for livestock products and livestock sanitary and exporting country's sanitary management system, safety management has been expanded.

C) Implementation Plan

MFDS will hold briefing session regularly for Embassy in Korea and overseas facility regarding imported livestock products system that is being changed by implementation of the Special Act to promote establishment of such system.

Also, a sanitation checklist for on-site survey in overseas facilities will be prepared, training will be carried out to train on-site survey teams to establish a standard for overseas on-site survey and expertise of the survey teams.

Notifications related to customs level management of imported livestock products will be revised to carry out efficient inspections that take into account of characteristics of livestock products.

3) On-Site Survey of Processing Facilities in Marine Product Exporting Countries

A) Background

The establishment of the World Trade Organization (WTO) in 1995 and a number of FTAs Korea have signed in the past 10 years have increased the trades of marine products but due to global industrial activities and the recent radiation incident in Japan, marine pollution has also become more serious and endocrine-disrupting chemicals and other new hazards that have not existed before are being discovered everyday.

To secure precautionary safety of imported marine products by cutting off imports of unsafe marine products and to protect people's health and lives, MFDS has signed and has been implementing sanitation agreements with major marine product trading countries. Currently, 7 agreements with 6 countries including Vietnam, China, Indonesia, Thailand, Russia and Ecuador are in effect. Through these sanitation agreements, processing facilities in countries that have signed the sanitation agreement are mandatorily registered and managed through a dual inspection system including the pre-import safety management and customs inspection. Also, if defective products are found through inspections of the facilities in countries that have signed the sanitation agreement, measures such as import prohibition are being enforced.

MFDS has made it mandatory for businesses that wish to export frozen edible fish heads[cod, southern hake, tuna, and all the edible parts of all the edible fish(except for puffer fish)], frozen fish intestines [edible fish pollock roe, squid nidamental gland (except for puffer fish)] to Korea to have their processing facilities registered. The countries that wish to export those 'by-products' must send the list of processing facilities in the country to MFDS. Also, the businesses that are importing marine by-products to Korea for the first time or if they wish to export new marine by-product items to Korea, they must requst MFDS for on-site sanitation inspection of the facilities in those processing facilities and acquire approval from MFDS.

B) Achievements

In 2016, MFDS and the Ministry of Maritime Affairs and Fisheries carried out joint sanitary inspections on 61 processing facilities in countries that have signed the Sanitation Agreement and MFDS carried out inspections independently on 3 by-product processing facilities and

requested the facilities for sanitary improvements and facilities repair after the inspections.

Also, for by-product processing facilities and the facilities in the countries that have signed the Sanitation Agreement, MFDS carried out consultations with the local personnel in charge of the Sanitation Agreement on giving sanitation guidance to those facilities that have a history of sanitary issues to prevent defects and sanitary problems in the future.

C) Implementation Plan

As pre-safety management of marine products from implementation 「Special Act on Imported Food Safety Management has become more important, in order to ensure safety of imported marine products, MFDS is planning to work together with the Ministry of Maritime Affairs and Fisheries to establish system for smooth implementation. When there is an issue with imported marine products, both MFDS and Ministry of Maritime Affairs and Fisheries will correspond together. The marine products imported from 6 countries that have signed the sanitation agreement take up approximately 63% (as of 2016, marine products inspection system) of the total marine product imports and MFDS will strengthen and improve the sanitary management for local processing facilities overseas and try to prevent hazardous marine products from flowing into Korea.

Also, when exporting countries request import approval to Korea for marine by-products such as roe, intestines, fish heads and etc, to import only safely processed marine by-products, MFDS will expand and strengthen the sanitary management in local by-product processing facilities overseas.

Also, priority inspection on Korea's hazard information and products that show a history of defect will be strengthened at the import inspection and hazardous and defective marine products will be prohibited at customs clearance. By this way, MFDS is planning make sure that only safe marine products are imported.

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C. Reinforcing Safety Management of Novel Foods including Genetically Modified Foods

1) Background

Genetically modified crops are grown in 28 nations around the world, and the areas for growing GM crops are rapidly increasing these days. In case of Korea, it is inevitable to import grains as its self-sufficiency rate of major crops is very low (below 10%) (Ref. 2015 statistics of the Ministry of Agriculture, Food and Rural Affairs), it is highly dependent on imports of soybeans and corns which are widely used in food processing industry. In 2016, for example, genetically modified soybeans and corns made up 78% and 50%, respectively, of the total imported soybeans and corns. Against this backdrop, MFDS has examined the safety of GM foods through scientific and systematic safety inspection and approved GM foods that are found to be safe for food, and these approved products are re-evaluated every 10 years for its safety.

In addition, MFDS collects opinions of the public before approving GM crops, and provides various information including safety evaluation reports, status of approval, educational materials, and etc. on its website. Various efforts have been made to enhance reciprocal communication with consumers by implementing awareness campaigns on GM foods for students or housewives and planning events using social networking services. Meanwhile, since 2010, MFDS has reviewed materials on safety of ingredients that have never been used for food in Korea and approved them as novel ingredients according to 「Temporary Standards and Specifications for Foods, etc.」.

2) Achievements

A) Safety Evaluation of Genetically Modified Foods

In 2016, MFDS approved 18 GM foods including re-evaluation of 3 events that were approved 10 years ago. Since 2000, As of 2015, MFDS has approved a total of 169 GM foods including 147 agricultural products (74 corns, 28 cottons, 25 soybeans, 13 canolas, 4 potatoes, 1 sugar beet, 1 alfalfa), 3 microorganisms, and 19 food additives through safety evaluation, and completed re-evaluation of 28 events.

In addition, 「Regulation on Safety Evaluation of GM Foods」was revised on Oct. 25, 2016. The revised contents are as follows. The scope of safety assessment data submission on GM microorganisms and stacked events was laid out clearly and it may omit some submission

data in case where GM microorganisms and newly inserted genes are removed from the final products. Also the definition of self-clonning microorganisms was newly established and they were excluded from the subjects of evaluation.

B) Safety Management including Imports of GM foods, Etc.

For Korea, it is inevitable to import grains as its self-sufficiency rate of major crops is very low (below 10%). Given its high dependency on imports of GM crops and the importance of the safety management, the most important task is to enhance the capability of workers of business handling GMOs and the relevant public officials, and for this, MFDS has carried out GMO safety management activities by issuing publications on the safety management and IP (Identity Preservation) handling of GMO and encouraging information sharing between persons in charge through nationwide education and workshops.

Also, In accordance with the Article 18 of 「Food Sanitation Act」, genetically-modified edible agricultural·livestock·fishery products shall undergo safety evaluation, and according to the Article 4 and 5 of the same act, agricultural·livestock·fishery products that have failed to undergo safety evaluation and deemed to be inedible as a result of the safety evaluation and foods made of these ingredients are prohibited from being imported·distributed·sold.

C) Follow-up Management including GM foods Labeling, Etc.

In addition, MFDS and local governments have provided and carried out continued instruction·examinations on labeling of GM foods during the manufacturing·distribution stages in order to guarantee their safety and increase consumer confidence. In 2016, 2,169 products (726 products were collected for examination) were examined and 13 cases were found to have violated labeling standards, and among 3,007 GM crops (533 cases were collected for examination) examined for labeling, there were no cases violating standards of labeling.

D) Labeling System of GM Foods, Etc.

As the Article 12-2 of the Food Sanitation Act and the Article 17-2 of the Health Functional Foods Act have been amended and enforced on February 4, 2017, the scope of GM labeling was expanded from “five major ingredients” to “all ingredients which have genetically modified DNA (or protein) in final products”. And, the font size for GM food label was changed from 10 points to 12 points.

Also, MFDS has organized and operated ‘GM Food Labeling System Review Council’[4] to execute relevant policies and collect opinions from various people. After dozens of meetings

over the past few years, the council 1) unified and standardized the term for GMO (in Korean) as 'genetically- modified', which were expressed in variety way like 'genetically recombined' or 'genetically changed', 2) determined to expand the scope of GM labeling from 5 'major ingredients' to 'ingredients' that are widely used in food products, and 3) increased the font size for GM food labels from 10 pt to 12pt.

E) Education·Campaign on GM Foods, Etc.

In order to communicate with the public by sharing accurate information on genetically modified foods, MFDS worked with consumer groups to carry out customized education programs. In 2016, 55 commissioned education sessions of "What is Genetically Modified Food?" were carried out for 2,700 2,916 middle·high school students and housewives. MFDS also provided 28 nationwide sessions of 'Education on GM Foods' for college students.

Also, MFDS organized 'GMO Communication Supporters' with college students who use social networking services like major blogs and Facebook pages to post articles regarding the definition, development status, and safety of GM Foods on social networking sites. In addition, with the GM Foods learning event carried out on its Facebook page (May, October : 4,693 participants, 164,419 visitors), MFDS provided accurate information on genetically modified foods, communicating with participants through comments.

F) Temporary Standards·Specifications of Novel Food Ingredients

Since 2010, according to 「Temporary Standards and Specifications for Foods, Etc. (MFDS Notification No. 2016-27)」, MFDS has reviewed documents regarding safety of agricultural·livestock·fishery products that are introduced as food ingredients for the first time and other ingredients extracted·separated·cultured from those products and consulted with experts, if needed, to acknowledge them as novel food ingredients. The main subjects for review are origin, details of development and the approval and usage status of those products, manufacturing process, characteristics of the ingredients, and safety information (such as consumption standards, effects on human body, and toxicity test results).

MFDS also had consultation meetings with relevant organizations including the Ministry of Agriculture, Food, and Rural Affairs and held workshop to share information on the standards and specifications for new ingredients and the status of development of these products. MFDS secured the expertise of evaluation by managing 'Novel Food Ingredient Expert

4) It was organized in April 2013, consisting of 20 members including 8 from consumer groups, 8 from industrial community, and 4 from academic community and others groups. As of March 2017, 29 meetings were held.

Committee'. In 2016, 10 ingredients including seed oil form Buglossoides arvensis and leaf of *Ampelopsis grossdentata* were approved through the on-site inspections and advisory meetings. As four already-approved edible insects as novel food ingredient including *Gryllus bimaculatus* had been newly listed on Food Code, anyone could use as common food ingredients. The current status of temporary standards and specifications for food ingredients is available on the website; www.nifds.go.kr or www.foodsafetykorea.go.kr.

Also, in order to provide convenience and efficacy to applicants, MFSD issued the Safety Evaluation Guidelines for Novel Food Ingredients and it provides explanation and and examples for dossier in detail.

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5. Establishment of an Alcoholic Beverage Safety Management System

A. Background

The MFDS signed Memorandum of Understanding (MOU) with the National Tax Service in June 2010 in accordance with changes in the alcoholic beverage market conditions and public interest in alcoholic beverage safety, and actively pursued policies for alcoholic beverage safety management. As a result, these efforts led the revision and enactment of laws and regulations to manage alcohol manufacturing license holders as food manufacturers and processors in the 「Food Sanitation Act」(July 2013).

Despite the overall hygiene level gradually improved as the MFDS became responsible for the safety management of alcohol manufacturers, most of the companies are small and have low awareness and compliance with hygiene and safety management. About 90% of alcohol manufacturers have less than 10 employees, and those with less than 100 million revenues account for about 68% that reflect their weak capital basis.

Most Korean traditional alcohol producers were found to acquire fermentation techniques through experience of family transfer, benchmarking of other companies rather than systematic education. Alcoholic beverage safety management and technical support for quality

improvement are lacking, and hence establishment of systematic and professional support system is required.

Also, the alcoholic beverage management system has diverse responsibility structure- as MFDS manages 'Safety Management'; National Tax Service manages 'License and Tax Resource Management'; and Ministry of Agriculture, Food and Rural Affairs manages 'Korean Traditional alcohol promotion business'—which requires coordination between relevant ministries and harmonization of laws and regulations related to alcohol for effieicent policy formulation and implementation.

[Table 2-1-4] Alcoholic Beverages-related Tasks for Each Department

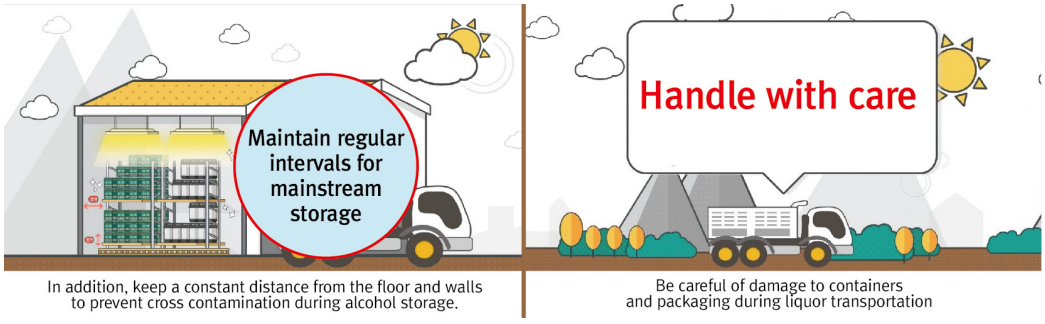
Depart.	License (Business) Type	License (registration) Agency and Target	Jurisdiction And Management
Ministry of Food and Drug Safety	Food Manufacturing Process	MFDS (Regional Korea Food & Drug Administration) Alcoholic beverage licensed by the National Tax Service	Food Sanitation Act Food manufacturing and processing business registration and alcohol manufacturer safety management
Ministry of Strategy and Finance (National Tax Service)	Alcohol manufacturing license	National Tax Service (Tax Office) General manufacturing, Korean traditional alcohol manufacturing, small-scale alcoholic beverage	Liquor Tax Act Management of alcohol manufacturing license and Tax Resource
Ministry of Agriculture, Food and Rural Affairs	Recommendation of Korean Traditional alcohol manufacture license	National Tax Service (Tax Office) Manufacture of Korean traditional alcohol (traditional sake, Local specialty liquor)	Act on the Promotion of Industry such as Korean traditional alcohol Promotion of alcohol industry such as for Korean traditional alcohol and etc.

B. Achievements

In order to allow alcohol manufacturers to adapt early to safety management-oriented management system, the 'Sanitary Management Grading System', which differentially manages according to sanitary level, was introduced and operated. Through designation and operation of regional alcoholic beverage safety management support center, MFDS has continuously strengthened the sanitary level of alcohol industry by supporting alcohol manufacturer, especially the small businesses. In the diversed management system of alcoholic beverages safety, MFDS promoted collaboration between relevant departments for systematic and efficient work, and information related to alcoholic beverage safety was provided to people to ensure consumers' safety.

1) Proliferation of Safe and Healthy Drinking Culture and Alcohol Consumption Culture

In order to produce safe alcoholic beverage and to establish healthy drinking culture, MFDS operates an alcohol safety information webpage (‘Sullejapki’). To alcohol manufacturers, MFDS provides alcohol safety information such as sales registration procedures, compliance with the Food Sanitation Act, and manual to reduce foreign substances. To alcohol distributors, MFDS produced a training video about the storage and distribution standards of alcoholic beverage and also produced promotional materials for draft beer hygiene tips.



[Image 2-1-5] Educational Video for Alcohol Distributors

MFDS has developed a public campaign to establish a healthy drinking culture, and provide safety information for consumers of homemade alcohol, weak alcohol through MFDS’s Facebook, SNS, and alcoholic beverage safety information homepage.

In addition, regarding the culture of alcoholic beverages that reuse empty bottles which continuously generate foreign substances, MFDS, in cooperation with the Korean Alcoholic & Liquor Industry Association, carried out campaigns to transform consumers’ perceptions in aim of reducing the number of foreign substances.

[Image 2-1-6] Promotional campaign to reduce foreign substance of Alcoholic beverage

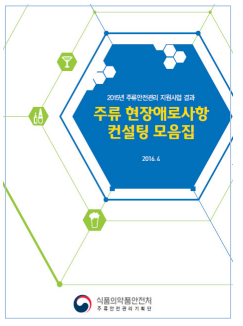
2) Alcohol Manufacturers' Continuous Improvement of hygiene level

Alcoholic beverage manufacturers are characterized by aging of facilities and salespersons and lack of information and technology on hazardous materials and safety management due to lack of hygiene management level compared with general food products. They also have heavy burden of cost for Self-quality inspection, and quality control.

Accordingly, MFDS designated and operated alcoholic beverage specialist organizations across the country (metropolitan area, central area, Honam area, Yeongnam area) as regional alcohol safety management centers, and visited small and medium alcohol manufacturers to provide solutions for their difficulties regarding environment and facility management, manufacturing management, and other issues. Also, in order to provide information related to hygiene and safety management in accordance with the actual situation of the company, MFDS conducted systematic education on safety and hygiene management. MFDS also conducted practical training to analyze basic items of alcoholic beverage such as alcohol content and total acid necessary for safety and quality control.

MFDS run an excursion program for excellent alcohol manufacturers, shared best practices, and expanded HACCP coverage of alcoholic beverages. Also, MFDS held briefing sessions for each seminar to introduce the amendments to laws and regulations, and enhanced communication with companies through listening their issues on the spot. In addition, for the liquor companies, MFDS produced educational manuals such as safety management manuals and labeling samples for different types of liquor to enhance the understanding of the Food Sanitation Act of the business owners and employees.

Safety Management Standard Manuals for Small scale alcohol manufacturers



Consulting for On-site difficulties

Sanitary Management Standards for Safe Liquor Manufacturing

Labeling Samples For Different Types of Liquor

[Image 2-1-7] Educational Manuals for Alcohol Manufacturers

3) Strengthen safety management by Liquor stage

A total of 1,117 companies (as of December 31, 2016) are registered in the MFDS for the food processing and processing business and manufacture alcoholic beverages, and more than 90% of the total companies are small scale companies with less than 10 employees. Since alcohol manufacturers have a wide variation in hygiene level by company, MFDS has operated 'Classification-Based Management System', which manages these companies efficiently with limited administrative power since 2012. In 2015, MFDS supplemented and improved the existing Classification-Based Management System, which is centered on facilities and environment, to the Sanitary Management Grading System to focus management on raw materials, water and manufacturing process.

[Table 2-1-5] Status of registered businesses of food manufacturing and processing business (liquor)

(As of December 31, 2016)

	Total	Seoul	Busan	Kyungin	Daegu	Gwangju	Daejeon
Company (location)	1,117	160	141	92	162	260	302

Hygienic management compliance rate has been improved due to intensive guidance and technical support for key management companies with insufficient hygiene management, and continuous guidance and education have improved the perception of manufacturers on compliance.

MFDS conducted an autonomous inspection system on the storage and handling standards of alcoholic beverages to distribute safe alcoholic beverage to alcoholic beverage distributors (1,113 stores) such as convenience stores, supermarkets, and large mart stores. MFDS conducted collecting investigation of alcoholic beverage to strengthen the management of the blind spot of alcoholic beverage, and solved anxiety of the public through prompt investigation of causes of alcoholic beverage accidents. In addition, the MFDS has conducted efficient alcohol safety management tasks through a recently conducted major planning and inspection of alcoholic beverage manufacturers that reflects alcoholic beverage consumption trends.

4) Regulation for Activation of Alcohol Industry

As a result of MFDS's promotion of revision of the Food Sanitation Act to alleviate the alcohol industry's burden, MFDS and the Ministry of Agriculture, Food and Rural Affairs have jointly

established a facility standard improvement plan based on the joint field investigation. In accordance with the 「Liquor Tax Act」, MFDS made it possible to recognize the quality analysis report as a self - qualification inspection report for liquor which received periodic analysis and appraisal. In addition, when a small-scale alcohol manufacturer provides its products to its customers, it has revised the labeling standards to allow the labeling of individual products to be omitted and to display separate signs.

MFDS strengthened support for quick registration of business registration for Korean traditional alcohol manufacturers in accordance with the licensing of the Liquor Tax Act's small-scale alcoholic beverage (raw rice wine, refined rice wine, and clear rice wine). MFDS produced and distributed a sanitary management standard for small-scale alcoholic beverage manufacturers.

C. Implementation Plan

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

MFDS plans to conduct periodic evaluations of all alcoholic beverage manufacturers in order to improve the efficiency of safety management through differential management of alcohol manufactures and to improve the safety management of alcoholic beverage companies. MFDS will enhance the safety management at the manufacturing stage by developing 'autonomous handling management guidelines' for beer that is most consumed by adults in Korea, and allowing beer makers to manage them step by step. In addition, MFDS plans to introduce and operate an autonomous alcoholic beverage safety management system that nurtures professional personnel to carry out independent safety management and quality control of alcohol manufacturers.

2) Active Responding to New Changes in Alcohol-Related Environment

MFDS will investigate the alcoholic beverage consumption status of Korean people to understand alcohol consumption trends and develop publicity contents accordingly to provide alcoholic beverage safety information that consumers can sympathize with

MFDS intends to strengthen on-line and off-line public relations to promote a safe and healthy drinking culture, and to provide information on life-friendly alcoholic beverage according to new alcohol-related environment. MFDS will strengthen the precautionary management of

alcoholic beverages sold at restaurants in accordance with the allowance of alcoholic beverages ordered with food, and continue to run an autonomous inspection system on the storage and handling standards of alcoholic beverages. Also MFDS is planning to conduct special inspections and collection inspections for alcoholic beverage with high consumption throughout the year.

3) Improving Alcohol Regulations and Promotion of Communication

The safety management base for alcoholic beverages has been established, as liquors should be manufactured at the same level as regular food through amendment of food sanitation act, education and support project according to the changes in the domestic and overseas industries and consumer's demand. However, since the alcoholic beverage management system is diversified, it is a burden to the alcohol manufacturers. Therefore, the MFDS plans to strengthen the cooperation and maintenance of communication systems between related agencies in order to solve the inconveniences of the manufacturers and activate the alcoholic industry. In addition, MFDS will take reasonable measures to improve the laws and regulations in consideration of the specificity of alcoholic beverages in order to promote the alcoholic industry and develop Korean traditional alcohol inheritance.

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Section 2

Internationalization of Scientific Food Standards and Specifications

1. Improving Food Safety Standards and Specifications

A. Background

As the number of food trade between countries increases, such as the Korea-EU FTA and the Korea-China FTA, the need for safety management for residues, harmful pollutants, and food poisoning bacteria that have not been set in Korea is increasing.

In order to unify food safety management, prevent double regulation, and increase efficiency of administration, systematic harmonization and maintenance of food and livestock product standards are required.

B. Achievements

MFDS integrated and standardized the standards and specifications of processed food products and livestock products in order to unify food safety management, prevent double regulation, and increase administrative efficiency. Also, MFDS has completed the introduction of statistical concepts to ensure the reliability and representation of the international harmonization and inspection of microbiological standards. MFDS introduced the Positive List System (PLS) for raw food material management to clarify the legal basis for the use of food ingredients. MFDS has strengthened the safety management of heavy metals by newly establishing inorganic arsenic standards for rice with high intake. We have increased the number of pesticide residues allowed for imported agricultural products such as coffee and blueberry, which have recently increased in consumption (247 cases). The remaining tolerance criteria for 21 kinds of veterinary medicines such as tilobarin, which have been approved but have not been established, have been established and a total of 66 kinds of residual tolerance criteria have been set.

MFDS allows the use of carbon dioxide or a mixture of nitrogen and carbon dioxide, taking into account safety and realities when filling packed milk formulas production, and MFDS

contributed to the revitalization of the industry by permitting non-sterilized crude oil to be used in the production of claws and natural cheeses in order to ensure that cheeses produced by using milk products with low fat content, such as fat-free, low-fat milk, and skim milk.

MFDS operated a 'Food and Drink Understanding Process' training program for officials in charge of food hygiene in local governments, so that it can be used in food hygiene work through strengthening the general understanding of food types and food raw materials of food circulation, and strengthened standard and interpretation ability for food hygiene business.

In order to efficiently promote tasks of food raw materials, pesticides, veterinary drugs and contaminants, and establishment and revision of the standards for food residue, which are scattered among the ministries, the MFDS operates the 'Consultation on Food Raw Materials Institutional Cooperation', 'Residual Pesticide Safety Management Cooperation Council', 'Animal Veterinary Residue Permit Standards Council' and 'Council on Pollutant Substance Management in Foods' and strengthened the collaboration structure between departments by sharing related information.

C. Implementation Plan

MFDS plans to improve the specification of the low-risk food-borne bacteria to the quantitative specification reflecting the characteristics of microorganisms. In order to cope with climate change, MFDS plans to prepare a preemptive safety management plan for unspecified food poisoning bacteria. With the rise of water temperature and development of fishing technology, MFDS plans to expand the recognition of new concept food raw materials after reviewing the safety of newly imported fish species.

MFDS conducts annual pollution survey on 19 kinds of harmful pollutants, and the standards and specifications for Dioxin and the two PCBs will be reassessed in 2017.

MFDS will set the pesticide residue tolerance standard for small area cultivated products quickly and set the limit on imported food residue for pesticide residues in Korea for the full introduction of a positive listing system for scientific safety management of pesticide residues. In addition, MFDS plans to strengthen the safety management of residual substances by continuously setting the residue tolerance standards for food products (animal species) that have already been approved for domestic use but have not been established.

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

A. Management of Food Additive Standards and Specifications

1) Background

Consumers perceive the need for food additives, but still have a vague sense of anxiety due to negative press reports. Therefore, MFDS is continuously promoting the establishment and revision of standards and specifications for the safety management of food additives in order to secure food safety at international level. In order to raise awareness of food additives, MFDS provides consumer-oriented safety information And to improve the perception of food additives through various communication channels with the public.

2) Implementation Plan

In order to clarify the purpose of use of food additives, the 「Standards and Specifications for Food Additives」 have been revised, including the revision of standards and specification for food additives in accordance with 31 use categories (April 16, 2016). In order to develop various foods, some food additives such as sorbic acid, which is recognized as a technical necessity of use, have been improved in terms of use within safe range considering the intake level (16 November 2016). In order to raise awareness of food additives, MFDS conducted customized education and promotional activities for general consumers and industry. As a part of correct information sharing of food additives, MFDS revised the information on food additive errors in middle and high school textbooks and requested 10 publishing company to revise them. MFDS also developed a micropage (safety taste iN) as a base for online PR base, strengthened mobile accessibility, and created and published various types of online contents such as card news, infographic and video with high readability.

3) Implementation Plan

In order to strengthen the safety management based on the re-evaluation of standards and specifications of food additives, MFDS plans to review whether the standards and specifications of 21 items such as eculsifiers, encapsulants, and antioxidants are appropriate. In order to improve the awareness of food additives and to provide the correct information, MFDS will actively promote the policy and carry out education.

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

1) Background

As a result of the development of various types of new utensils, containers, and packaging products due to changes in diet patterns and the convenience of food cooking, the necessity of safety management for harmful substances that can be transferred to food when cooking or storing food using products Is also emerging.

2) Achievements

In order to ensure efficient safety management of instruments, containers and packaging and to harmonize with international standards, the dissolution specification of melamine, which is a raw material of melamine resin, has become strengthened, the name of cellophane has been changed to processed cellulose so as to include fiber form in addition to film form, and the names of paper and processed paper has been revised in paper form to harmonize with the names of other materials (enforced on July 30, 2016). In addition, the use concentrations of disinfectants such as di-n-alkyl (C8-C10) dimethylammonium chloride were revised and two components such as polyalkylene glycol butoxy monoether, which have similar components became integrated. In order to provide life-friendly information, MFDS produced a Q&A to provide information on how to use the synthetic resin correctly, and published series articles on material characteristics, and precautions when using them.

3) Implementation Plan

MFDS intends to strengthen its safety management by re-evaluating unreacted raw materials (5 items) * among the viable substances from utensils, containers and packaging. In addition, MFDS plans to continuously improve the standards, specifications, and standards of containers, packaging, etc. in harmony with international standards. It is possible to implement equipment, containers, and packaging. MFDS will improve standards and specifications for biodegradable resins such as synthetic resin (hydroxybutyl polyester), which is a concern for us, and make reasonable improvements for safety standards such as heavy metals and test methods, It plans to maintain a list of ingredients that can be used as a manufacturing ingredient in sanitizing and disinfecting agents such as machinery through the management status of major foreign countries and domestic use situation. By continuing to provide information on life-friendly

information of the nation's eyes, MFDS will resolve the public anxiety about the sterilization income system of apparatuses, containers, packaging and apparatus caused by misuse, and resolve the health risks.

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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.

Meanwhile in Korea, the increasing participation of women in 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 2005 to 2.13 million children in 2015. While parents' interests in child care services are increasing due to the increase in the number of children cared in these facilities, there has also been increased anxiety among parents regarding children's meal services as there has been media coverages on usage of expired foods and rot foods in the meal service industry. Most of children's meal services are doing their best to provide children the safest and healthiest food possible. However, the ones that are small in size face difficulties employing experienced professional dietitians and this in turn increases the risk of food safety issues. For the safety management of children's meal service facilities, MFDS established the center for children food service management with local governments and carried out sanitary and nutritional management of children meal service facilities with the experts and dietitian at the center.

B) Achievements

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

Beginning with 12 centers for children's food service management in 2011, MFDS established and have been managing 22 centers in 2012, 88 centers in 2013, 142 centers in 2014, 190 centers in 2015 and 207 centers in 2016. MFDS is also supporting food safety management for a total of 25,107 children's meal service facilities and 850,000 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, supporting sanitation and nutrition management for targeted audiences (children, facility, principal, parent), development of diet plans for children, and consulting on sanitation and nutrition.

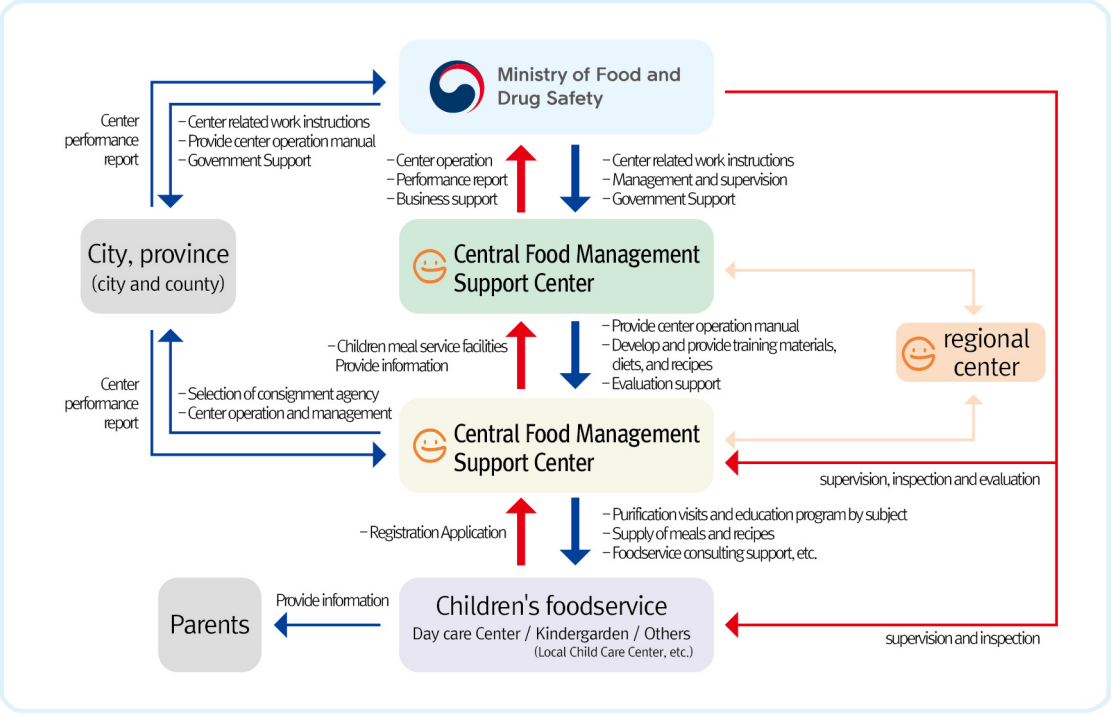
The surveys on directors and teachers at daycare centers and kindergartens that are supported by the Centers showed high satisfaction scores of 86.8 points in 2013, 89.6 points in 2014, 91 points in 2015 and 91.0 points in 2016. The Center's efforts received a lot of support and positive responses to 87.0 points in 2015 and 88.9 points in 2016 from the parents since the more children learned to wash their hands before meals and eat balanced meals. A survey on the cost-effectiveness of the Centers' efforts showed results at around 11.1~15.7 which amounts to a maximum of 1.356 trillion won.

To promote the important role 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 at daycare centers and kindergartens and parents.

(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 to the number of 207 in 2016, 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, 「Special Act on Safety Control of Children's Dietary life」 was revised (Jan. 28, 2014, effective on Jan. 29 2015) and, by securing budget for 2016, the Headquarter 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 2-3-1] Operation System of Children's Food Service Management Centers

By efficient managing and dividing responsibilities between the Center or Children's Food Service Management (CCFSM) and the CCFSM Headquarters, instead of managing sanitary conditions in the short-term, MFDS 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.

(3) Implementation Plan

With the Centers for Children's Food Service Management established to support all children at child care facilities and kindergartens 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.

B. Strengthening Safety Management of Children's Food

1) 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.

2) Achievements

A) 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 2016, there were 8,564 green food zones and 2,506 'exemplary children's food stores' across the country.

B) Improvement of the Distribution Environment for Children's Food

The proportion of high-sugar, high-fat, high-sodium snacks such as confectionary, drinks, bread, and ramen is higher than snacks such as fruit and milk, and the proportion of children's obesity has been increasing steadily since 2008 due to changes in dietary habits. The fast food intake rate and the carbonated drink consumption rate have been steadily increasing since the survey began in 2009.

In order to encourage children to select healthy and safe foods, MFDS designated children's foods that have higher calories and lower 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 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.

C) Expansion of food quality certification for children

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

Quality Certification System evaluates whether the food meets the safety standards, nutritional standards, and standards regarding additives. Certified children's food item may mark the symbol or the letters of the certification.

D) Restriction on and Prohibition of Advertisement of Children's Food

Globally, the regulation on advertisements is being reinforced in efforts to reduce and prevent obesity in children and to promote a healthy diet. In Korea, under the 「Special Act on Safety Control of Children's Dietary Life」 Article 10, the advertisement for high-calorie, low-nutrition and high-caffeine foods and the ads that incite children's food purchase are prohibited and also prohibits and limits these TV ads during 5:00 PM to 7:00 PM and during children's television programs.

E) 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 is right and healthy for their health.

Also, education and promotion of children's preferred foods should be carried out in a way that helps the children develop the ability to be healthy and put healthy and suitable dietary life into practice. Also, principals of elementary schools are required to 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. Education is provided since 2014 to expand the program to middle and high schools.

Also, MFDS held the 'Outstanding Education Contest' since 2012 for school dietitians teaching food safety and nutrition courses and held the 'Children Dietary Life Safety Poster Contest' to increase children's awareness of proper and helathy dietary habits.

3) Implementation Plan

A) Strengthen food safety management for children

In order to create a healthy food sales environment, MFDS will conduct intensive sanitation inspections for businesses that are susceptible to hygiene, which requires continuous management such as breakout points and school stores, in cooperation with local governments, and launches campaigns for sanitary masks and aprons for cooking establishments. And other various policies from the perspective of parents and students will also be implemented.

B) Improving the Distribution Environment of Children's Favorite Food

To prevent children from consuming high-caffeine, in February 2016, the scope of high caffeine-containing foods was extended to milk products such as cow's milk. In 2017, In order to improve the sales environment for children's favorite food, MFDS concluded a business agreement with the children's group to encourage the participation of parents and students, and commissioned the "Children's Safety Food Explorers" and will conduct practical campaigns to promote children's healthy eating and drinking habits.

C) Expansion of food quality certification on Children's preference food

In order to encourage voluntary participation of companies in order to activate the quality certification system for children's preference food, MFDS will strengthen the customized PR for the people so that they can know and purchase quality certified food, and will try to expand through reasonable system improvement such as revision of quality certification standards..

D) Children's dietary safety index survey and dietary safety and nutritional assessment

MFDS plans to improve the safety level of children's eating habits by surveying and evaluating the '2017 Children's Dietary Safety Index', which objectively confirms and evaluates efforts and levels of improving the dietary life of children in 228 local governments nationwide.

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

As the obesity of children is continuously increasing, MFDS is restricting and prohibiting the advertisement of high-calorie, low-nutrient and high-caffeine-containing foods, preparing high-calorie and low-nutrient food markers for consumers' convenience, and also constantly monitoring the sale of high-calorie, low-nutrient and high-caffeic-containing foods near school and food safety zone in order to create an environment in which children can purchase healthy food.

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

MFDS will continue to educate and promote dietary safety management for children and adolescents by expanding food safety and nutrition education so that children can self-select the right food by themselves and maintain healthy and correct eating habits.

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

A. Improvement of Kitchen Culture

1) Background

Due to the recent changes in diet and life style stemming from the increasing nuclear family, the increase of female participation in the economic activities, and the increase of one-person household, the eating-out population has also been increased as 1 out of 3 Koreans eats out at least one meal a day(National Health and Nutrition Survey, 2014). People's poor awareness of food safety, however, has been raising societal needs for the safety management of eating out food.

2) Achievements

For the sake of improved sanitation of restaurants, MFDS operated a pilot project which sponsors 39 small-sized restaurants among food service providers to construct facilities or equipment required for an open kitchen and a sanitary facility. The survey which was conducted on the restaurant owners after renovating their kitchen to be open style showed that the remodeled kitchen contributed to not only increasing sales but also satisfying both the owners and customers.

In addition, the ministry developed and distributed to the related association in the industry the Manual on 「Sanitary Management of an Open Kitchen Restaurant」which provides recommended criteria for the establishment and implementation of CCTV and standard design by business type to help the owners of the restaurants and foodservice shops easily understand

what the culture of open kitchen is and how to adopt it to their businesses. Furthermore, it hosted a poster contest titled 'Open and Clean Kitchen' in an attempt to explore, select and award the best practices of kitchen culture improvement and share them to spread the culture of the clean open kitchen.

Moreover, MFDS established an infrastructure for Sanitary Management Grading System for restaurants, which is to be implemented from May 2017 and test-operated the system with the volunteered restaurants in the pilot project to pave a way for early adoption.

In order to make the grading system customized to Korean context, MFDS worked with Kora customer organizations on analyzing the grading of other countries including the US, UK, Japan, etc. and collecting opinions from all sectors including consumers, business owners, academia, lawmakers, etc., and this effort resulted in a drafted sanitary grading sheet that anyone could easily read and understand the grading.

Also, MFDS not only trained 200 civil workers from the Consumer Food Sanitation Watchdog and local governments to nurture them to be sanitary inspectors but also created promotion leaflet and video clip to raise consumers' awareness of the restaurant sanitation rating system. The leaflet was distributed to the regional offices of MFDS, relevant organizations, and associations, and the video clip was made like a movie trailer to be played in multi-use facilities such as KTX, movie theaters, etc. and to be aired on TV as public service advertising to win the interest of consumers and business owners.

3) Implementation Plan

In 2017, MFDS plans to consign the sanitary management grading work to the Korea Institute for Food Safety Management Accreditation so as to designate and operate 6,000 sites including the accredited best practice restaurants after on-site inspection on their sanitary conditions. Prior to the implementation of the restaurant sanitary management grading system(effective from May 19, 2017), MFDS plans to establish a computerized civil compliant system(application, reception, result registration, certification issuance, etc.) in April and train and nurture 400 people to increase the number of inspectors in the file before the grading system takes into effect.

It also plans to promote the grading system through a series of briefing session(about 30 times) for business owners and multi-use facilities to increase their participation and raise consumer awareness. In addition, in connection with 2016, it plans to operate a pilot project on a clean, open kitchen(40 sites) to encourage nearby restaurants and new business owners to voluntarily participate in the clean open kitchen culture. For efficient operation of the kitchen culture improvement campaign, it will discuss how to improve the food culture in the form

of a cooking talk program and produce it as a video. It will be posted on SNS such as YouTube to spread the "Clean, Open Kitchen Culture."

B. Strengthening of Preventive Measures for Food Poisoning and Safety Management of Group Meal Services

1) Background

Recently, the pattern of food poisoning has changed according to the increase in the use of eat-out and meal services and climate change such as abnormally high temperature, and the food poisoning cases cause hygienic, economic and social problems which incur costs for solutions. Thus prevention is the best way than ever. In order to prevent and manage food poisoning efficiently, MFDS is establishing and implementing comprehensive joint prevention measures for food poisoning by related agencies through a pan-government food poisoning countermeasure consultation agency, which has a total of 32 institutions including central government, local governments and private organizations.

2) Achievements

A mock exercise for a rapid reporting of food poisoning was conducted in April 2016 to strengthen the rapid reporting system, spread to the relevant institutions, and let institutions understand their responsibilities in the early stage of the food-borne illness. In May, the following month, MFDS carried out an on-site response simulation training involving the local offices of MFDS, local governments, education offices, schools, etc. to train them on identification of and interview with the victim, preserved food, environment and human body sampling, and quick test based on a large-scale food poisoning case scenario.

In addition, in order to prevent food poisoning, food poisoning occurrence information for the past five years (2011-2015) was analyzed, and 17 provinces (226 cities, counties, and districts), 17 education offices (77 district offices of education), and 5 associations such as the Korea Food Service Industry Association. Moreover, as part of promoting the "Government 3.0", MFDS has developed a food poisoning prediction map, using Big Data, and launched a customized service for the public in March 2016 to provide information on the risk of food poisoning in advance through the homepage. Also, in the public experience event of Government 3.0, MFDS held an experience exhibition of 'Checking Food Poisoning Risk Information of My Town with a Map', so that consumers could be interested in and prevent food poisoning.

Since many cases of food poisoning occurred at schools right after the vacation due to school meal services, in March and September of each year at the starting time of school terms in spring and autumn, MFDS supervised and inspected the schools and food suppliers in cooperation with the local offices of MFDS, the Ministry of Education, and local governments.

The school canteens conducted thorough inspections to improve the 69 violations of the 「FOOD SANITATION ACT」, including storage of foods which passed shelf life and the violation of hygienic handling standards of foods, etc. In addition, another effort was made to prevent food poisoning at schools by conducting special training on food poisoning prevention for school principals and dieticians twice a year.

Also, field study and outdoor learning activities of elementary, middle, and high school students are increasing in April, so sanitary supervision and inspection was conducted on 2,483 restaurants and food processing companies which produce kimbab and boxed lunches for prevention of food poisoning at the canteens in the teenagers training facilities which accommodate a lot of students in times of increased outdoor school activities. As a result, improvement measures were applied to 130 companies which violated the 「Food Sanitation Act」.

In order to maximize the effect of preventing food poisoning, MFDS encouraged the practice of "hand washing, eating, boiling" which is the three main points of prevention of food poisoning, In particular, it broadcast seasonal videos of food poisoning prevention in the time slots of cooks when they are available to hear and watch them via TV, radio, subway media, etc., and also promoted publicity at any time by using outdoor advertisement, internet, railway(KTX), newspaper, magazine, etc.

In addition, through the 'Hand washing UCC Contest' held in April, it encouraged children to have their interest in hand washing and making it into daily practice, and developed and distributed educational materials such as board games, bacterial paintings and Pororo puzzles to prevent food poisoning to training the children on who to prevent food poisoning.

One hundred and fifty thousand copies of posters and 2 kinds of leaflet on the three ways of food poisoning prevention: 'Hand washing, eating, boiling' were developed and distributed to cities and provinces(city, county, district), education offices(district offices of education), and group meal services, general restaurants, and relevant associations all around the country. Also, 35,000 copies of food poisoning prevention diagnosis consulting the manual, and 55,000 copies of food poisoning prevention management manual, and 3,000 copies of food ingredients inspection manual were prepared for and distributed to foodservice workers and the Center for Children's Foodservice Management for them to use at their workplaces.

Particularly, by analyzing the statistics of food poisoning occurrence in the last 5 years in

2016, MFDS made prevention news to promote SNS on Facebook, blogs, etc. by producing card news that continuously exposes preventive tips and key messages of food poisoning.

All of the above education and publicity materials are posted on the 'Food Poisoning Prevention and Promotion Site(http://mfds.go.kr/fm)' so that anyone can easily browse or download the materials.

For an effective food poisoning education, MFDS trained professional instructors through the 「Professional Instructor Training Course on Food Safety and Prevention」 which was conducted 4 times a year. Besides, the food poisoning prevention and management capacity were strengthened by the 「Food poisoning cause investigation process」 which was conducted four times a year for the staff in charge of local governments and the education offices (district offices of education) in times of food poisoning occurrence.

MFDS has introduced a mobile food poisoning inspection vehicle to prevent the spread of food poisoning through rapid identification of the causes of food poisoning and to support international food events with inspection on food poisoning bacteria in the food materials in advance so as to have safe food and beverages without food poisoning. Currently, four units are in operation, and one in 2016 was further produced and relocated to Gwangju office of MFDS. Using the real-time gene amplification device, the mobile rapid test can simultaneously test 35 genes of 17 kinds of food poisoning bacteria within 4 hours and it is possible to promote the analysis with the LED monitor for public promotion.

3) Implementation Plan

Since the occurrence of food poisoning depends on the season and the facility, it is important to prevent food poisoning before it occurs. Accordingly, MFDS plans to conduct preventive activities such as preemptive guidance and inspection, education and publicity analysis by season, facility, and cause. In 2017, MFDS will be making a video for promoting food poisoning prevention by season: 1) Beginning of school year: Clostridium perfringens, 2) Summer: vegetables - Pathogenic Escherichia coli; meat - Pathogenic Escherichia coli, and Salmonella, Campylobacter jejuni; and Fishery products - Enteritis Vibrio, and 3) Winter: Norovirus. MFDS will also promote through media to allow people to access more information via TV, radio, and subway channels that are conducted throughout the year. In addition, MFDS plans to enhance promotion through SNS by producing 'Card News' that consumers can easily access.

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

A. Background

1) Introduction of 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 August 2002 and came into effect on January 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 of health functional food 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, 1 trillion and 631 billion won in 2014, and 1 trillion and 823 billion won in 2015 showing continuous growth every year.

B. Achievements

1) Advancement of Certification System and Standards and Specifications of Health Functional Food

A) Advancement of Health Functional Food Certification System

(1) Restructure of Screening System of Recognizing Functions

In December 2016, the 「Regulations Concerning Recognition OF Functional Ingredients and Standards and Specifications for Health Functional Foods」 was partially amended to unify the physiological activity grade of functional raw materials. MFDS maintain the existing disease risk reduction function and unified the 1 and 2 grades of physiologically active function as 'helpful for OO'.

(2) Strengthening of Human Body Application Test Validation

In December 2015, the “Regulations for the Operation of the Health Functional Food Deliberation Committee” was revised, and the human body application testing and evaluation unit was newly established to strengthen the verification of the human body test data. MFDS expanded the file of specialists such as doctors, pharmacists, oriental medicine doctor, and professors in various fields such as blood vessels, blood digestion function, nervous system function, organ function, and other physiological activity functions.

(3) Re-evaluation of Safety and Functionality of the Functional Raw Materials

In May 2016, the 「Enforcement Regulation of The Health Functional Foods Act」 were amended to introduce a reassessment system for the safety and functionality of previously recognized functional ingredients. The re-evaluation of functional foods is divided into periodic revaluation of raw materials that have passed 10 years after the functional raw material recognition and regular reevaluation when new risk information is confirmed and reevaluation is needed promptly.

B) Strengthening of Safety and Functionality Management at the Production Level

(1) Improvement of Self-quality Inspection System and Establishment of Basis for Inspection of Raw Material Authenticity

In February 2016, it was obliged to report non-conformity, which is the result of self-quality according ot the amended Health Functional Food Act, and it is also obliged to carry out authenticity testing on the raw materials that are difficult to distinguish visually or when it is deemed necessary by the Minister of Food and Drug Safety in order to ensure safety and functionality of health functional food.

(2) Gradual Application of Good Manufacturing Practice(GMP) on Excellent Health Functional Food Products

In February 2016, MDFS revised the Health Functional Food Act to require gradual application of Good Manufacturing Practice(GMP). MFDS has expanded the scope of application so that existing manufacturers are phased in by 2020 and new manufacturers are granted GMP certification when they are granted business licenses. MFDS has been providing on-the-spot technical support consulting for GMP designated companies since early 2016 in order to facilitate the early establishment and participation of the system.

C) Strengthening of Consumer Protection in the Sales (Consumption) Stage

(1) Strengthening Management of False & Exaggerated Display & Advertising

In December 2015, MFDS set up a manual for monitoring on false and exaggerated advertisements and strengthened the capacity and upgrade the standard level of personnel dedicated to monitoring. In addition, MFDS revised and announced the relevant law in December 2016 to limit the supply of disease-related health information and human application test information that may mislead and confuse consumers by over-displaying or advertising the R&D methods or connecting the health information with products.

(2) Establishment and Operation of an Abnormal Case Response System

In December 2015, MFDS made efforts to communicate information by analyzing the cases of malpractice or by informing the consumers of the administrative investigation measures by text message and e-mail. In addition, MFDS organized and operated an emergency case response team composed of civil servants and civilian experts to inspect the site and review the toxicity data. In order to ensure smooth operation, MFDS has established "abnormal case investigation and management manual" stipulating the criteria, methods and follow-up measures for abnormal cases, and has established a cooperation system with the experts for the cases of abnormal cases of the drug safety management center. MFDS revised the Health Functional Food Act in February 2016 to introduce a consumer administrative inquiry request system that allows consumers (more than 20 people) suffering the same damage to request collection and inspection of the companies concerned.

(3) Enhanced Operation and Management of Internet Health Food Sales Site Monitoring System

MFDS is conducting thorough follow-up management such as collecting, inspecting and monitoring the health functional foods that are being distributed due to various risks such as drugs for sexual dysfunction and blood pressure enhancers, and new harmful substances. MFDS has taken measures to block access to illegal trading sites, which are confirmed to sell false and exaggerated advertisements and health food containing harmful substances, in cooperation with related organizations such as the Korea Communications Standards Commission.

C. Implementation Plan

1) Establishment of Foundation for Re-evaluation

In order to supply consumers with safer and better functional foods, MFDS will introduce a re-evaluation system for functional food ingredients and re-evaluate 28 kinds of functional ingredients in 2017. The re-evaluation targets are 19 species (periodic reevaluation) such as soy oligosaccharide, which is a functional raw material more than 10 years old as of 2017, and 9 species (regular reevaluation), such as Garcinia cambogia extract, which has raised concerns about safety and functionality in and out of country.

2) Improvement of Recognition Standards for Health Functional Foods

MFDS is planning to improve the recognition of functional foods to eliminate distrust of the functional evaluation of the person in charge due to the lack of accreditation standards that are open to industry and consumers. Also, in order to secure credibility of consumer and the industry on the accreditation, it is necessary to disclose the results of the accreditation evaluation(evaluation summary) at the food safety information portal and to expand the consultation on functional raw materials accreditation to make a supporting system from design to implementation of the application test on human.

3) Expulsion of Problematic Food Service Providers to Ensure Sound Sales Activities

MFDS will keep track of people who manufacture and sell bad health food products, and will endeavor to punish them severely and remove them from the market forever. If the violation is obvious and prompt action is needed to prevent the danger, MFDS will set up a regulation that allows temporary suspension on the business before administrative disposition. MFDS also plans to strengthen the crackdown on the re-entry period to prevent the punished business from reopening in the same place through other people, such as relatives and to regularly crack down on intentional violators and strengthen inspection of the problematic products by collecting them.

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4. Strengthening of Safety Management of National Nutrition

A. Expansion of National Movement to Reduce Sodium and Sugar Intake

The World Health Organization(WHO) has proposed a recommended amount of sugar and sodium, along with the need to reduce these nutrients, from the scientific evidence for the link between the excess intake of sugar and sodium and obesity and high blood pressure. In addition, excessive sugar intake increases the possibility of obesity and dental caries, and especially obesity is closely related to chronic diseases such as diabetes, so it is recommended that sugar intake should be controlled within 10% of total calories. According to MFDS' 'Acquisition of DB and research on sugar in the commonly-consumed food', the total sugar intake per calorie intake increased from 59.6g in 2007 to 72.1g in 2013, an increase of 3.5% a year, and sugar intake of people aged from 3 to 29 through processed foods exceeded WHO criteria that should be within 10% of daily calories.

According to the "Socio-economic impacts of major health risk factors and the evaluation of regulatory policy effects" provided by the National Insurance Policy Institute at the National Health Insurance Service in 2016, the health risk factor that caused the most socioeconomic costs in the past 8 years is obesity, which has increased by 2.22 times compared to 1.62 times for smoking and 1.56 times for drinking.

In light of the socioeconomic costs of obesity, MFDS has promoted policies such as strengthening nutritional labeling on reduced sugar intake by children and adolescents, and supporting the development of coffee products with less sugar. products.

MFDS imposed nutritional labeling on pizza, ice cream, confectionery and bakery products (more than 100 stores) in 2010 and on processed foods such as confectionery in 2006. In addition, MFDS has introduced an voluntary nutrition labeling system for sugar to expressway service areas(March 2010), family restaurants(Dec. 2010), snack bars(Oct. 2011), children's playgrounds(May 2012) and coffee shops(Oct. 2012). In the case of coffee products, the contribution of adults to sugar consumption was high, so coffee beverage specialty stores were able to develop 22 products with reduced sugar, and 8 sugar reduction recipes were developed and applied to 1,125 stores. In 2016, 8,390 stores will participate in the voluntary nutrition labeling system, which had 3,933 stores in 2015.

In addition to supporting nutrition labeling and sugar reduction products development, MFDS has developed and distributed a 'sweet taste assessment tool to check the degree of sweetness of individuals from 2013 through simple tests. Also, MFDS has developed educational materials for students and teachers and disseminated them about 30,000 books to 526 schools to train

infants and elementary school students on sugar reduction.

In 2016, taking into account the increasing trend of sugar intake, MFDS announced the first comprehensive sugar reduction plan for systematic reduction of sugar intake and preemptive and systematic management. MFDS is striving to establish a base for promoting eating habits that eat less sweet foods, creating a selective environment for reducing sugars, and promoting sugar reduction policies, with the goal of managing 10% of the daily intake of sugar from processed foods for all citizens from 2016 to 2020.

In order to promote smooth implementation of the sugar reduction plan, it is necessary to implement sugar reduction policies in earnest. To this end, MFDS will continue to induce changes in eating habits through targeted personalized promotion and education, and will support the reduction of sugar in cooked and processed foods so that the market for low-sugar products can be more vitalized. In addition, MFDS plans to monitor changes in consumers' perception and the amount of sugar consumed by each class including their recognition of the proper level of sugar intake and their efforts to reduce the amount of sugar, and the major food source of sugar.

B. Induction of Proper Sodium Intake

The correlation between excessive sodium intake and the occurrence of chronic diseases such as high blood pressure and stroke is well known and the World Health Organization emphasizes reducing salt intake to maintain a healthy lifestyle. In Korea, mean daily sodium intake was 3,890mg in 2014, which is more than 20% lower than 4,878mg in 2010, but still more than twice the recommended amount of 2,000mg. Therefore, MFDS are trying to reduce the excess of sodium intake of Korean people through the constant promotion of sodium reduction program.

In 2011, MFDS set a target of "Average daily sodium intake of 3,900 mg per day by the year 2017 (20% reduction compared to the 2010 intake)", aiming to improve consumers' eating habits and awareness through promotion, education, and participation programs for each generation and each target. MFDS has also been making efforts to disseminate the technology for sodium reduction in the industry from the food supply stage. In addition, MFDS has continued to cooperate with private organizations such as related societies and associations and related ministries to spread the nationwide reduction campaign of sodium. As a result, MFDS set a new goal of achieving our primary goal in the earlier stage and establishing a second comprehensive plan for sodium reduction in March 2016 to "reduce our daily intake of sodium to 3,500mg by 2020."

Above all, to reduce sodium intake, it is necessary to improve consumers' awareness and individual eating habits. MFDS provides information on how to implement sodium reduction through public advertising at the public media that people can easily access in their daily lives. In addition, the 'Strong Eating & Drinking Exploration Team', which is operated by the field experience classroom program for children, has been training children to participate in the practice of reducing sodium, cooking practice, and food poisoning prevention.

Sodium-reducing menu was developed for the purpose of citizen participation, and a 'Cooking Contest with Les s Sodium' was held annually. The sodium recipes selected from among the winning entries and other entries presented for the contest were made into a cookbook titled 'Dining Table with Less Sodium.' In addition, MFDS continued to educate foodservice users on how to practice sodium reduction for diners, and organized a promotion idea contest for sodium reduction by ordinary citizens in every quarter for each of the following items: UCC, posters, characters, and theme song, and utilized the ideas and materials in policy implementation.

As part of efforts to reduce sodium, MFDS is steadily reducing sodium in processed foods, group meal services, and restaurants. Since 2015, MFDS has designated and managed "Sam-sam(not salty) Cafeteria", which provides a daily dose of 1,300mg of sodium per day(for lunch). From 2011 to 2014, MFDS launched a pilot restaurant designation project for the "Healthy Restaurant to Reduce Sodium" in the food service sector, setting up a foundation to reduce sodium voluntarily, and supplementing weaknesses, and designated and operated the "Restaurant Practicing Sodium Reduction"

In the case of processed foods, companies are encouraged to participate in the reduction of sodium. By 2016, 332 products in 9 food groups have reduced their sodium content (soy sauce〉 3%, general food〉 9%). In order to reduce the sodium content of processed foods, MFDS has been developing guidelines for reducing major sodium source foods. In 2012, the guidelines on sodium reduction for 6 food groups including bean paste and bag noodles, and 7 food groups in 2013, 2014, and 2015, respectively, were introduced and distributed. In 2016, the guidelines for 3 food groups including dumplings, processed dried meat, and cereal were added.

Individual eating habits are difficult to change in a short period of time, and the food industry, which places an emphasis on consumers' preferences, has a limit to reduce sodium, so MFDS is implementing a nationwide campaign to reduce sodium with experts from each field including consumers organization in Korea. Each year, MFDS promoting a campaign to reduce sodium with 6 local governments by region. In addition to strengthening the local government cooperation system, MFDS signed an working agreement with the Ministry of National Defense

in September 2016 to promote the reduction of sodium in the military units.

In 2017, MFDS will continue to focus on key business areas such as food manufacturing, processing, food service, and meals, taking into account changes in market conditions and dietary patterns. In order to promote the development of sodium reduction guidelines for substitute meals such as lunchboxes and to expand the menu with reduced sodium of franchise companies, MFDS will strengthen support for franchise headquarters to strengthen management of its franchises.

MFDS is planning to draw up the expertise and creativity of the private sector by selecting and operating the managing institution which manages possibly hazardous nutritional ingredients for health education and publicity on sodium reduction practice participated by consumers and run by the government. The government expects that it will be able to concentrate on policy work such as establishing mid-and-long term goals and making and implementing comprehensive planning for food and nutrition safety.

C. Expansion of Nutrition Labeling and Provision of Nutrition Service

1) Background

Chronic diseases such as obesity due to over nutrition or nutritional imbalance are emerging as the major cause of death due to westernized diet patterns of Koreans such as changes in diet environment and increase in eat-outs due to increased income, increased number of working couples. As a result, public interest in health increases, and the demand for personalized nutrition and dietary information for self-health care is increasing day by day. In order to create a healthy food selection environment for the public and to guarantee consumers' right to know about nutritional information of foods, MFDS is expanding nutrition labeling not only for processed foods but also for restaurants and providing reliable nutrition information through mobile and the web.

2) Achievements

A) Creation of a Healthy Eating Environment Through Nutrition Labeling

(1) Nutrition Standards and Labeling of Processed Food

The Korean Nutrition Labeling System was first introduced in 1995. In 2015, foods that are required to have nutrition labels have been gradually expanded to pasta and coffee, and

are now expanded to a total of 13 food groups including retort foods, confectionery (confectionery, candy, and ice confectionery), baked bread and dumplings, chocolate, jam, edible oil, fish sausage, instant food (kimbab, hamburger, and sandwich), coffee (except roasted coffee and instant coffee), and soy sauce (except Korean meju, traditional soy sauce, Korean soybean paste and fast-fermented bean paste. In addition, milk and dairy products(milk formula, raw milk, fermented milk, processed oil, ice cream, powdered milk, natural cheese, and processed cheese) in processed livestock products, sausages and ham in food processing products, and livestock products which desires to have or highlight nutrition labeling are obliged to have nutrition as mandatory according to the Livestock Product Sanitary Control Act. In 2006, as 4 nutritional components of sugars, saturated fats, trans fats, and cholesterol were added to have nutritious labeling as mandatory to prevent chronic diseases caused by dietary habits, it now provides information on the 9 nutritional components of calories, carbohydrates, sugars, proteins, fats, saturated fats, trans fats, cholesterol, and sodium.

On the other hand, based on the results of the 2015 Nutrition Label Recognition Survey, in 2016, MFDS set the direction for consumers to understand and prefer and nutrition labeling units were changed from 'per serving' to 'total content' (85% of consumers preferred) for nutrient content values. Also, the labeling design was changed to the nutrition labeling order and the nutrition labeling standard design. This makes it possible to realize nutrition labeling that meets the needs of policy beneficiaries. As a result of the revision of 'Korean Nutrient Intake Standard' (Jan. 2015), nutrient standard has been changed reflecting the people's nutritional status to vitamin D (5 ㎍ → 10 ㎍), chromium (50 ㎍ → 30 ㎍), carbohydrate (330g → 324g), and fat (51g → 54g). In addition, the daily standard value of nutrients of sugar(100g) was newly established so that consumers can easily understand the sugar content of the product.

In addition, in order to disseminate and promote consumer awareness of nutrition labeling, a campaign was conducted on the spot to distribute leaflets for 'reading nutrition labeling' in cooperation with a number of public participation events such as the Food Safety Day and Youth Fair. As a part of reducing the intake of possibly hazardous nutrients such as sugar and sodium which are closely related to high blood pressure and obesity, MFDS promoted the nutritional labeling so that the labeling can be actively used.

(2) Nutrition Labeling on Children's Favorite Foods

As part of the Comprehensive Safety Measures for Children's Food Safety, MFDS started voluntary nutrition labeling for pizza shops, coffee shops, confectionery and bakery companies starting from fast food companies (Lotteria, Mc Donald's, Popeyes and KFC, and Burger King).

In accordance with the enactment of the Special Act on the Safety of Children's Eating Habits, since January 2010, the salespersons (more than 100 stores) who cook and sell hamburgers, pizza, confectionery, bakery products, and ice cream must indicate the content of sugars, protein, saturated fat and sodium per serving as mandatory.

(3) Self-Nutrition Labeling of Restaurants

Since nutrition labeling of cooked foods for children has been mandatory, it has been necessary to promote voluntary nutrition labeling of various restaurants as consumers and the media continuously demand to expand nutrition labels for general restaurants. Therefore, the food service companies have organized a working group with each industry(family restaurants, tteok bok ki, snack bars, highway rest area, children's playgrounds, snack corner in large movie theaters, department stores, and large market food courts, and cafes including coffee). As of August 2016, 11,625 out of the nation's food service companies are participating in the nutrition labeling efforts.

In 2016, as part of the technical support for industry, the establishment of a database of food and nutrients linked to the DB of the food safety integrated network and the improvement of the 'nutrient composition calculation program' supported the technology for nutrition labeling by businesses for the sake of restaurants' participation in the voluntary nutrition labeling.

B) National Nutrition Service

(1) Operation of National Food and Nutrition Management Network

ince 2009, MFSD has been establishing and operating a nationwide management network for food and nutrients and has developed a reliable national nutrition database by collecting, analyzing and analyzing the quality management system to provide nutrition information. In addition, based on the database constructed, the 'eating out nutrition guide' for 130 kinds of food items in 2012, 108 kinds in 2013, 78 kinds in 2015, and 72 kinds of commonly consumed food in the year of 2016 will be produced as books and e-books.

(2) Development and Distribution of Mobile Phone Nutrition Management Program

MFDS transferred 'Calorie Cody(2010)', which is a personal nutritional assessment management program, to 'Food Safety Information Portal(2015)' to provide nutrition services to citizens so that they can experience them at hand. Accordingly, in 2016, MFDS carried

out content improvement projects such as mapping and coding of food nutrition component DB, elimination of redundant information and error improvement so as to match the standard code of the 'Integrated Food Safety Network' and increased the reliability and convenience of users' nutrition information. Also, the number of food items that provide nutrition information through Calorie Cody is greatly increasing to 583 items in 2013, 3,973 items in 2014, and 21,677 items in 2015.

(3) Nutrition Service for Diet Management by Life Cycle

In 2016, MFDS developed and provided 'nutrition and diet card news' which includes food selection tips and dietary safety guidelines for pregnant and lactating women who need special nutrition management as part of providing information for consumers' nutritional and dietary management. MFDS also published and distributed food intake guidelines, such as eating attitudes and methods for the elderly, who are difficult to swallow food, and how to control the viscosity of food. In addition, in order to create a societal environment where consumers can find and select nutritional information from unproven or inaccurate food nutrition information in the media and broadcasting as the public's interest in health increases, MFDS formed a 'National Design Team' and actively communicated nutrition information with the public to identify nutritional issues reflecting consumer needs. Through this channel, MFDS operated 'Nutrition Information Academy (Nutrition Information Tip School)' (Sep. to Oct. 2016) to efficiently provide the right nutrition information in the public's perspective.

3) Implementation Plan

In 2017, MFDS plans to expand nutrition labeling education and promotion for consumers so that the nutrition labeling system can have a substantial effect on people's eating habits. As consumer organizations and the education office will increase awareness of the use of nutrition labeling by increasing the frequency of exposure through customized 'nutrition label reading' advertising and advertising on large media. In addition, MFDS will develop and utilize various educational contents to enable consumers to understand and use nutrition labels well.

In addition, for the advancement and activation of the nutrition labeling system, MFDS will analyze the trends of foreign countries related to nutrition labeling and continue to reflect changes in social trends such as changes in eating habits of Koreans, increase in eating out, and increase in chronic diseases. In addition, in order to motivate health and create a self-health care environment, first, MFDS will continuously develop and disseminate nutrition and dietary education contents for each lifecycle. Second, MFDS will complement and expand the nutrition

information database, such as nutrient components, from the national administration level, and provide customized database services for each consumer. Finally, MFDS will build a comprehensive nutrition information database and counseling system tailored to individual characteristics so that everyone can more easily access and use the right dietary information for their health.

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III

Medical Products

Section 1

Medicine

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

A. Backgrounds

1) Introduction and Improvement of the of Good Manufacturing Practice

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. Accordingly, Korea has implemented the GMP since June 28, 1977. 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 raw material 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 Efforts for 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 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.

As 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. Since then the MFDS has continuously promoted joining the PIC/S through 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 January 2014, Korea's Ministry of Food and Drug Safety (MFDS) was finally approved (effective on July 1) at the PIC/S committee meeting in the same year held in 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. Also, it was significant as Korea 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.

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 August 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 October 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.

In November 2016, MFDS added the GMP regulations of the PIC/S to the 「Good Manufacturing Practice for Medicinal Products」 [Annex 17] in order to continuously harmonize the GMP amendment regulations of the Pharmaceutical Inspection Cooperation Scheme and it was carried out from January 1, 2017.

On the other hand, management of manufacturing facilities of beta-lactam antibiotics, which require attention due to possible hypersensitivity, is strengthening in the US, Europe, and the advanced member states of the PIC/S.

In order to reduce the possibility of crossover and civilian accidents and to create a safe environment for the use of medicines as the standard of manufacturing facilities of international beta-lactam antibiotics, the MFDS revised the 「Enforcement Regulation The Decree on Standards for Facilities of Medicinal Product Manufacturers and Importers」 in October 2016, and ordered the enforcement after two years considering the preparatory period of pharmaceutical companies for facility improvement.

C. Implementation Plan

1) Continuous International Harmonization of GMP standards

In 2017, the 「Enforcement Rule of Medicinal Product Safety」 was amended to strengthen the management of additives used in sterilization of pharmaceutical manufacturing factories of aseptic medicines and the manufacture of finished medicines. Also, MFDS is planning to provide 'the GMP Guidelines for Finished Medicines' and the 'Risk Assessment Based Additive Management Guidelines (tentative name)' to enhance the understanding of the industry.

2) Supporting the Expansion of the Domestic Pharmaceutical Industry Overseas by Utilizing the Status of Participating Countries

MFDS will continue to pursue the whitelist that allows exemption from EU written

confirmation to support the export of raw materials to the European Union (EU). MFDS filed an application in January 2015 for the purpose of promoting a written exemption from the written confirmation and has responded to the European Commission (EC) assessment and on-site evaluation. In 2017, MFDS plans to actively respond to the supplementary requirements of the EC and ensure a smooth final entry.

In addition, MFDS plans to launch GMP Mutual Recognition between Korea and the European Free Trade Association (EFTA) in 2017 to expand the entry of Korean medicines into the European market and to conduct a pilot project to exchange information on GMP status of medicines with Swiss Agency for Therapeutic Products Medical Device Division (Swiss medic).

Furthermore, MFDS will organize the 3rd Korea-ASEAN GMP Cooperation Conference inviting regulatory authorities from 10 ASEAN countries to strengthen the ongoing cooperation system between Korea and ASEAN, and to invite the ASEAN GMP Inspector to educate and train GMP-related domestic and overseas status and latest technologies to promote Korea's drug management system and excellence in domestic pharmaceuticals.

3) Introduction and Continuous Diffusion of Pharmaceutical Quality Improvement System

MFDS plans to continue to develop QbD application model and basic technology development project based on drug formulation design which was underway since 2015. In 2015 and 2016, MFDS has developed a lab-level example model for tablets and capsules and plans to develop an example model for trial production in 2017. In addition, MFDS is planning to hold workshops on quality by Design (QbD) related to drug design based on the pharmaceutical industry and plans to introduce domestic phased implementation.

☆ QbD (Quality by Design): A new concept paradigm that unifies the current system, which is diverted by the manufacturing process and quality control, into one.

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2. Internationalization of Medicine Approval and Evaluation System

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

1) Disclosure of Drug Approval Screening Results

Since 2004, MFDS has been disclosing the results of drug screening in order to meet the public's right to know and to support drug development by domestic pharmaceutical companies.

The results of the bioequivalence study of generic drugs are continuously disclosed, and the generic drug approval screening report is published. In addition, the MFDS is continuously expanding the disclosure items in 'Drug Approval Report' of the new Drug and data submission and has made the safety and efficacy screening review open for new drugs licensed since July 2016.

In the future, MFDS will continue to disclose information on product licensing and screening results, thereby enhancing the consistency, transparency, and expertise of licensing and screening to ensure reliability.

2) Development of Assessment Guidelines Through International Harmonization

The MFDS clearly specifies the screening criteria for pharmaceuticals and provides guidelines for the review of pharmaceuticals in order to improve the predictability of drug approval review. To this end, it continuously reflects the development of science and technology and the amendments to the International Council on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) Guidelines in domestic drug regulations and guidelines for the purpose of strengthening the global competitiveness of the domestic pharmaceutical industry.

Since 2004, MFDS has been operating 'Good Review Practice' (GRP) to ensure the consistency, transparency and reliability of drug screening, and MFDS has been continuously revising it so that the inspectors and applicants can utilize it for reviewing and applying for medicines.

MFDS established and revised a total of 24 guidelines and commentary including 'Quality Risk Assessment Guidelines for Medicines' in 2016 that reflects the International Council on Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH) guidelines.

On the other hand, a total of 16 medical examination manuals (8 examination criteria, 4 licensing tasks, 3 other types of duties, 1 disclosure of information) were revised, and the 'Criteria for Risk Management Plan and Review' was established to improve predictability and consistency of tasks.

MFDS will continue to enact and amend the Guidelines for evaluating international harmonized drugs, including actively introducing ICH guidelines. In addition, MFDS plans to operate and continuously revise the Pharmaceutical Affairs Excellence Assessment Standards Operational Manual.

3) Providing Medical Safety Information

Since 2010, MFDS has been continuously publishing manuals on safe use of medicines on various topics through its website so that consumers can use them safely and correctly in real life.

In 2016, in order to provide safety information on medicines for pediatric dengue disease treatment, MFDS continuously provided information on 9 medicines for asthma and other diseases in the daily newspaper as an article series, called "Children's Medicine Story".

In addition, MFDS continuously provided information on the nine disease treatments, including dementia treatment, through the "Story of the Right Medicine with MFDS" magazine. Similarly, MFDS published a safety manual on 'glaucoma' and 'tooth whiteners' to help consumers use safe medicines. In 2017, MFDS is planning to provide information in the form of card news in order to improve the accessibility of the information for consumers.

B. Efforts for International Harmonization of Pharmaceutical Evaluation

1) Korea's Activities for the International Council on Harmonization of Technical Requirements for Pharmaceuticals for Human Use in Korea

Korea has steadily participated in the International Council on Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH) Assembly since 2006, and became a member country of ICH in November 2016 as Drug Regulatory Authorities.

Taking part in the joint development of 'APEC Harmonization Center (AHC)-ICH Online Education Program' with ICH, MFDS has piloted the guidelines education program on ICH E2 (Safety information management) through e-learning center of AHC since August 2016 (test run period: Aug. 2016 - Aug. 2017, after then, officially operated). In 2016, it participated

in the International Pharmaceutical Regulators Forum (IPRF) to present the status of regulatory improvements of Korea and share the activities and action plans of the Biosimilars Working Group as the chair country.

As a member of regulatory authorities, MFDS (NIFDS; National Institute of Food and Drug Safety Evaluation) will attend the ICH meetings to be held in Canada and Switzerland in May and November 2017, respectively, and will steadily participate in IHC expert groups to jointly develop IHC guidelines.

2) Efforts for Regulatory Harmonization of AHC (APEC Harmonization Center)

APEC Harmonization Center (AHC)[5], which was established in the MFDS (NIFDS) in June 2009, has held a total of 32 workshops until 2016 and co-organized education sessions on pilot operation of CoE (Center of Excellence).

In 2016, AHC hosted 5 workshops and education sessions for CoE at home and abroad, enhancing the capabilities of regulatory authorities of developing countries in the APEC region and supporting the exports of domestic companies. By co-hosting workshops on pharmaceutical distribution system and monitoring of medical products and education sessions for specialized education and training institutions in the fields of biosimilars and good regulatory registration, AHC strengthened its position as an organization to promote regulatory convergence.

In 2017, AHC will hold workshops on international harmonization in the fields of medical product monitoring and biosimilars and provide education sessions on distribution system of medical products and cell therapy products to specialized education and training institutions. In addition, it will develop and provide online education program for regulatory harmonization and regulatory science through e-learning centers.

3) International Cooperative Activities on Generic Drugs

To harmonize regulations of pharmaceutical evaluations for generic drugs and to support development and exports of domestic medical products, MFDS has implemented various international cooperative activities.

International Generic Drug Regulatory Programme (IGDRP)[6] had a total of 7 pilot meetings

5) The APEC Harmonization Center(AHC) was established in MFDS (NIFDS) after the endorsement of the APEC (Asia-Pacific Economic Cooperation) ministerial-level talks and summit as an official and permanent organization, specialized in training.

6) 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.

from 2011 to 2014. The official activities of IGDRP began from 2015. The 2nd IGDRP Assembly was held in Seoul in November 2015, and as of November 2016, the 4th IGDRP Assembly was held.

WHO Pre-qualification (PQ) is a system to evaluate the quality, safety and effectiveness of medical products supplied by WHO to underdeveloped countries. Since 2014, MFDS has participated in a total of 6 sessions (~2016) of joint evaluation by dispatching Korean evaluators every year. Also, with Communication channel for supporting WHO PQ Certification (2014) and workshops and tailored technical consultations regarding WHO PQ (2015-2016), it actively helped domestic companies to enter the market of WHO-supplied medicine.

MFDS will strive to participate in international cooperative activities on generic drugs and endeavor to enhance its capabilities as evaluator by sharing evaluation information with other countries, transferring technologies, and securing international networks.

4) Renewal of MOU and Strengthening Cooperation with USPC

On April 2, 2012, MFDS signed an MOU with the United States Pharmacopoeia Convention (USPC) focusing on development of standardized items for KP (Korean Pharmacopoeia) and USP (US Pharmacopoeia), interchange of personnel, and joint symposium.

The project to develop of standardized items for both pharmacopoeias in Korea and the US, will help increase the exports of Korean medical products to the US market as well as Pharmerging markets, as it makes it available for domestic pharmaceutical products to be listed in the highly regarded USP.

In addition, the symposiums held by the two organizations every year is considered to have contributed to enhancing the global competitiveness of Korean pharmaceutical industry by providing opportunities to understand trends of standards of developed countries in early stage and to harmonize with international standards.

The major plans of MFDS for 2017 are: to participated in joint development of Gemifloxacin, a new drug approved by the US FDA for the first time in Korea, to support domestic companies to take part in WHO-PQ projects, to take part in USPC's Visiting Scientist Program, and to hold joint symposia in order to promptly understand the trends in standards of developed countries.

It consists of ASMF/DMF (Active Substance Master File/Drug Master File), Working group, Biowaiver working group, and Steering Committee. Currently, generic drug regulators from 12 nations and 3 institutions are participating as members.

C. Advancement of Pre- and Post-Management System of Clinical Trials

1) Continued Efforts for International Harmonization of Clinical Trial Approval System

A) Background

Clinical trials are a key part in securing capabilities for new drug development, contributing to the public health and creating knowledge-based high added values, as it can lead to development of relevant industries and institutions including those carry out commissioned clinical trials. Against this backdrop, to compete with emerging powers in pharmaceutical industry, more and more emphasis is being placed on internationally harmonized system.

B) Achievements

In 2016, clinical trial approval system has been improved as follows:

First, the documents to be submitted when applying for approval of clinical trial plan were specified in the 「Regulation on the Safety of Pharmaceuticals, etc.」 and the items to be included in the clinical trial plan were also specified in detail.

Second, the process to change clinical trial plan was streamlined to reduce administrative waste and help accelerate clinical trials. It is determined that non-critical changes such as change of testing institution should be reported, being exempted from the change approval process, and the items to be approved for change and those to be reported are defined in detail.

Third, the 「Regulation on the Safety of Pharmaceuticals, etc.」 was amended to make the matters to be included in the clinical trial plan and the scope of the documents to be same as the clinical trial and these amendments will be implemented on Apr. 29, 2017.

C) Implementation Plan

In 2017, in order to build an environment where clinical trials can be quickly carried out, MFDS will review foreign cases and increase the scope of matters to be exempted from approval process of clinical trial plan at a level that can secure safety and effectiveness.

2) Continued Operation of the “Differential Management System” for Clinical Trial Testing Institutions

A) Background

To safely and scientifically conduct clinical trials, “International Conference on Harmonization

-Good Clinical Practice (ICH-GCP)" and the internationally harmonized 「Good Clinical Practice (GCP)」 must be followed. Also, it is prescribed in the Article 34-2 of the Pharmaceutical Affairs Act that clinical trials shall be conducted by institutions designated by the Minister of Food and Drug Safety.

[Table 3-1-1] Institutions designated for Pharmaceutical Clinical Trial

(As of Dec.31, 2016, Unit : an institution, Ref. : Clinical Trial Management Division)

Province	Seoul	Gyeonggi	Busan	Gyeong sang	Chung cheon	Jeolla	Daegu	Daejeon	Gang won	Gwang ju	Incheon	Ulsan	Jeju	Total
Total	56	30	19	14	10	12	10	9	5	8	7	2	2	184

As it has been 20 years that MFDS introduced 'Clinical Trial Institution Designation system' (in 1994), it carries out periodical inspection on the institutions to check if they conduct clinical trials in accordance with the relevant regulations. With the number of domestic clinical trials increasing and the capacities of institutions conducting clinical trials improving, more efficient management system is required, in order to carry out inspections in different periods, for example. Therefore, in 2013, MFDS introduced the 'Differential Management System' for clinical trial institutions and changed the inspection system to a post-management system that differentiates the cycle of inspection according to the rating of clinical trial institutions.

B) Achievements

In 2016, MFDS carried out the differential evaluation on 8 institutions. Four institutions were given "Average" rating and the other 4 institutions, which need to improve their system to conduct clinical trial, were given "Insufficient" rating.

C) Implementation Plan

In 2017, MFDS will improve the existing differential evaluation system for more focused and efficient post-management.

The method to select and evaluate institutions to be inspected will be changed to divide the institutions into 2 categories, on-site inspection (13 institutions) and document inspection (16 institutions) by taking into account the scale, risk, and participants of the on-going clinical trials.

3) Strengthening of Training and Education for Personnel Involved in Clinical Trials, Etc. (Clinical Trials, Bioequivalence Tests)

A) Background

To safely and scientifically conduct clinical trials, the personnel participating in the clinical trials must conduct them with ethics and sufficient knowledge about trials and the relevant regulations.

B) Achievements

In order to enhance professionalism and protect persons subject to the clinical tests, from 2016, personnel intending to conduct clinical trials, etc. shall complete education courses in institutions designated to provide education sessions pursuant to the Pharmaceutical Affairs Act.

Considering the education courses and qualifications for instructors, MFDS designated 28 institutions for clinical trial education including Korea National Enterprise for Clinical Trials, for 6 training sessions (for evaluators, examiners, clinical trial pharmacists, persons monitoring the trial, coordinators, and persons for quality assurance). As most of the designated institutions are located around the capital area, it also selected external training institutions and commissioned clinical trial education for those living in the rural areas, including 200 coordinators and QA personnel and 800 persons subject to the clinical trials and those in evaluation committee.

C) Implementation Plan

In 2017, MFDS plan to help more institutions for clinical trial education to be designated in order to increase the number of training institutions, and will continue to educate and train the instructors of training institutions to provide more quality education courses that those provided according to the International Conference on Harmonization-Good Clinical Practice.

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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 drugs 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.

In addition, 'Pharmaceutical Safety Keepers' comprising online monitoring agents and ordinary people who work for preventing domestic and overseas illegal and unwholesome

pharmaceuticals from being distributed have made efforts in various ways. They have monitored the illegal drug distribution online and strengthened measures such as blocking the access to or eliminating websites or postings for selling drugs illegally. Also, they have cooperated for the investigation on the distribution of illegal and unwholesome Pharmaceuticals by sharing information with judicial authorities such as Korean National Police Agency and collaborated with Korea Customs Service to block off illegal and unwholesome drugs' entry into the Korean market.

Furthermore, they have promoted settling the culture of safe use of drugs through a national promotion campaign on the hazard of illegal pharmaceuticals, and made some efforts for international cooperation including their activities such as identifying international trend, collecting the latest regulation information, promote the activities in Korea at a WHO meeting on illegal and unwholesome medical products.

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 the 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

In order to preemptively respond to drug distribution through illegal routes such as the internet, MFDS plans to introduce an online illegal sales analysis system and conduct intensive inspection by identifying the web sites which sell potentially hazardous products. It also plans to expand the illegal distribution monitoring of drugs through the Pharmaceutical Safety Keepers, while it strengthens domestic and overseas collaboration measures by blocking and coordinating with the Advanced Analysis Team of MFDS, Korean National Police Agency, Korea Customs Service and Interpol and expanding private sector collaboration. In addition, MFDS

will participate in WHO meeting on illegal and unwholesome medical products and the ICMRA (Global Healthcare Product Regulatory Commission) meeting to continue to promote international cooperation and publicly inform people of the hazard of illegally distributed drugs that can not guarantee safety and 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. postings for selling drugs illegally. Also, they have cooperated for investigation on the distribution of illegal and unwholesome pharmaceuticals by sharing information with judicial authorities such as Korean National Police Agency and collaborated with Korea Customs Service to block off illegal and unwholesome drugs' entry into Korean market.

Furthermore, they have promoted settling the culture of safe use of drugs through a national promotion campaign on the hazard of illegal pharmaceuticals, and made some efforts for international cooperation including their activities such as identifying international trend, collecting the latest regulation information, promote the activities in Korea at a WHO meeting on illegal and unwholesome medical products.

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B. Collection, Evaluation, Production and Supply of Safety Information about Released Drug Products

1) Background

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 adverse events 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. The collected information is developed into new safety information through scientific statistical analysis, documentary surveys, investigation of overseas approval, experts' advice and feasibility evaluation. Safety information results are followed by appropriate safety actions such as drug safety labeling changes, ordering of investigation or research, marketing suspension and withdrawal and, drug safety communications to consumers, doctors, pharmacists and related stakeholders.

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 pharmacovigilance safety manager at pharmaceutical companies mandatory and periodical and immediate reporting of drug adverse events 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 adverse events and also established regional Pharmacovigilance centers. As a result, the drug adverse events reports in Korea increased from 92,375 reports in 2012 to 183,554 in 2014, 198,037 in 2015, and 228,939 in 2016, showing 2 times increase and the number of accumulated reports reached approximately 1,000,000.

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

Analysis on drug adverse events reports, documentary surveys and consultation of the Central Pharmaceutical Affairs Council MFDS developed 'signals (safety information)' and took safety actions including 17 drug safety labeling changes .

These safety actions have continued to increase, starting from 3 cases in 2012, 11 cases in 2013, 14 cases in 2014, 17 cases in 2015 and 21 cases in 2016.

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

Foreign safety information was collected with real-time monitoring of international organizations, foreign governments or overseas mass media, and timely safety actions were

taken by distributing 3 drug safety communications including Olmesartan and Lysozyme/ Pronase. In addition, MFDS changed the drug safety labeling of about 3,300 products that contain 125 medicines. For example, the drug safety labeling change include the dosage and administration of Midodrine.

D) Introduction to the 'Good Pharmacovigilance Practice (GVP) for Released Drug Products'

MFDS pushed forward to introduce 'Good Pharmacovigilance Practice (GVP) for Released Drug Products' and as a result, the law was revised to be Appendix Table 4.3 Safety Management Standards on Released Pharmaceuticals of the 「Rules on Safety of Pharmaceuticals」 as of October 2016. This includes drug safety information of the entire process from the approval to use of drugs including pharmacovigilance planning, hazardous drug reduction strategy, monitoring adverse events of released drugs, periodic safety update report, and signal information analysis. By doing so, active safety management will be strengthened through periodic analysis and evaluation on benefits and hazards of released drugs.

E) Providing DUR(Drug Utilization Review)[7] Information

The development and provision of DUR information has been carried out by MFDS (previously called Korea Food and Drug Administration (KFDA)) since September 2005, following the transfer of the 'development and use of information provision services', which used to be conducted by the Ministry of Health and Welfare (National Health Insurance Review and Assessment Service). The DUR information which is in the process of development and provision is generally open to the public as well as doctors and pharmacists at MFDS homepage. Also, some information such as pregnancy precaution and age precaution are delivered to doctors and pharmacists real time through the DUR under National Health Insurance Review and Assessment Service as well.

F) Providing Drug Safety Information Customized to Consumers

As part of its efforts to provide drug safety information customized to the features of consumers and prevent consumers from being damaged by drug adverse events, MFDS developed and distributed brochure and leaflets to public health centers, obstetricians and gynecologists nationwide so as to inform women of the right way of using the necessary drugs

7) DUR(Drug Utilization Review): A system to make sure that drug prescription is appropriate and medically required and that it does not produce inappropriate medical results.

in their life cycle ranging from adolescence to fertility, pregnancy, childbirth, and menopause to celebrate the Pregnant Women's Day(October 10). Also, MFDS distributed prescribed medication notebook titled 'Senior Health Keeper' and leaflets to public health centers and elderly nursing homes in every corner of the country to celebrate the Senior Citizen's Day(October 2).

G) Providing Results of Linkage Analysis on Drug and Medicine Information

MFDS disclosed the results of analyzing the correlation between the use of medicine and the occurrence of adverse events by using the claims data of the National Health Insurance Corporation and the Health Insurance Review and HIRA(Health Insurance Review & Assessment Service). In 2015, MFDS conducted a analysis of three Ingredients, including pioglitazone, methylphenidate, and diclofenac. In 2016, it conducted a risk analysis of SCAR(Severe Cutaneous Adverse Drug Reaction) by anti-epileptic drugs (lamotrigine) and hypoglycemic agents (DPP-4 inhibitors).

3) Implementation Plan

In order to utilize and analyze the insurance claim data held by the National Health Insurance Corporation and the HIRA, MFDS is upgrading the cooperative system which analyzes medical information in the linkage of those of different medical institutions. It is also working on constructing Common Data Model(CDM) by utilizing Electronic Health Record(EHR) of medical institutions in order to overcome the limits of insurance claims data such as uninsured medicine and missing examination results. If the linkage analysis between adverse events of drugs and various medical information is activated, it will be possible to provide various safety information based on reliable analysis results and to promote independent safety measures for released drugs.

C. Adverse Drug Reaction Relief System

1) Background

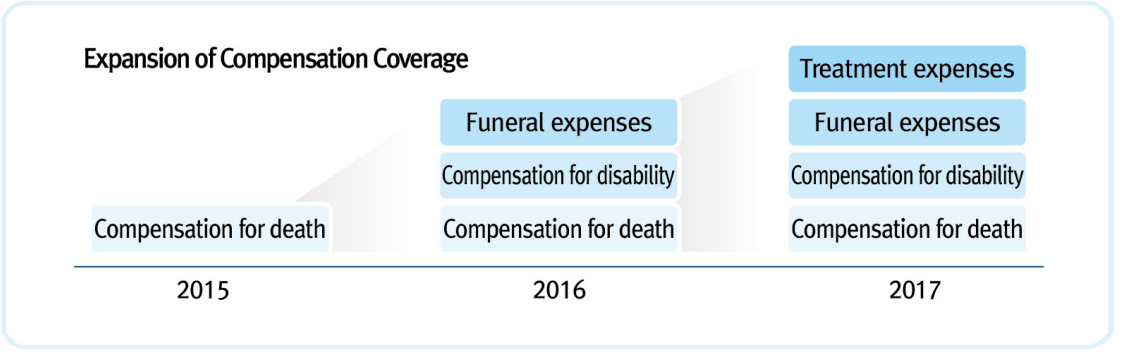
Every medicine has adverse events due to its diverse features and adverse events may also occur even with proper use depending on people. A adverse drug reaction relief system in which the government compensate the victims who die, get injured or hospitalized due to adverse events was introduced and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

2) Achievements

Preparation of a system for evaluating the causality between adverse events and medicine, financial operation of damage expenses, and social consensus are the premise for stable introduction of a damage relief system against adverse events of medicine. In this regard, 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.

The coverage of adverse drug reaction relief system for pharmaceutical adverse drug reaction has been gradually expanded, and compensation will be given for deaths in 2015; cover disabilities and funeral expenses as well by 2016 and include treatment costs by 2017.

3) Implementation Plan



[Image 3-1-1] Expansion of Compensation Coverage for Adverse Drug Reaction

The compensation system is expected be completed in 2017 as the coverage of adverse drug reaction relief system is to be expanded to treatment expense from funeral expenses and compensations for disabilities and death.

MFDS will actively work on promotion and stable settlement of the system so that the system can be positioned as a firm and warm social safety net which protects those who are unjustly victimized by medicines.

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4. Strengthening the Competitiveness of the Pharmaceutical Industry by Stable Operation of the Patent-Regulatory Approval Linkage System

A. Background

The pharmaceuticalpatent-regulatory approval linkage system is a system that takes into consideration whether or not a patent infringement on a new drug is violated in a drug approval procedure. If a latecomer applies for a generic pharmaceutical license based on the developed data of the original drug during its patent life, the original patented drug holder should be informed of the application for the generic drug, and if a patentee who has been notified receives a patent referee or a lawsuit, the generic drug is not sold for a certain period. The patent-regulatory approval linkage system was introduced in 2007 under the Korea-US Free Trade Agreement (“KORUS FTA”). Following the implementation of basic steps such as filing patent applications for medicines in March 2012 and notification of applications for product licenses, the system has been in full swing since March 2015, including the prohibition of sales and permission for priority sales items.

There was a concern around the patent-regulatory approval linkage system since the introduction of the KORUS FTA about its adverse effects of the implementation of the system, including increased patent disputes and delays in the entry of generic pharmaceuticals into the market. In order for domestic pharmaceutical companies to actively respond to the patent-regulatory approval linkage system and enhance their competitiveness, a strategic approach is required based on a clear understanding of the system.

MFDS is pursuing a variety of projects to minimize the adverse effects of the implementation of the new system and to help pharmaceutical companies respond to the system and utilize it.

B. Achievements

1) Operation of Patent-Regulatory Approval Linkage System

The MFDS has amended the Pharmaceutical Affairs Act and the Subdivision Law (March 2015) to introduce the sales prohibition, priority sales item approval, impact evaluation, etc. in order to minimize the adverse effects that may arise from the implementation of the new system and to ensure the stable implementation of the system.

After the implementation of the patent-regulatory approval linkage system, 74 products (18

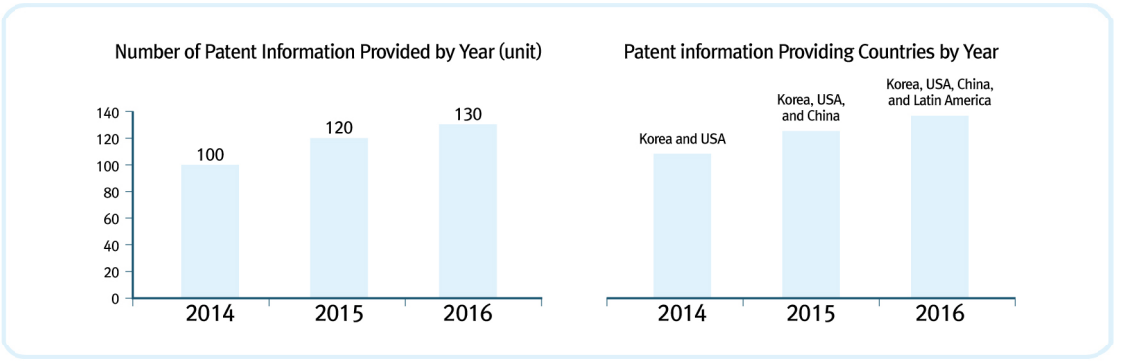
components) were banned from sales at the end of 2016, and 216 new products (34 components) were filed for “first authorized sale items” which reflect the steady operation of the new system. In particular, the 69 pharmaceutical companies that applied for “first authorized sale items” accounted for 69.5% of small and mid-sized pharmaceuticals (less than 100 billion won in 2014 sales), and this indicates positive signs for the development of the pharmaceutical industry as the challenges of small- and medium-sized pharmaceutical companies are becoming more active in the “first authorized sale items”, which were expected to be dominated by some top-tier pharmaceutical companies.

In addition, in 2016, the first analysis and evaluation of the effects of the patent-regulatory approval linkage system on the domestic pharmaceutical industry, health policy, and the results were reported to the National Assembly.

2) Expansion of Patent Information on Pharmaceutical

In 2007, as a result of the KORUS FTA, the patent-regulatory approval linkage system became a major issue in the development and launch of pharmaceutical products. As part of the efforts to strengthen the competitiveness of the domestic pharmaceutical industry, MFDS has collected and analyzed domestic and foreign patent and license information related to pharmaceutical products and provided integrated information through Patent Informatics DB system since 2008.

By 2016, MFDS has established patent and licensing information on 781 ingredients including new drugs, and it will provide information on patent applications for 360 medicines in 16 Latin American countries to support the launch of the emerging pharmaceutical market, Argentina, Colombia, and other major countries, and in 2016, information on patent applications for 360 medicines in 16 Latin American countries and information on patent expiration dates for major pharmaceuticals in four major countries including Brazil, Mexico, Argentina, and Colombia have been set up to support entry into the Latin American market.



[Image 3-1-2] Patent information provision status (2014-2016)

3) Consulting Support for Small and Medium-sized Pharmaceutical Companies

In order to support small- and medium-sized pharmaceutical companies that have difficulty in establishing a patent strategy due to the lack of a patented manpower, even though they have the ability to produce pharmaceuticals, MFDS promoted 'Consulting Support for pharmaceutical company's patent strategy' by introducing patent-regulatory approval linkage system.

For the 11 companies with annual revenues less than KRW 100 billion, MFDS supported up to KRW 10 million in patent consulting expenses per company. The participating companies received consultation on analysis of the patent status of the items to be developed, grasped the patent contents, prescription design and proposal for pharmaceuticals so as not to infringe on patent rights.

As a result of the project, four out of the 11 participating companies achieved actual results such as signing up for the "first authorized sale items" application, new patent application, and patent appeal, and all participating companies were satisfied with the consulting results as it has been investigated that the project solved their uncertainty and helped to set the development direction.

In order to support pharmaceutical companies to understand the patent-regulatory approval linkage system and their effective response and utilization of the system through the enhancement of work capacity, MFDS operates three professional courses such as experts in the field of intellectual property in the pharmaceutical field, patent dispute countermeasures in the pharmaceutical field, and understanding and response of patent-regulatory approval linkage system, and consequently, MFDS trained 440 employees in pharmaceutical industry.

In addition, MFDS provides an in-depth analysis of overseas patent cases such as the US, Japan, and Europe of listed drugs, which are subject to the patent-regulatory approval linkage system of pharmaceutical companies.

C. Implementation Plan

MFDS plans to build user-oriented patent-regulatory approval linkage administrative services and to strengthen the support of institutional use for effective utilization of patent-regulatory approval linkage system of pharmaceutical companies. To this end, MFDS has established an electronic payment management system for entry fees to increase the convenience of payment and management of registration fees for pharmaceutical companies and to disclose the MFDS examination data related to the examination of patent lists. MFDS also plans to organize a

Q&A session that systematically summarizes the questions related to the operation.

In order to support the use of patent-regulatory approval linkage system by pharmaceutical companies, MFDS plans to continuously expand the information needed for product development and export through expanding the number of consulting support companies to 15, establishing patent information on new listed drugs, and providing information on patent and patent system of ASEAN countries, the emerging pharmaceutical market.

In addition, MFDS will continue to make efforts to strengthen the competitiveness of the pharmaceutical industry by sharing the latest issues and trends related to institutional response through the establishment of a forum for government-industry-expert communication such as the patent-regulatory approval linkage system capacity enhancement policy forum and the patent information public consultation body.

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5. Establishment of a Management System for Preventing Abuse and Misuse of Narcotic Drugs

A. Background

The lack of handling information for the distribution and management of medical narcotic drugs such as propolol and illegal leakage and use of medical narcotic drugs by some institutions (medical institution employees) are becoming a continuing social problem. Recently, various routes such as Internet, international mail, SNS increased the exposure to narcotic drugs, and consequently new problems such as the increase of juvenile drug abuse occur, and the necessity of establishing a management system to prevent this has arisen.

B. Achievements

1) Announced Comprehensive Measures to Eradicate Narcotic Drugs Crime (April 26, 2016)

MFDS has established ‘Comprehensive Measures for the Elimination of Narcotic Crimes’ in

order to secure national security through eradication of drug crimes. In order to prevent illegal circulation, illegal use and abuse of drugs, and to promote post-management and publicity promotion, MFDS acted as a control tower for cooperation among departments (MFDS · Ministry of Justice · Supreme Prosecutors' Office, Customs Service, and Police).

2) Established Legal Basis for Implementation and Operation of the Second Pilot Project of Narcotic Drugs Integrated Management System

As the establishment of the 'Integrated Drugs Management System' (December 2014) which can monitor all processes from import and manufacture of narcotic drugs such as propol and drugs to distribution and use stage, MFDS conducted the first pilot project in 2015 for medical drug companies in six regions such as Seoul and Busan in order to provide an efficient and stable system environment for the purpose of mandating the reporting of narcotic drugs as a whole.

MFDS implemented the system stabilization project that reflects the results and the second pilot project in 2016 as a nationwide unit of psychotropic drug companies. MFDS established the basis for establishing efficient management system by securing manpower and organization for operation of narcotic drugs integrated management system such as through composing a TF.

3) Amendment of laws that can block and punish illegal drug advertising and Posting of drug manufacturing methods

Until now, it has been possible to remove narcotic drugs sales advertisements that were detected through illegal drug-related monitoring on the Internet, and punishment was only possible if sales were confirmed through investigation. However, from June 2017, the amendment of the Act has been completed and it enables punishment of such actors as well as the blocking and removing the posts.

4) Dispatch of Drugs Specialists to United Nations Office on Drugs and Crime (UNODC)

In order to preemptively block foreign illegal drug inflows and to acquire the policy system of developed countries related to drug control, the MFDS completed promotion of dispatching an officer to the UN Drug Crime Office.

5) Guidance and Inspection of Narcotic Drugs and Raw Materials Handlers, and Prevention and Abolition of Narcotic Drugs Abuse by All Citizens

MFDS has continuously conducted guidance and inspection through narcotic drugs and raw materials handlers (medical clinics, pharmacies, etc.) in cooperation with related organizations (local governments, prosecutors' offices, police agencies, etc.). Also, MFDS promoted preventive and post-management by constructing the "on-line education system for the prevention of abuse of drugs" and the education and promotion through customized public service advertisements and web drama for youth.

C. Implementation Plan

1) Operation of User-friendly Narcotic Drugs Integrated Management System

MFDS will continue to promote system improvement and stabilization such as processing speed and security enhancement so that narcotic drugs handler can report handling details using convenient and easy to use integrated drug management system. Also, MFDS will implement a successful integrated drug management system by conducting customized training and promotion for users to prepare and distribute a standard guidebook for linkage program development and practical application through inspection of the entire process of the user, and to prepare for distribution and reporting.

2) Prevention of Narcotic Drugs Misuse and Preliminary Coaching, Guidance, Inspection and Promotion

MFDS will continue to monitor the planned joint monitoring of narcotic drugs (narcotics, prosecutors' offices, police agencies, etc.) for narcotic drugs and raw materials handlers (such as doctors and pharmacies) to prevent illegal spills and misuse, and plans to strengthen drug safety through anti-drug education and publicity campaigns for drug abuse.

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Section 2

Biopharmaceuticals and Cosmetics

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

A. Improvement of Safety Management and Quality Management of Biopharmaceuticals

1) Background

Unlike synthetic (chemical) drugs, which have already reached the maturity stage when it comes to commercialization technology and market conditions, new products using ever-developing advanced technology are continuously appearing in the field of biopharmaceuticals. 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.

Currently, regulatory authorities and pharmaceutical companies around the world have held strict quality standards, putting every effort to produce safe and effective medicinal products and the Ministry of Food and Drug Safety (hereinafter, 'MFDS') also strives to provide high-quality medicinal products by thoroughly checking whether if biopharmaceuticals are in accordance with the Good Manufacturing Practice (GMP) during the manufacturing stage.

2) Achievements

A) MFDS established 'Good Manufacturing Practice (GMP) for Biological Products, etc.' (in 2001), separately from synthesis (chemical) drugs, to introduce pre-GMP system for each item (in 2003), and prepared GMP guidelines and manuals that reflect the characteristics of biopharmaceuticals. In particular, the system was improved for pharmaceutical companies to apply for preliminary review for their GMP implementation status even before applying for approval, contributing to the rapid commercialization of biopharmaceutical products and shortening the time to market. MFDS also supported the exports of biopharmaceutical products by revising related guidelines so that the GMP English certificate required for the export of

biopharmaceutical products can be written according to the requirements of the destination countries.

Also, in 2014, MFDS joined the Pharmaceutical Inspection Convention and Pharmaceutical Inspection Cooperation Scheme (PIC/S) which has 46 member countries (49 authorities) including the United States, Japan, and European countries. To meet the internationally harmonized standards of PIC/S in terms of detailed matters of GMP implementation of drugs, MFDS established the 「Regulations on Manufacturing and Quality Management of Pharmaceuticals」 (Notification of MFDS) (in Jun. 2015) and in 2016, it also established 'Regulation on the Safety of Drugs, etc. [Attached Table 17] Manufacturing of Drug Product' (in Nov. 2016).

In order to strengthen the safety management of imported biopharmaceuticals, a total of 52 overseas manufacturing sites were examined by 2016, and the systematic reports on the results of the inspection on standards on manufacturing and quality management of pharmaceuticals were provided to companies in an effort to strengthen the transparency and improve their GMP level.

B) Improvement of the National Lot Release System

In June 2012, MFDS revised the National Inspection System of Biologics to 'National Lot Release System' to improve the existing test-based examinations by reviewing the overall manufacturing records and summaries on quality management of manufacturers at each manufacturing process and conducting a direct national test on the finished product at the same time.

In July 2015, it prepared detailed criteria for risk assessment of each review item to differentiate the Drugs under National Lot Release according to the risk level, and in 2016, MFDS revised 'Detailed Guidelines on Risk Assessment for Differentiated Test Items of Drugs under National Lot Release' to add a separate criterion for items for WHO Pre-qualification and modify other details to reflect the reality.

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

For prompt information sharing and consistent response in the event of a serious abnormal case after vaccination, MFDS established all-time cooperation system (in 2013) among relevant ministries (organizations) and shares information on adverse events regarding vaccination

collected from each organization on a quarterly basis. And it also has strived to build a ground for the life-cycle safety of vaccines by preparing a 'Roadmap for Integrated Management of Information on adverse events after Vaccination' (in Jan. 2016).

In addition, in order to enhance the competitiveness of domestic biopharmaceutical manufacturers and to support the Pre-qualification (PQ) of WHO which can be a bridgehead for the exports of domestic vaccines, MFDS has provided administrative and technical supports to each applicant manufacturers by organizing 'One-to-One Customized Expert Consultative Group', and as of the end of 2016, 20 products from 4 companies have been certified.

As MFDS signed a cooperation agreement with WHO on vaccine PQ in December 2016, the level of MFDS' regulation were recognized internationally and when Korean vaccine manufacturing companies applies for WHO PQ certification, they are exempted from the actual inspection of WHO with the MFDS inspection reports and the period for certification can also be shortened by about six months or more.

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 Introduce the QbD System」 (in 2013) and 「Procedures for Developing QbD-applied Model」(in 2014). Then, in 2015, MFDS initiated a QbD model development project by utilizing gene recombinant products to develop a model focused on cultivation·fermentation processes and prepared guidelines for the model, and in 2016, it developed a model focused on retrieving·refining processes to complete the development of QbD model on the substance manufacturing process of gene recombinant products.

Also, MFDS revised 'Guidelines on Biopharmaceuticals Manufacturing Process Validation' (in Sep. 2016) to reflect process validation and the relevant QbD concept for utilization in the domestic market.

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 the 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

As the stem cell therapies and gene therapies require long-term post safety management, MFDS made it mandatory to conduct a 'long-term follow-up inspection' (implemented from Jan. 2017) to identify serious long-term abnormal cases and prepared a 'Detailed guideline on long-term follow-up inspection' regarding the subject, period, required information, and detailed criteria of the long-term follow-up inspection, providing safer ground for using those drugs.

3) Implementation Plan

Considering the various factors such as inspection history, the status of domestic and overseas quality incidents, and import records that can have an impact on the domestic market, MFDS will continue to conduct regular examination based on risk analysis which is carried out to assess the risk level and identify the major checklists.

The sampling of drugs under National Lot Release, which were extracted and collected by public officials, will be required to be directly submitted by the applicant manufacturers. MFDS will systematically enhance the support for vaccine PQ of WHO, inviting experts at home and abroad to share information on WHO certification and relevant cases and consistently providing customized services through on-site consultation for those who want this service.

Also, in order to introduce the QbD system in biopharmaceutical field, MFDS will a)develop a model focused on formulation·vial filling·freeze-drying processes and publish a manual for the model, b)support and improve relevant systems to strengthen the competitiveness of biopharmaceuticals while operating various education programs to nurture international-level manufacturing and quality control inspectors, and c)carry out a systematic education sessions on the manufacturing and quality management standards for GMP inspectors of foreign

regulatory authorities who were selected and dispatched by WHO as it designated Korea as an international education center for manufacturing and quality management standard.

In addition, as an effort to strengthen the drug monitoring for safe use of biopharmaceuticals, MFDS will establish a system to share and manage information on abnormal cases after vaccination and come up with a plan for comparative analysis of electronic systems of each organization and establishment of a system for collecting, analyzing and evaluating information on abnormal cases (reaction) after vaccination.

For blood products, 'Blood Products GMP Manual' and 'Evaluation Table' will be prepared to help evaluators and those in the relevant industry to understand the newly established GMP standards regarding blood products, and seminars and on-site training, demonstration of evaluation on manufacturers, and consultation services will be also provided.

To operate the long-term follow up inspection on the safety of stem cell therapies and gene therapies as a state-led system, the relevant regulations will be amended, and more safety information will be provided by analyzing the reevaluation results of new drugs, the usage history during the period, and voluntarily-reported hazardous cases.

B. Safety Management and Quality Improvement of Human Tissues

1) Background

Human tissues such as bones and skin taken from living or dead donors in order to restore physical integrity, treat diseases and prevent disorders have been used as important treatment means in medical field along with drugs and medical devices.

After the enactment of 「Safety, Management, Etc. of Human Tissue Act」in 2005, MFDS has put efforts to secure the safety of the tissues donated in Korea or imported from foreign countries and made it mandatory for the Health Insurance Review and Assessment Service to check the donor's medical history and medication history to strengthen the management of donor's transplant compatibility since 2015. Also, it requires to attach standard codes and bar codes to the label of all human tissues and established a tracking management system by registering those tissues in the Human Tissue Safety Management System.

Moreover, in order to enhance the safety management of imported human tissues, MFDS has carried out surveys on foreign manufacturing companies, and in 2015, the import approval system was introduced to allow imports of human tissues only after whose safety is verified through the pre-examination on the adequacy of imports.

2) Achievements

A) Mandatory Good Tissue Practices (GTP)

In order to establish a basis to provide quality and safe human tissues under management standards on human tissues for collection·processing·storage·distribution phases, MFDS prepared the Good Tissue Practices (GTP) and required the phase-by-phase application of all tissue banks. 'Good Tissues Practices (GTP) Manual' was also prepared and distributed for the early and stable establishment of GTP and minimization of the capacity gap between tissue banks, and a standard model on 'Standard Operating Procedures', which were required for a quality management system, were also prepared and distributed.

B) Mandatory Standard Code and Barcode System for Human Tissues and Establishment and Operation of Human Tissue Safety Management System (HUTIS)

In order to facilitate the tracking and management of human tissues, MFDS has implemented mandatory labeling system requiring standard codes and barcodes on the containers/packaging of human tissues to identify individual tissues in them since January 2016.

Also, MFDS established and operated the Human Tissue Safety Management System (HUTIS) in November 2015 for prompt and effective tracking & management of human tissues from tissue donation·collection to transplantation.

Through HUTIS, all tissue banks can create, print and label standard codes and barcodes for each tissue and register history of each process such as warehousing, processing, and distribution stage. Therefore, MFDS will share safety information on human tissues and promptly track and respond to any risk incidents including human tissue-related side effects.

C) Strengthened Inspections on Foreign Manufacturers of Imported Human Tissues

Since 2011, MFDS has carried out inspections on foreign manufacturers of imported human tissues, along with the periodical inspections on domestic tissue banks, and since 2016, it has selected manufacturing companies with high risk and conducted special inspections. Also, MFDS reinforces the safety management of imported human tissues by introducing the import approval system (in 2015) in order to prepare a basis for prior inspection and to assess the adequacy of imports for the tissue types that are imported for the first time.

D) Enhanced Education for Personnel in Tissue Banks

Since 2014, MFDS has carried out education programs for personnel working in tissue banks

to strengthen their capabilities. And from 2016, in addition to the basic education course for Tissue band staffs, which are provided twice in a year, MFDS came up with an intensive course (in Nov. 2016) to educate them on the human tissue-related legislations, GTP, tracking management and reports of side effects, collection·processing procedure by tissue type, and requirements for quality management.

3) Implementation Plan

As the GTP became mandatory for all tissue banks, conducting focused-investigations on GTP is necessary but providing support for tissue banks to comply with GTP is also required. For this, MFDS will increase the number of tissue bank personnel who need to attend the education courses and provide educational video-clips to create an environment where they can learn regularly along with the intensive education courses.

In order to strengthen the safety of imported human tissues which account for a large part of the entire tissues distributed, MFDS will also mandatorily carry out on-site inspections before import approval and register all overseas manufacturing companies that imports human strengthen the safety management on the imported human tissues focusing on overseas manufacturing companies by registering all foreign manufacturing companies importing human tissues in advance.

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2. Safety Management of Herbal and Natural Medicine 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 Traditional Korea Medicinal(TKM) Substance(hGMP)' in June 15, 2012 and made it fully mandatory in January 1 2015 requiring all TKM substance 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.

A. 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 'hGMP' 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, 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.

B. Implementation Plan

In 2017, 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 alos revised the 「The Regulation on the Approval & Registration of TKM products(Herbal Medicinal Products)」 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

Since the Cosmetics Act has been fully revised (since February 12, 2005), MFDS has strengthened corporate responsibility for cosmetic safety and quality assurance, and the government has focused on follow-up management of products on the market to ensure rapid market entry. In order to promote the development of new cosmetics raw materials and to activate the industry and to meet regulations at the international level, the cosmetic ingredient

management system has changed to the 'Negative List' method, which notifies raw materials that can not be used in cosmetics and allows other raw materials to be used.

MFDS revised the regulations on cosmetic safety standards, and improved the standards for use of raw materials that cannot be used and need to be used, and safety management standards for cosmetics for distribution. MFDS has strengthened the safety of cosmetics by revising the safety standards of raw materials through collecting safety information at home and abroad and risk assessment.

MFDS is constantly revising the criteria for raw materials that cannot be used and that need to be used in a way that reflects the harmful cases of domestic and foreign cosmetic raw materials that are controversial about safety and the results of the risk assessment. The safety management standards for cosmetics distribution will also be revised to meet international standards.

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

MFDS encourages cosmetics manufacturers to comply with the standards for excellent cosmetics manufacturing management, and also notifies Cosmetic Good Manufacturing Practice (CGMP) which is the management standard for excellent cosmetics.

Since March 2011, MFDS has been awarded excellent cosmetics manufacturing and quality control standards, and a total of 110 companies (as of the end of December, 16th) have been approved for excellent cosmetics manufacturing and quality control standards. In order to spread the GMP of cosmetics, some process manufacturers have been allowed to evaluate the implementation status, and the evaluation method for each product group has been changed to the evaluation method for each manufacturer. In order to alleviate the burden on applicants for Cosmetics GMP evaluation, the treatment period was shortened from 120 days to 90 days.

In order to secure international competitiveness of cosmetics quality and to improve productivity, it is necessary to manufacture excellent cosmetics and spread quality control standards. For this purpose, MFDS plans to provide customized consulting services for cosmetics GMP companies to improve quality control standards of small businesses. In addition, cosmetics GMP designation evaluation is planned to be transferred to each local MFDS to ensure the consistency of GMP designation evaluation and follow-up management.

2) Strengthening of Industrial Competitiveness through Productive Safety Management

A) Strengthening the Control of Harmful Substances in Cosmetics

MFDS designates raw materials that can not be used for cosmetics manufacturing as prohibited raw materials, and in the case of controversial raw materials which are suspected to be harmful to national health and to contain harmful substances at home and abroad, the risk factors are quickly assessed and it is decided whether they contain harmful substances.

MFDS has established an unintentional detection tolerance of prohibited raw materials in cases where it is unintentionally derived from the packaging material during manufacture or storage and technically complete removal is not possible. MFDS also established management standards for 'wet wipes' which converted classification as cosmetics as of July 2015.

In the future, MFDS plans to improve the related regulations, such as specifying the unintentional detection limit of prohibited raw materials, reflecting domestic and foreign harmful cases and the results of risk assessment

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. MFDS is striving for the dissemination and diffusion of cosmetic GMP, and when new technologies or knowledge related to manufacturing and quality management of cosmetics in Korea and abroad are known, or when Guidelines for the Cosmetics Good Manufacturing Practices (CGMP)」 are revised, MFDS reflected them in the contents of the commentary for the improvement of the quality control level of cosmetics manufacturers.

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 carries out a 'Master Plan for the Management of Cosmetics Manufacturing and Distribution.'

In 2016, MFDS carried out a planned joint inspection of children's cosmetic producers and

the producers and sellers of cosmetic products containing CMIT/MIT since those products have caused a big social issue.

To establish a safety management system for cosmetic products that consumers can rest assured, in 2017, MFDS will promote voluntary inspection of cosmetics manufacturers and sellers and carry out a planned joint inspection of the cosmetic products for those who are vulnerable such as children's cosmetics and the products that possibly contain prohibited ingredient mixtures to analyze and focus on inspection of the cosmetics 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 labeling, there were no effective measures to manage them until recently.

But in 2016, to strengthen the inspection on various cosmetics advertisements on online shopping sites, social networks, and company websites, MFDS set up a monitoring system with the increased number(from 3 to 4) of exclusive personnel dedicated to this monitoring task.

In 2017, MFDS will continue to carry out an inspection of TV shopping channels and online shopping sites all year-round as well as the status of cosmetics labeling and advertisements in order to closely monitor false and exaggerated ads that falsely advertise cosmetic products as pharmaceutical products.

C) Collection and Testing of Cosmetics

To secure safety and quality of cosmetics, MFSD 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(Nature) Medicines, Cosmetics, and Quasi-Drugs.'

For special sampling and testing work of 2017, MFDS secured 246 million won budget. In addition, over 800 items in total are regularly collected and inspected on a yearly basis after selecting the test items per product type and the target number of items tested per local governments.

In 2017, MFDS plans to intensively collect and test the items of which quality is suspected to be poorly managed including the items, suspectedly containing CMIT/MIT that has recently caused social concern as humidifier sterilizer. Also, MFDS is making an effort to collect domestic

and overseas information of hazards in real time to preemptively prevent unsafe cosmetic products from being distributed in Korean market will continue to inspect and manage the controversially unsafe ingredients by conducting hazard evaluation.

B. Safety Management of Quasi-Drugs

1) Strengthening Safety Management of Quasi-Drugs

A) Background

Quasi-drugs are everyday items that are most frequently and widely used and deeply linked to people's live such as sanitary pad, toothpaste, pesticide, etc. Hence, consumers are very sensitive about the safety of quasi-drugs, and 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. In this regard, MFDS is supplying safe quasi-drugs and laying a foundation for the appropriate use of the drugs by strengthening management such as reasonable system improvement and observance of the relevant regulations.

B) Achievements

(1) Improving Quasi-Drug Regulations

For the purpose of establishing the foundation for the use of quasi-drugs, 'Methylchloroisothiazolinone·methylisothiazolinone' (hereinafter referred to as 'CMIT / MIT') as a preservative is limited to use only in products that are washed after use, and 4 other products including inhalation product containing 'Polyhexamethylene guanidine·Ethoxyethyl guanidine chloride(hereinafter referred to as 'PHMG·PGH')' was further designated as ingredients with safety and efficacy problems (March 2016).

In addition, the use of 'parabens', a preservative used in toothpaste and oral care products, is limited to two kinds of 'methyl·propylparaben' and the use standard is below 0.2% and 'Triclosan' is prohibited the use of oral care products. In order to strengthen consumers' right to know and to use the preservatives and tar pigments in quasi-drugs, it was obligatory to label the products in containers and packaging (October 2016).

In addition, as part of the rational operation of quasi-drug product licensing, declaration and examination systems, MFDS has expanded the scope of use of new additives for sanitary products (such as medical devices and industrial products) in order to rationally improve the

safety and efficacy screening scope, including the establishment of standards for the exemption of screening of hair dye formulations (June 2016).

(2) Improving Labeling System of Quasi-Drugs for the Vulnerable such Children for their Safe Use

To operate consumer-oriented product labeling system, MFDS has prepared the details for the important information, which is directly related to consumer safety, such as warning, prohibition, and caution, i.e. "prohibition of use under certain age" to be displayed with easily understandable and noticeable patterns and figures to ensure the consumers' safe use of quasi-drugs(October 2016).

(3) Introducing Sales Blocking System of Hazardous Quasi-Drugs

In order to actively block the consumer use of hazardous quasi-drugs such as the products of inadequate quality and products that are to be withdrawn or suspended for sale, MFDS has established and operated the 'Sales blocking system of hazardous quasi-drugs' (for 2,936 stores of 18 retailers, as of November 2016) since June 2016 in order to rapidly provide quasi-drug seller with product information to block sales of the product at the site in real time. Accordingly, it has promoted informatization and modernization of the information of quasi-drugs, minimized the possibility of purchasing and using hazardous quasi-drugs, and actively secured national safety and improved consumer confidence in the currently distributed quasi-drugs.

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

Since the beginning of 2016, there has been a growing concern about the occurrence of viral infections caused by mosquitoes such as 'Zika virus infection' and 'dengue fever,' MFDS provided mosquito-fighting tips and information of mosquito repellent which is quasi-drugs online from March to the end of the year to prevent mosquito-borne infection and its spread. In June, MFDS produced a promotional video of "How to choose and use mosquito repellents in a right way" and transmitted through the screens of movie theaters and the monitors in the elevators of apartment complexes in June, ahead of the summer season when mosquitos are fully active.

For the safe use of children's oral care products that are also quasi-drugs (such as toothpaste, mouthwash, oral wipes, etc.), MFDS prepared leaflets for children and distributed them through the Centers for Children's Foodservice Management for them to use in education and promotion of safe use of quasi-drugs by children. In addition, MFDS provided customized safety

information of quasi-drugs which are normally used in people's daily lives, such as healthcare mask (in March and December), toothpaste·mouthwash·denture cleanser (in May, the month of family), smoking cessation supplement (on May 31, Smoking Cessation Day), and oral care products (on June 9, Oral Health Day) that are based on social issues, seasons, and consumers' interests, etc.

(5) Monitoring Quasi-Drugs

In 2016, MFDS conducted an intensive inspection to determine whether the companies which did not submit the reevaluation materials of quasi-drugs carried out administrative measures and whether unauthorized quasi-drugs are distributed upon the expansion of the scope of quasi-drugs. Particularly, MFDS carried out an intensive inspection of the companies manufacturing or importing the 'supplements for improving smoking habits', the newly designated quasi-drugs without permission and the companies selling unauthorized quasi-drugs for a month or more in October.

In addition, MFDS planned for a precautionary surveillance for seasonally highly consuming quasi-drug products on quasi-drug sellers and intensively inspected the products with misleading labeling or advertising, for example, a face mask for industrial use as a 'healthcare mask' in March and a normal bracelet as a 'mosquito-repellent bracelet' which is quasi-drug in June.

Also, MFDS carried out an inspection of all Korean toothpaste manufacturers for some controversial products using ingredients with a little amount of CMIT/MIT and conducted regular and the irregular inspection on pharmacists to monitor quasi-drug manufacturers and importers in order to strengthen safety management of quasi-drug according to the increased interest in the sector.

(6) Quality Control of Quasi-Drugs

A total of 3,322 items were collected from 2,366 items of MFDS and 956 of local self-governing bodies during the period of 2015-2016 for all quasi-drugs that can be distributed on the market. Of these, 3,126 cases (during 196 items) were tested, and 51 items were judged to be inadequate quality, including administrative disposition, collection, and disposal.

C) Implementation Plan

A system of displaying all ingredients of quasi-drugs will be implemented (from December 2017) to strengthen consumers' right to know and right to choose products. Also, MFDS

plans to restrict the use of 'micro-plastics' added for the purpose of improving the detergency of wash off products, such as toothpaste and to reflect this in the quasi-drug sector in order to enhance the competitiveness of the quasi-drug industry through international harmonization.

In addition, in order to preemptively secure consumer safety for the life chemical products directly applied to the human body according to the 「Measures for Safety Management of Life Chemical Products」 jointly developed by the relevant ministries and agencies, the two products including the 'products used to temporarily control tooth color by applying to the tooth surface' and 'air-creating or oxygen-containing portable products that are used by direct suction to the human body' will be newly designated as quasi-drugs.

In order to efficiently operate the 'Sales blocking system of hazardous quasi-drugs' for creating a safe environment for consumers, the scope of the distribution network in which information on hazardous products is provided will be expanded from a large retailer to a variety of distribution networks including direct sales, small retailers, pharmacies, and wholesalers.

To prevent consumer damage caused by false and exaggerated advertisements and to promote safety promotion for prevention of misuse and abuse of quasi-drugs, MFDS plans to continuously provide and promote information of daily life tips for the safe use of quasi-drugs (such as right choice and usage, and caution) for quasi-drugs according to social and seasonal factors (yellow and fine dust, summer mosquitos, etc.) and characteristics of consumers(adults, children, and smokers).

In 2017, under the key strategy of securing preemptive safety management from raw materials to complete products, MFDS will strengthen inspections of manufacturers and importers for the appropriateness of quality control of quasi-drugs, monitor the compliance with the quasi-drug preservation criteria to ensure safety of each product, and continue to focus on consumer concerns about popular items that are seasonally consumed, as well as sales activities through false and exaggerated advertising.

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

A. Background

Biopharmaceuticals are being developed as new types of drugs based on biotechnology, such as using new types of targets and biomarkers, and they are focused on improving efficacy and effectiveness of existing drugs and treating intractable diseases. Biopharmaceuticals produced using components and information such as nucleic acids and proteins are continuously growing in the global pharmaceutical market as an alternative to overcome the shortcomings of chemical drugs.

As the existing blockbuster biopharmaceutical patents expire in 2015-2022 and the development of innovative new drugs becomes to slow down, it is expected that competition in the 'biosimilars' market is accelerating, including strategic alliances, licensing and mergers with biopharmaceutical companies around the world and that competition in the global market is getting fierce gradually. There is a growing interest in the development of biopharmaceuticals as well as pharmaceutical companies, and investments are being made in technology innovation and research and development of biopharmaceuticals.

The global biosimilar and vaccine market is expected to expand due to the spread of various chronic diseases and the entry into an aging society, and the development of vaccines that can generate high added-value such as 'premium vaccine' is increasing rapidly. Biologics are expected to show high growth as they are highly therapeutic and have a relatively low R&D risk and high return on investment.

The number of clinical trials of biopharmaceuticals such as biologics, biosimilars and stem cell treatment drugs currently under development in Korea is 225, and many domestic products are expected to be released in the future. A number of pipelines have been formed in the area of international comparative advantage, which support this view.

[Table 3-2-1] Status of Clinical Trial Items by Product

(As of Dec. 2016, Unit : EA)

	2014	2015	2016
Biological Product	29	14	32
Cell Therapy Product	24	25	33
Genetic Recombination Drugs	110	158	151
Genes Therapy	7	5	9
Total	170	202	225

Since biotechnology creates various new industries through fundamental changes of existing industries such as medicines and pharmaceuticals and convergence with other technologies, it is necessary to establish customized strategies such as strengthening internal and external competitiveness. Korea is also increasing government investment such as R&D expenditure every year by selecting the bio industry as the future growth engine industry to actively support the government. In addition, MFDS is making efforts to secure global competitiveness in the world market with the development of cutting-edge biopharmaceuticals and advancing into the global market.

B. Achievements

In particular, MFDS is strengthening cooperation with international regulatory agencies such as WHO and APEC in order to support the entry into the global market of biopharmaceuticals through establishment of high-tech biopharmaceutical safety management system, expansion of customized support for strengthening global competitiveness of domestic vaccine, WHO Pre-qualification[8], and domestic and overseas regulatory information provision and consulting.

MFDS established a forum for sharing knowledge and promoted global growth in the field of biopharmaceuticals designated as future new growth engine industry by hosting "Global Bio Conference" held in conjunction with the International Pharmaceutical Regulators Forum (IPRF) and the Asia-Pacific Economic Cooperation Harmonization Center (AHC) in order to realize a strong biopharmaceutical power. At the conference, MFDS proposed future developments such as new infectious disease treatments and rare disease treatments as well as understanding on the recent international trends and development strategies for biopharmaceuticals.

The 'WHO Certification Support Committee' supports consultation and technical documentation on clinical, GMP, etc. for pharmaceutical companies applying for WHO PQ certification. Through this consortium, the oral cholera vaccine, Yuba Bio Logics Ubiquel, was certified to WHO PQ in December 2015 and exported to developing countries, which showed a visible effect on the export support of the Global Vaccine Product Support Council.

The 'Global Vaccine Product Supporting Group' is composed of a pharmacy service center and a technical advisory group. It aims to find solutions to the problems that may arise during

8) WHO Prequalification (PQ: Prequalification) This is a system to assess the quality, safety and efficacy of products for the purpose of supply to developing countries through international procurement of medicines. (Currently 20 products(packing unit) in 13 items at 4 companies approved)

the development stage of Korean vaccine development companies that make products from raw materials to products. Especially, We have been providing customized one-stop consulting services throughout the entire period.

The Global Vaccine Product Support Team supported 7 products from 10 companies in ’13 - ’14, 8 products from 4 companies in ’15, and 10 products from 4 in ’16. In July of 2016, Green Cross received approval for the product of SKYNEUMO PREPARED SIRINJE, a vaccine for Pneumococcal vaccine in July. In November 2016, Green Cross received approval for the grant of ‘Green Cross Tide Prefilter Cyrin’ (adult diphtheria and parasite vaccine) Respectively.

We also provide customized technology support for the development of essential and pandemic vaccines, and are carrying out institutional support to promote the development of new and advanced vaccines, including new mixed vaccine licensing guidelines and standardized test methods.

In December 2016, the Food and Drug Administration signed MOUs with six other countries, including the Ministry of Health of Mexico, to cooperate with foreign regulatory agencies. The joint declaration with the German Federal Ministry of Health, the World Health Organization Essential Drugs and Health Products Bureau (WHO EMP) has entered into a cooperation agreement for work related to vaccine dictionary qualification (PQ) procedure. MFDS will be able to share information and data on the screening of licenses and promote the entry of Korean companies into overseas markets through ongoing agreements with advanced regulatory agencies, Memorandum of Understanding and expansion of international cooperation.

In order to expedite the approval of biosimilars, MFDS has set preliminary licensing and screening standards in Europe and are actively cooperating with international organizations such as the World Health Organization and other regulatory agencies in order to enter the world market. In order to provide the control tower function for these various support projects and to receive opinions of the difficulties of the product development process in the industry, the ‘Dynamic Bio’, ‘Biotechnology Industry Development Strategy Planning Team’ .

In addition, the pharmacy service will continue to promote the establishment of a bio-IT platform, a customized export support program for biopharmaceuticals from 2014, to provide overseas license and regulatory information and industrial information to the biopharmaceutical industry, And the lack of information related to licensing.

In 2016, biotechnology regulatory information and guidelines for biopharmaceuticals in 12 countries including the United States, the European Union, China, Japan, Brazil, India, Turkey,

Mexico, Thailand, Russia, Saudi Arabia, Bpis.or.kr). In addition to providing passive information, MFDS also provided on-line and visiting consulting services to companies wishing to consult in order to actively provide information.

C. Implementation Plan

As the global biopharmaceutical market is growing fast and developed countries are concentrating on high - tech products such as biosimilars, it is necessary to expand the support to the international market in order to gain international competitiveness and secure international competition in the advanced biopharmaceutical industry.

Through the global biopharmaceutical support policy, MFDS plans to expand the number of biosimilars to 7, stem cell treatments to 1, gene therapy to 1, vaccine to 18, The goal is to expand the global market of biosimilars to overseas markets through the provision of overseas regulatory information and industry information through consulting on licensing and licensing, biosimilars prime business and mutual agreement between foreign regulatory agencies.

MFDS will continue to promote the bio-IT platform business currently in operation to provide information on the countries in which the biopharmaceutical industry is expected to enter overseas. This project will analyze and provide regulatory information and guidelines related to biopharmaceuticals such as vaccines, recombinant drugs, antiretroviral drugs and gene therapy in overseas countries, and provide customized consulting services for industry information such as market size. In the future, MFDS will make biopharmaceutical regulatory and guideline information already available. We will also expand the country's biopharmaceutical formulations and information providing information through the homepage of bio-IT platform. MFDS will provide 'Smart Information Guidance System' to users at a glance so that users can use complicated regulatory information effectively.

MFDS is continuously trying to promote the commercialization of biopharmaceuticals through mutual discussions by continuing to operate public and private consultation for product consultation and review from the product development stage. MFDS is also working on the development of advanced biotechnology products such as stem cell therapy and gene therapy. It will provide early introduction of detailed guidelines to help commercialize the product, thereby helping to accelerate the commercialization period. Among the regulations on the current stem cell treatment drug, it is necessary to promptly identify the necessary or unnecessary regulations for promoting commercialization.

In order to systematically and efficiently manage advanced biopharmaceuticals that reflect the latest technological trends, MFDS is actively responding to the era of high-tech biotechnology to provide support grounds for research and development of advanced biopharmaceuticals, cell therapy drugs, and gene therapy drugs.

It is anticipated that various types of fusion products such as tissue engineering preparations processed from biomaterials, fusion complex preparations formed by binding cells, supports, growth factors, and 3D printing products using cells are expected to appear. To prevent delays in the evaluation stage after the development of new products, MFDS plans to provide classification criteria and procedures for biocomposite products to support the development of fusion products and boundary zone products.

By establishing and distributing cell lines for the production of vaccines and expanding vaccine self-supporting items such as operating a support team for global vaccine production products, the company will be able to supply vaccines capable of (32%), 11 (39%) in 2015 and 20 (71%) in 2020 to expand vaccine self-sufficiency.

In the event of emergencies such as bioterrorism and pandemic infectious diseases, MFDS will establish standards and procedures for the rapid supply of vaccines and blood products, and establish a National Stable Supply and Supply Council to establish a comprehensive plan for stable supply of national drugs.

In order to promote vaccine development by establishing a cell line that is essential for vaccine production at the pet food clinic, it is continuing to organize and operate a global vaccine product support team (consultative body) to provide vaccine production technology support and regulatory information. WHO pre-qualification assessment for advancement of domestic production vaccine into global market We will continue to operate consultation through 1:1 customized consultation with registered applicants such as technical and administrative counseling services and GMP technology support for WHO site due diligence to be.

In order to clarify the definition of a gene therapy agent that reflects the characteristics of a gene therapy agent being developed, such as gene correction technology, and to promptly review the approval status of an article, MFDS will introduce examination system. In case of information provided to experts, information such as clinical tests, pharmacology, etc. should be provided in order to provide necessary information for diagnosis prescription or preparation. In order to provide consent for cell donation during cell collection used for the production of gene therapeutic agent and cell therapeutic agent, MFDS will amend the permission and examination rule.

In order to supply safe and high quality biopharmaceuticals, MFDS has set up necessary

systems from R&D to commercialization to global market and established organic cooperation relationship through sharing information between government, industry, academia and research institutes. MFDS will establish and implement a customized support plan so that the domestic biopharmaceuticals will grow into global biopharmaceuticals in the world and secure international competitiveness so that the Korean biopharmaceutical industry will be a leader in the fourth industrial revolution.

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5. Establishment of Advanced Approval & Evaluation System for Biopharmaceuticals

A. Strengthening Global Competitiveness of Korean Biopharmaceuticals through International Cooperation

1) Background

The global Biopharmaceuticals market has been growing exponentially annually. This can be attributed to the rapid growth of markets for gene and stem cell therapies, and biosimilar products. As part of its efforts to becoming one of the world's top 7 biopharmaceutical powerhouses, the Korean government drafted a "Global Biopharmaceuticals Support Plan" in August 2013 and has been providing administrative and technical support and related infrastructure, strengthened international cooperation, and established and implemented measures to support businesses that are trying to advance to a global market.

2) Achievements

A) Maximized International Cooperation through Information Sharing with International Organizations and Major Regulatory Authorities

(1) World Health Organization (WHO)

In January 2011, the MFDS participated in a joint study as one of the World Health Organizations' Collaborating Centres for Standardization and Evaluation Biologicals. In 2015,

it took part in the international joint research efforts with an aim to establish international quality standards for the coagulation factor VIII. And in 2007, the MFDS was designated as an education center for WHO Global Learning Opportunity (GLO) and accordingly, it has been providing education sessions on manufacturing and quality management standards for vaccines. Furthermore, in 2011, it signed a Memorandum Of Understanding (MOU) with WHO Regional Office for the Western Pacific (WHO WPRO) for mutual communication, and since 2015, it has been carrying out Official Development Assistance (ODA) projects . In April 2015, a donor agreement was signed with WHO WPRO to conduct joint aid projects. In December 2016, the MFDS signed a cooperation arrangement with WHO for Pre-qualification (PQ) of vaccines manufactured in Korea, laying a foundation for Korean vaccine manufacturers to enter the global market.

(2) International Pharmaceutical Regulators Forum (IPRF)

The MFDS was elected as a chair country of 'Biosimilar Regulation Harmonization Working Group' at the International Pharmaceutical Regulators Forum (IPRF), which was held in conjunction with the ICH (International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use) Assembly simultaneously in Osaka, Japan, in November 2013. Since then, the MFDS took part in a variety of activities including the establishment of review & approval criteria, identification of regulation status and differences by region and country. This prevented overlapping of biosimilar-related activities among the international organizations such as WHO, and helped with further international harmonization on drug monitoring, etc. Recognizing the importance of scientific evaluation of safety and efficacy of cutting-edge pharmaceuticals and the demand for regulatory harmonization, Korea also participated in IPRF as a member country of cell therapy (Mar. 2011) and gene therapy (Oct. 2012) working groups.

(3) Asia-Pacific Economic Cooperation (APEC)

At the APEC Senior Officials' Meeting (SOM) held in September 2011, the MFDS was elected as a champion country for Biotherapeutic Products Roadmap and hosted workshops organized by APEC Harmonization Center (AHC). In February 2016, the MFDS was approved by the APEC AHC for running the Center of Excellence (CoE) as a pilot project and it provided pilot programs for representatives from regulatory authorities in the APEC region.

(4) Improved International Cooperation among Advanced Regulatory Authorities

In October 2013, MFDS established a cooperative relations with Paul-Ehrlich-Institut (PEI)

in Germany and built collaborative relations with the U.S. Food and Drug Administration (FDA) by signing Confidentiality Commitments. In addition, it established cooperative relations with many regulatory authorities: it signed acooperation agreement with the Japanese Ministry of Health, Labour and Welfare, a regulatory cooperation agreement for Biopharmaceuticals field with the Health Canada, and an MOU for cooperation with the Vietnamese Ministry of Health, respectively in 2015.

B) Establishment of an Experts' Network and Building of Expertise

In January 2015, MFDS launched the "2nd MFDS Special Advisory Board for the Advanced Biopharmaceuticals with 18 eminent scholars and experts around the world. The MFDS Special Advisory Board offers advice on biopharmaceutical policies and regulations, strategies to address major issues, and the latest science and technology trends. It continued its efforts to hold international forua and workshops in an effort to build further knowledge and foster capabilities in the field of advanced biopharmaceuticals. For example," Global Bio Conference」, which is held at the end of every June since 2015, has become a gathering where approximately 2,000 experts from government organizations, industries, academia are gathered together.

3) Implementation Plans

To become a global top seven country in the biopharmaceuticals field by 2020, MFDS is planning to continue its effort to help increase exports of biopharmarceuticals and engage in various international cooperation activities by establishing bilateral and multilateral cooperative relations.

A) Becoming the Hub of Multilateral Cooperation

(1) World Health Organization (WHO)

The MFDS, which was designated as WHO Collaborating Centre in January 2011, was redesignated by WHO after evaluating its work performances for the last 4 years. Accordingly, the MFDS will run the WHO Collaborating Center until January 2019 and the scope of work was extended, too. The Official Development Assistance (ODA) project called 'Technical Support for Biopharmaceutical Evaluation and Approval System of Developing Countries in the West Pacific Region' was carrious out continuously carried out. Furthermore, MFDS has been conducting a joint research with WHO to develop standard formats and guidelines.

(2) International Pharmaceutical Regulators Forum (IPRF)

As a chair country of Biosimilar Working Group, Korea organizes 3 video conferences and 1 face-to-face meeting a year. It will continuously communicate with cell therapy and gene therapy working groups.

(3) Asia-Pacific Economic Cooperation (APEC)

For biopharmaceutical regulatory harmonization in the APEC region, MFDS designated and operated CoEs (Center of Excellence) for biopharmaceuticals based on the results of analysess of regulatory differences found during the workshops.

B) Expanding Bilateral Cooperation

In 2017, MFDS will discuss on-site training and cooperation plans with Paul Ehlich Institute (PEI) in Germany to help build expertise by pharmaceutical evaluators further. It will also sign a working agreement with Health Canada. MFDS will continue to work together international organizations such as WHO, National Institute for Biological Standards and Control (NIBSC), and US Pharmacopoeia (USP).

C) Strengthening Professional Expertise through Regulatory Harmonization

To support and help domestic biopharmaceutical companies to make their ways to the global market, MFDS will hold an annual Global Bio Conference' from June 26 to 30, 2017, with experts invited from home and abroad. At this conference, participants will be able to take part in different international biopharmaceutical fora and it will provide them with opportunities to cooperate with each other further to share their knowledge and experiences in a way that willhelp Korea to become a global biopharmaceutical powerhouse. The latest international trends and prospects in the biopharmaceutical field and recent regulatory issues will also be discussed by the experts attending the conference.

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B. Improving the Approval·Evaluation System and Leading the International Standards for Biopharmaceuticals and Herbal Medicine·Cosmetics, Etc.

1) Establishing a Future-Oriented Approval·Evaluation System and Securing Global Competitiveness

As Biopharmaceutical industry has become a core field which countries around the world are now focusing on to nurture as a new growth engine, Korea also has come up with more government-funded projects in this field. Therefore, it is required to establish the evaluation criteria for promptly assessing this new and latest biopharmaceutical products in a safe way.

In order to effectively improve the criteria and procedure for approval evaluation of biopharmaceuticals, MFDS has made every efforts by: 1) newly defining the subjects for special approval through a fast track evaluation, etc, 2) modifying documents to be submitted for approval evaluation, 3) including the medical products with submitted documents in the scope of evaluation results to be disclosed, 4) preparing the procedure to 'formalize meetings for those approved for new drugs and new product items', and 5) trying to secure transparency, consistency, and predictability of approval evaluation through the development of Good Review Practice and guidelines. Also, it enhanced the professionalism and capabilities of evaluators through evaluator education programs by field, and invited biopharmaceutical experts from major regulatory authorities of foreign countries and academic field to share information on the latest trends in biopharmaceutical product development, safety management and regulatory trends of each country, and the criteria and direction of biopharmaceutical evaluation.

In order to operate biopharmaceutical approval·evaluation system in a predictable manner, MFDS will continue its effort to identify and monitor difficulties of the industry, to prepare standardized specifications for Korean pharmacopoeia and establish·revise the evaluation guidelines for each product, coming up with reasonable evaluation criteria for new and cutting-edge biopharmaceutical products.

2) Expanding Customized Support for Commercialization of Biopharmaceuticals

By providing consultation and education services according to the phase and level of the development of advanced biopharmaceuticals as pump-priming measures, MFDS supports the commercialization of biopharmaceutical products manufactured by Korean companies.

The number of participating companies, items and the relevant fields has increased for these biopharmaceuticals pump-priming projects each year. In 2016, four customized councils were

organized and operated in cell·gene therapy products, antibody biopharmaceutical products, global vaccines, and blood products. With customized councils for products ready to be commercialize including 5 cell·gene therapy products, 8 products from antibody new biopharmaceutical product manufacturers, 27 global vaccines, and 5 items from domestic blood product manufacturing companies, MFDS has supported commercialization of these products by removing institutional obstacles and helping the implementation of relevant regulations·rules. As a result of these efforts, a gene therapy product and 1 new blood product were applied for getting approved as a pharmaceutical drug and 3 vaccine items were approved.

In addition, MFDS has provided workshops for supporting the development of antibody new biopharmaceutical products and operated professional education sessions on approval of advanced biopharmaceuticals and non-clinical distribution tests in order to give opportunities for researchers and developers with little experiences developing products to do their researches while developing theories

Moreover, MFDS also provides customized consulting services for each stage from development to approval of vaccines, recognizing that the vaccine self-sufficiency is directly associated with the public health. As of 2016, 13 vaccines can be produced in Korea. MFDS plans to increase the number of vaccines that can be produced in Korea to 20, enhancing Korea's vaccine self-sufficiency.

3) Strengthening International Cooperation in the Biopharmaceutical Filed

Considering the development speed of advanced technologies, prompt response is required for the evaluation system of biopharmaceutical products, and more communication with major regulatory authorities around the world is also needed to identify·lead the international regulatory trends of new and advanced pharmaceutical products.

With the improved reputation and reliability, MFDS was selected as a chair country for IPRF Biosimilar Working Group in November 2013.

After singing a Joint Declaration (JD) with Paul Ehrlich Institute (PEI) in 2013, MFDS carried out training programs for those evaluating vaccines and genetic recombination products to strengthen the cooperative relationship. In 2015 when MFDS signed a Regulatory Collaboration (RC) with the Biologis and Genetic Therapies Directorate (BGTD) of Health Canada (HC), it shared matters regarding the information disclosure during the biosimilar approval·evaluation process in an effort to exchange information between regulatory institutions, and provided a training program for evaluators in the biopharmaceutical field at the international regulatory forum on food and drug safety organized by Health Canada.

By providing globalized biosimilar evaluation criteria and enhancing the predictability of the approval·evaluation system, MFDS will continue to actively support the development of safe and effective biosimilars and lead the international regulatory harmonization in the biosimilars field through strengthened cooperation with international organizations and regulatory authorities around the world.

4) Supporting the Development of Herbal (Crude) Medicinal Products

In Korea, the medicines made of natural substances are approved and evaluated pursuant to the 「Regulation on Approval and Notification of Herbal (crude) Medicinal Preparations, Etc.」based on the approval·evaluation of synthetic pharmaceuticals, and recently the notification has been revised to enhance the quality management.

Accordingly, MFDS issued a manual for the 「Regulation on Approval and Notification of Herbal (crude) Medicinal Preparations, Etc.」, Q&A sheets on the approval and notification of herbal (crude) medicinal products , a handbook on how to register herbal (crude) medicines as drug substances, and Guidelines for Setting Chemical Profile of Herbal Medicine to help understanding of the revised notification. In 2017, Guidelines for non-clinical trials of herbal (crude) preparations, Guidelines for quality evaluation of herbal (crude) medicines for clinical trials, and Guidelines for preparing Common Technology Document of herbal (crude) medicinal products (Quality part) to support the development of herbal (crude) medicines.

5) Efficiently Improving the Evaluation System for Quasi-Drugs and Cosmetics

A) Enhancing the Safe and Reliable Evaluation System for Quasi-Drugs

Recognizing the need for an reasonable and systematic evaluation system with the expanding scope and increasing number of quasi-drugs, MFDS has been developing guidelines and amendments of the relevant regulations. In order to support the industry's product development, MFDS prepared guidelines for efficacy evaluation system by item, improved the quasi-drug testing methods for quality management of quasi-drugs, and established manuals on evaluation by item to enhance the consistency and objectivity. Also, MFDS will continue to strengthen the quasi-drug review system and develop efficacy evaluation and standard specification guidelines and revise the standard and test methods for quasi-drugs to help the industry's product development. Moreover, to improve the consistency and efficiency of the approval and review system, MFDS will develop evluation manuals for rodenticides and continue to communicate with the industry by holding public seminars on the approval

and review system.

B) Strengthening Competitiveness of Cosmetics through Improvement of Relevant Regulations

In order to secure safety of colors used in cosmetics and help the development of high-quality, functional cosmetic products, and enhance the consistency and efficiency of evaluation, the amendments of cosmetic-related regulations were prepared and the handbook on the evaluation of functional cosmetic products was also revised. Also, to protect customers from false·exaggerated cosmetics advertisements and suggest the right direction for product development, MFDS also came up with the objective standards for reviewing substantiation. It established the regulation on Animal Alternative Test according to the regulation on banning animal testing in manufacturing cosmetics to support the production development and respond to the changes around the world. According to the Cosmetics Act (May 29, 2016) and the Enforcement Rule of the Cosmetics Act (Jan. 12, 2017) amended regarding the increased scope of functional cosmetics, it added new items to the standard and testing method for functional cosmetics in order to maintain the consistency and efficiency of the evaluation on the newly added cosmetics and to actively support the development of safe and quality functional cosmetics. It also improve the evaluation system by continuously revising the regulations on the evaluation of functional cosmetics responding to the changing environment. MFDS will work on improving cosmetics laws and regulations for safe management of cosmetics, support new products development by holding public seminars to raise 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. Strengthening Life-Cycle Support System and Safety Management of Medical Devices

A. Background

With increased use of cutting-edge medical devices due to the development of Information Technology(IT), ageing and increased life expectancy, the volume of the global medical devices market is expected to grow 5.4% annually, and the volume of the domestic medical devices market also records 5.1% annual growth, driving the industry to be promising for the next generation. Along with this trend, the paradigm of global medical practice has been shifted to 'customized medicine', tailored to the needs of each patient to prevent and treat diseases by comprehensively considering the causes such as the patient's genetic information, living environment, life style, etc. To realize the new paradigm, it is required to have the 'genomic analysis techniques' such as Next Generation Sequencing(NGS) which provides genome information, the base technology, and to rapidly apply the techniques to the medical sector, other countries like the US has already pushed forward with an active nurturing policy. Accordingly, it is time for Korea to establish a new system to quickly introduce the NGS technique to the domestic field.

Meanwhile, the needs for managing the reuse of medical devices at medical institutions due to the recent controversial issue of reusing disposable medical devices demands an internationally standardized medical device code and integrated information system for the follow-up management to establish a safety management system based on the life-cycle of medical devices, which covers from approval to manufacturing, distribution, and use of the devices.

B. Achievements

In an attempt to speed up the commercialization of the cutting-edge convergence medical devices, MFDS has operated the '100 Next Generation Medical Devices Project' supporting

20 products from development to export which were selected through recommendation and open recruitment by the Ministry of Science, ICT and Future Planning, Ministry of Trade, Industry and Energy, Ministry of Health and Welfare, and Small and Medium Enterprise Administration since 2015, and it will support up to 100 products over the five years by 2020 building on the 20 products selected in 2016.

In addition, for the clinical application of NGS techniques, MFDS has introduced NGS Clinical Laboratory Certification System that is concurrently operated with the existing approval system, so once a NGS device passes the evaluation and certification of quality control system, skillfulness, test performance, etc. in the clinical laboratory, it is regarded authorized and then sent to the field for application. Previously, the individual NGS device needed to achieve authorized after passing the test for safety and efficacy in order to be introduced.

To strengthen the follow-up management of medical devices, MFDS is working on establishment and operation of integrated information system of medical devices which can track and manage the whole process from authorization to distribution and use. In order to do so, MFDS revised the Medical Devices Act in December 2016 to provide all manufactured and imported medical devices with internationally standardized codes and to register their integrated information. Now MFDS has formed a 'working-level consultative group for integrated information management of medical devices' with related ministry and organizations such as Ministry of Health and Welfare, Health Insurance Review & Assessment Service, and Medical Device Information & Technology Assistance Center and they are discussing a systematic and efficient management plan.

C. Implementation Plan

In an attempt to advance into new overseas markets in 2017, MFDS plans to expand the provision of life-cycle information of medical devices by adding the promising emerging importers such as Mexico, Canada, Vietnam, etc. to the 'Integrated Information Bank of Medical Devices' and publishing a specialized regulatory trends newsletter which includes best practices of highly useful technology development, patent information, and specialists' comments on domestic and overseas markets, regulations, and technologies and a specialized technological trend newsletter including 3D printing on a quarterly basis. It also plans to continue to expand the scope of support for venture companies that have technological ability to develop promising medical devices of the future but lack experience and information, and add expertise in necessary fields to build an in-depth technical and institutional support system. Since the

introduction and implementation of the NGS Clinical Laboratory Certification System has laid the foundation for universal genomic analysis technology, it will establish a detailed evaluation standard and system that reflects characteristics of each NGS test area in order to improve the reliability and safety of the results of genomic analysis and test and recruit specialists in the future.

In addition, MFDS plans to gradually operate the integrated medical information system from 2018. As a result, a pilot project will be conducted for the medical devices subject to tracking control medical devices and those with the possibility of infection, and in so doing, MFDS will verify and complement completeness, convenience, application of the integrated information system on the basis of registration of medical devices' standardized codes, supply history report, and information linkage verification, etc., and to consider with the international introduction trend and the acceptability of the medical industry in order to gradually apply the integrated information system to medical devices from grade 4 as mandatory. It is expected to provide consumers with safer use and better distribution environment of medical devices by establishing and operating the integrated information system.

Shin Joon-soo, Director of Medical Device Policy Division
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2. Strengthening 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 crucial than ever.

B. Achievements

For the strengthened preventive monitoring practice, MFDS reorganized its monitoring system into a 'target' based one focusing on risk factors and conducted a risk-based monitoring to

concentrate on the selected targets. To this end, MFDS set targets such as quality control vulnerable products, products with high social impacts, and products with serious physical hazards,

In order to strengthen preventive monitoring, MFDS reorganized it into a 'target' monitoring system focusing on the risk factors and conducted a risk-based selection and concentration monitoring. To accomplish this, MFDS set targets such as quality control vulnerable products, products with high social impacts, and products with serious physical hazards, and checked out 150 places and discovered 17 places.

MFDS also conducted inspections on 909 medical devices that receive the most complaints from consumers and medical personnel for quality control and gave suspension of sales, order for recall, and administrative penalties to 78 verified products out of 782 which failed to meet relevant quality standards, contributing to create a safe and effective distribution environment for medical devices in the end.

Furthermore, together with local governments, MFDS reinforced management of medical devices as it conducted inspection of 1,333 medical device sellers twice in the first and second half of 2016, respectively that target the vulnerable groups including elderly with false and exaggerated advertising in the form of free trial room, resulting in the exposure of 111 illegal sites.

C. Implementation Plan

In 2017, MFDS will continue to operate a 'Target' monitoring system by selecting hazardous factors and products that are at the center of social issues, and will carry out quality verification inspection on defective products that are reported through medical device monitoring center, commonly consumed products due to population aging, and products that consumers complaint about its quality and that are socially controversial to contribute to improving using environment so that consumers may trust more about the distributed medical devices. Also, MFDS will survey and disclose the prices of medical devices handled in free trial rooms to prevent the elderly from being damaged by purchasing expensive medical devices.

Ju Seon-tae, Director of Medical Device Management Division
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3. Establishment of a Safety Evaluation System for Medical Devices

A. Background

Domestic medical device market is steadily growing with the rising social demand for heath care including increased treatment demand for chronic diseases due to population ageing and needs for disease prevention arising from improved income level. Accordingly, it results in placing greater importance on medical device safety management on the market and quality management system which contain collecting and managing medical device adverse events and medical device re-evaluation.

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 licensed(approved) or registered medical devices that need re-assessment on their safety and efficacy. MFDS re-evaluated safety information on compliance with the common standard for medical devices from 2009 to 2012 and implemented re-evaluation on 10,263 commonly consumed high-risk medical devices from 2013 to 2016, and it gave orders for clarification of precautions for use and methods of use and changed the approval status on 2,996 products from among these. MFDS also carries out re-evaluation seminars, publishes work manuals and provides 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」 on May 30, 2004. On-site inspections have been conducted on foreign manufacturers since April 8, 2012. And 'Mandatory System Designating Medical Device Quality Manager' has been introduced since the year 2014. And, by 2016, a total of 3,119 business entities including 2,001 manufacturers and 1,118 importers acquired GMP certification.

C. Implementation Plan

The number of adverse incident reports in Korea is very low compared to that in the US and Japan. 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 so at to continue to carry out follow-up management on the medical devices being distributed.

MFDS will also reassess not only high-risk medical devices but also devices that have caused a lot of adverse incidents and are the subject of the social issue in order to verify the safety and efficacy of marketed medical devices.

Moreover, MFDS will continue to develop and improve training programs and guidelines 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. Supporting Rapid Commercialization of High-tech Convergence Medical Devices

1) Training Professional Personnel for Supporting Medical Devices the Commercialization

Medical equipment is a convergence of multiple technologies and systems, and it needs to go through procedures from product development to licensing for commercialization, requiring and specialized manpower at each stage. In this regard, MFDS has entrusted the development and operation of training programs to specialized training institutions to nurture professional workers to support the commercialization of medical devices since 2015. In 2016, the research developers and licensors were divided into two groups for the training programs.

The research developer program consists of 17 user-tailored training courses, covering medical device's lifecycle from development to use, and total 322 researchers and clinical trial designers completed 36 sessions of the 17 training courses. The licensor training program trained reviewers who directly review the medical devices on the domestic and overseas medical device regulatory trends and guidelines. In particular, 25 sessions of 8 training courses on clinical field application, clinical practice training, and test inspection practice nurtured total 291 professional reviewers. MFDS will continue differentiated training courses such as the advanced course for researchers and developers and capacity building course for license reviewers in 2017.

2) Rapid commercialization of newly developed medical devices through strengthened cooperation across government departments

Although government departments are supporting R&D to nurture the medical device industry, the case of commercialization is less than 5%. This led to the commencement of the commercialization project of the new convergence medical device. Particularly, in 2016, MFDS published in advance the guidelines for evaluating safety and performance and for evaluating trial plans of 7 products with imminent commercialization including image-guided robotic system, artificial cornea, wound care device using plasma, cardiovascular and biodegradable drug-eluting polymer stent, portable blood coagulation time measurement system, portable hemorrhage diagnostic device, compound test equipment for bleeding time and antiplatelet agent resistance. In the near future, MFDS will further strengthen the role of approval agents with cooperation among multiple organizations to extend the scope of commercialization to the in-vitro diagnosis field, and also will strengthen the capacity training for key talents for nurturing regulatory personnel and develop training materials for clinical field training and consistent education.

3) Screening of Licenses for the Development of High-Tech Convergence Medical Devices

MFDS introduced a 'phase-based review system' in which high-tech medical device manufacturers are not required to have all existing approval screening data, but are allowed to conduct preliminary screening as soon as the screening materials are prepared and to approve the device immediately after product development is completed in order to support the preparation process of the license data from the stage of product development of the medical

device and conduct review at the same time to reduce trial and error and resolve uncertainty. As the phase-based approval systems has been introduced to speed up the commercialization of high-tech medical devices, MFDS revised part of the 「Regulations for Approval, Notification, and Review of Medical Devices」 and made the 'Guideline on phase-based approval and review of high-tech medical devices' in order to raise understanding of the revised regulations and help manufacturers conveniently prepare for approval and review documents. Then, MFDS distribute the guideline to technical document review institutions, test inspection institutions, and related industries and held a briefing session for the public(October 2016). MFDS will promote the operation of phase-based approval and review of high-tech medical devices and strengthen the international competitiveness of medical device manufacturers as they enter the market in the high-tech medical devices in the early stage.

4) Supporting Rapid Commercialization of In Vitro Diagnostic(IVD) Medical Devices by Designating Exemption Target for Clinical Trial Plan

The Department of In Vitro Diagnostic Devices, the Ministry of Health and Welfare operates a public-private communication meeting to find out the difficulties of the in-vitro diagnostic industry (manufacturing and importing companies) and continuously reflects them on institutional improvement. Accordingly, an effective plan to approve the exemption of clinical plan approval for in-vitro diagnostic medical devices has been prepared and its contents have been reflected in the 「Regulations for Approval, Notification, and Review of Medical Devices(August 31, 2016). In accordance with provision C, Article 33 (2) of the said Regulation, planning approval has been exempted from performing clinical performance tests, except (1) the test of 4th grade medical device for IVD diagnosis, (2) the test with high risk of the method for collecting the sample from the human body, (3) the test that cannot verify the result of clinical performance test with the existing medical diagnostic method or an IVD medical device, and (4) the test to diagnose accompanying with medicines, etc. Also, in order to expedite formal product licensing and focus on safety management of high-risk products, the second-grade review and certification work was entrusted to private institutions(Effective date: January 1, 2017). In order to strengthen the expertise of the private review institutions, MFDS developed technical document review guidelines for all the second-grade items (21), strengthened the training of reviewers, and provided continuous communication channels to maintain consistency of examination level between MFDS and review institution on a daily, weekly, and monthly basis.

B. 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)

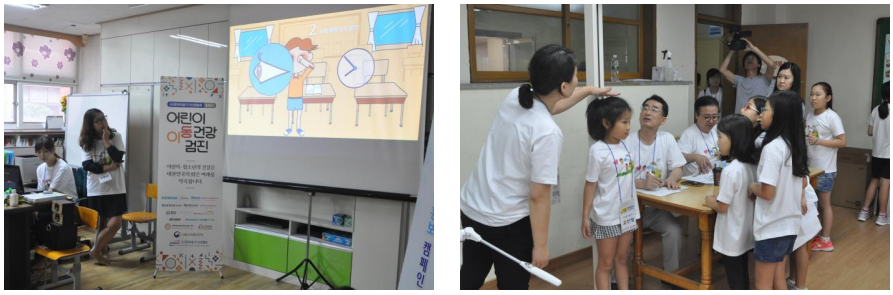
Since 2015, MFDS has been appointed as chairman of the Asian Harmonization Working Party (AHWP), leading the way in harmonizing the international regulation of medical devices. In 2016, as chairman of the AHWP, MFDS held four times of Secretariat operation meeting and Technical Committee Leaders Meeting. During the AHWP Annual General Meeting, MFDS hosted the [Korea Regulatory Special Session] to globally promote the excellence of medical device regulation in Korea. In particular, in order to strengthen the activities of the chairman of the AHWP, the Mirror Committee, which is composed of experts from domestic industries and related organizations, has been established to promote the development of international common guidelines. Based on the Korean regulations, the 'Guidance for Minor Change Reporting' was finally adopted as an AHWP International Common Guideline.

In March and September 2016, as the AHWP presidency, MFDS attended a meeting of the International Medical Device Regulator Forum (IMDRF) to present the major tasks of the AHWP, the regulatory plan for cutting-edge medical devices, and the Medical Device Single Audit Program(MDSAP) promotion plan. In addition, to help Korea's medical equipment industry to advance into Latin America, MFDS invited Brazil among the IMDRF members to hold a Korea-Brazil medical device G2B collaboration, made a field visit to a manufacturer in Korea and held an one o' one meeting with the company.

MFDS will continue its international cooperation activities in 2017 for the international harmonization of medical devices and for growing to become a global leader in this industry.

2) Providing Safety Information of Life-friendly Medical Devices

MFDS provides safety information on life-threatening medical devices to enhance understanding of safe and correct use of medical devices. MFDS produced educational videos and leaflets on how to use the "contact lens" which is highly used by the youths, and used it as the educational material for correct use in connection with the medical service of Korea Medical Device Industry Association.



[Image 3-3-1] On-site Promotion of the Safe Use of Life-Friendly Medical Devices - Mobile examination

In addition, videos and leaflets were posted on EDU-NET for middle and high school students and ICE CREAM which is teachers' training programs for elementary school education offices so that they could be easily used as educational materials for elementary, middle, and high school teachers and students.

In addition to the publicity leaflet, it was promoted through live telephone interviews to the public in order to inform the public about the precautions for purchase of medical devices via broadcasting programs.

The medical device industry is a major industrial field for the realization of creative economy. It needs preliminary preparation through finding out future issues and listening to the voice of the field, discussing trends in the latest medical device technology development and civilian difficulties, It is necessary to strengthen the public-private communication to cope with the situation. It is necessary to establish a foundation for enhancing the institutionalization and competitiveness of manufacturers for the advancement of Korea as a medical device powerhouse, cooperation with international organizations to become a medical device reading country, and strengthening networks with foreign regulatory authorities. In the first half of 2016, the '2nd International Medical Device Communication Forum (MDCF)' was held in order to establish a global network with international regulatory bodies related to medical devices, and the '4th International Medical Device Communication Forum(MDCF)' was held in order to explore the direction of international harmonization and development of the domestic medical device system and to share high technology development trend expected to be applied to medical devices in the second half of the year(November, 2016). The 3rd International Medical Device Communication Forum and the 5th Medical Device Communication Forum will be held in 2017, and the results of the satisfaction analysis will be actively reflected to prepare a more practical communication space.

3) Establishment of Preliminary Approval Screening Basis for Future Medical Environment

A) Preemptive Safety Standards for Medical Devices with Artificial Intelligence Technology

Research and development of medical devices that have been applied artificial intelligence technology in the field of medical devices is being actively carried out. Therefore, by introducing the preemptive safety standards of medical devices to which artificial intelligence technology is applied to industry, it is needed to have transparency of civil appeal. In this regard, MFDS proposes a preliminary approval screening method for new type and shapes products that integrate artificial intelligence technology and have prepared the guidelines for rapid productization. Through the consultation with industry, academia, and medical institutions Guidelines (drafted) were developed. The main contents are description of medical device classification standard and item classification related to license screening, clinical validity verification method, learning data management, change permission/authentication method, and permission screening (performance) application form. In the future, MFDS will develop a clinical validity evaluation guideline for clinical decision support system based on artificial intelligence. The guideline will include examples of retrospective clinical studies and precautions for clinical studies.

B) 3D printing medical device management plan and patient-customized medical device management plan

In order to perform fast and professional license screening for patient-customized medical devices manufactured with 3D printing medical devices, MFDS has identified major issues related to 3D printing medical devices and is pursuing business by each issue.

In order to provide the necessary technical documentation and the types of attachments required to apply for approval for medical devices manufactured in a patient-customized manner using 3D printers in 2015, MFDS recommends customized medical device licensing examination guides manufactured using 3D printers Line. In 2016, MFDS have developed guidelines for licensing examination of 3D printing medical devices that reflect the characteristics of each item. As a target item, a metal-made orthopedic implant that has already been commercialized and manufactured is imminent, and a licensing examination guide for patient-customized orthodontic implants manufactured by a 3D printer is set as a dental implant fixture similar to a raw implant and a raw material and manufacturing method. In October,

guidelines for licensing examination of patient-customized dental implant fixtures made with line and 3D printers were published, respectively. In addition, two safety and performance evaluation guidelines for artificial skin and artificial vascular biodegradable scaffolds made of water absorbent polymer materials, which are actively developed, have been published in December, respectively.

In 2017, MFDS will continue to develop a guideline for each product that reflects the characteristics of each product, and conduct a comprehensive education for medical device license screening, 3D printing medical device manufacturing such as materials and software.

C) Providing safety standards for IVD medical devices based on (NGS) technology

The development of Next Generation Sequencing (NGS) technology has made it easier to analyze patients' sequences, but there are also a number of problems in terms of technical aspects, data management and results from analysis. Therefore, the guidelines for performance evaluation of in vitro diagnostic medical devices using the next generation sequencing method for personalized medical care have been published, and users (clinical or diagnostic testing center) and to clarify the limitations. The guideline was prepared by collecting opinions of the consultation body composed of 18 experts from industry, academia, and government. In order to establish a preliminary approval screening basis against the future medical environment, guidelines for performance evaluation of in vitro diagnostic products using multiple gene amplification method (2017 June), performance evaluation guidelines for in-vitro diagnostic products for self-examination September 2017), guidelines for approval and screening of in vitro diagnostic products for congenital malformations (October 2017), and approval and screening guidelines for norovirus products (November 2017). MFDS will continue to support the in-vitro diagnostic medical device industry by enhancing the transparency and reliability of license screening work and supporting rapid commercialization through the development of guidelines for permitting screening of products with advanced new technologies and highly licensed products.

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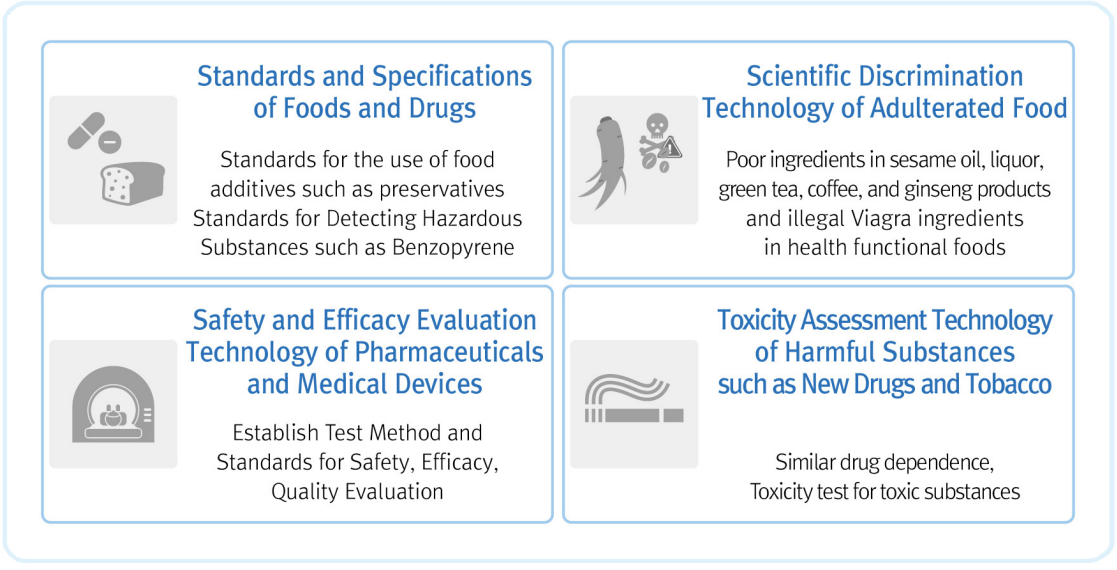
IV

Risk Prevention

Section 1 Establishment of a Basis for Consumer-Focused Preemptive Risk Prevention and Crisis Response System

1. Establish Roadmap for R&D on Safety Technologies for Food and Pharmaceuticals



[Image 4-1-1] Research and Development (R & D) business in the Field of Food and Pharmaceuticals

The 「Support of the Safety of Food, Drugs, etc.」 was passed by the National Assembly on August 18, 2015 with a total of 18 articles, including the mandatory establishment of a basic plan for the promotion of safety technology, the basis for granting research fund contributions, (Law No. 13333, May 18, 2015) was enacted on November 19.

The same Act Enforcement Ordinance (Presidential Decree No. 26657, November 18, 2015) and the same Act (Prime Ministerial Decree No. 1206, Enacted on November 19, 2015) were enacted and enforced in order. MFDS enacted and enforced its own regulation on food safety and safety management technology for pharmaceuticals (MFDS Directive No. 84, Jan. 18, 2016) and it became a big turning point for completing the legal and institutional framework for research and development of MFDS.

[Table 4-1-1] Main Contents of the Safety Technology Promotion Act

Classification	Composition of Provisions
General Regulations	The purpose (Article 1), the definition (Article 2), the responsibility of the state (Article 3), the relation with other laws (Article 4)
Preparation of Safety Technology Promotion Plan	Basic Plan (Article 5), Safety Technology Consultation (Article 6)
Promotion of Research and Development Project according to Promotion Plan	Promotion of research and development project (Article 7), contribution payment (Article 8)
Establishment of Safety Technology Promotion System	Promoting the transfer of R & D project performance (Article 9), Collection of Royalties (Article 10), Creation of safety technology classification system (Article 11), Field demand survey (Article 12), Diagnosis of technology development capability (Article 13), Evaluation of technology impact and technology level (Article 14)
Cooperation business	International joint research (Article 15), cooperation between the two Koreas (Article 16)
Provisional provisions	Authority delegation and entrustment (Article 17), civil penal agenda (Article 18), supplementary rule

In addition, as the Act was enacted and enforced, MFDS's 「the first Basic Plan for the Promotion of Safety Technologies for Food, Drugs, etc. ('16~'20)」 was established and implemented from April 2016.

In order to secure legal safety, MFDS, based on the insufficient deliberations of the 'Food and Drug Safety Technical Committee'in "Act on the Promotion of Technology for Ensuring the Safety of Food, Drugs, Etc.", plans to improve the safety technology R & D management regulations for food and medicine, and plan to efficiently promote research and development of food safety technology.

2. Establishing a Basis for Preventing Safety Accident

The MFDS has prepared and operates a crisis countermeasure manual that specifies the measures to be taken in the field of food and pharmaceuticals. The current Crisis Response Manual was enacted in response to specific measures such as food ('09), medicines ('09), medical devices ('11), and cosmetics ('12) and the Nuclear Safety Sector Crisis Management Practice Manual ('15) was made after the Fukushima nuclear accident in Japan that happened in March 2011.

In particular, in order to ensure consistency in responding to incidents surrounding food, cosmetics, and medical devices, the manual for five crisis response manuals was prepared in 2016, and the manual for food, medicine, medical devices was categorized into four stages of

attention(Blue), Caution (Yellow), Alert (Orange), and Serious (Red). Actions to be taken in each emergent situation were described and it provided minimalized unnecessary form and procedures so that can be practically used.

In addition, the 'Food Industry Crisis Management Guideline' ('13) was prepared and distributed to related organizations and industries in order to promptly respond to field accidents. Also, practical educations on crisis management manuals and countermeasures, practical training and simulated simulations of crises were set up for employees of MFDS, and civil servants and cyber education courses were provided for civil servants who are unable to participate in on-the-job training can participate in education at any time. Through such effort, MFDS is constantly striving to strengthen our crisis response capabilities.

[Image 4-1-2] 2016 Response Disaster, Safe Korea Training

[Image 4-1-3] The 3rd International Symposium on Food and Drug Safety Emergency Response

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3. Advanced Prevention by Preliminary Investigation of Hazards/ Risk Factors of Food and Pharmaceuticals

In order to secure the safety of domestic produce or imported food, MFDS collects hazard information through various channels such as domestic and foreign government agencies and international organizations, and public media, and analyzes and evaluates the importance of information, urgency and necessity of countermeasures. When prompt response measures are needed, management measures are taken into consideration to prevent food safety accidents such as a prohibition of imports, sales, and distribution.

For this purpose, MFDS, since 2006, has carried out preliminary surveys by collecting foodstuffs that may contain substances of concern from domestic and overseas and analyzing them in order to prepare safety measures based on food hazard information collected. And, in the case of unconfirmed items/ingredients from the standards and specifications, MFDS conducts risk assessments to check whether the standards are set, or take safety management measures such as inducing reduction of the substances.

Since 2015, MFDS has focused on factors that are not set in the direction of the preliminary survey and has improved and strengthened the implementation system to eradicate blind spot in safety management. In 2016, 918 cases were collected and inspected for seven items of food. In 2016, MFDS examined domoic acid (amnesic shellfish poison) among shellfishes and crustaceans, acrylamide among confectioneries, natural poison among honeys, and substances of concern for hygiene products, and most of them were found to be safe as they are non-detectable or below the level. (1 case of unsuitable cleaning agent among sanitary products was disposed of by administrative disposition, and 7 cases among cookies, exceeding self-recommendation rate of acrylamide company were taken safety measures by induction of reduction).

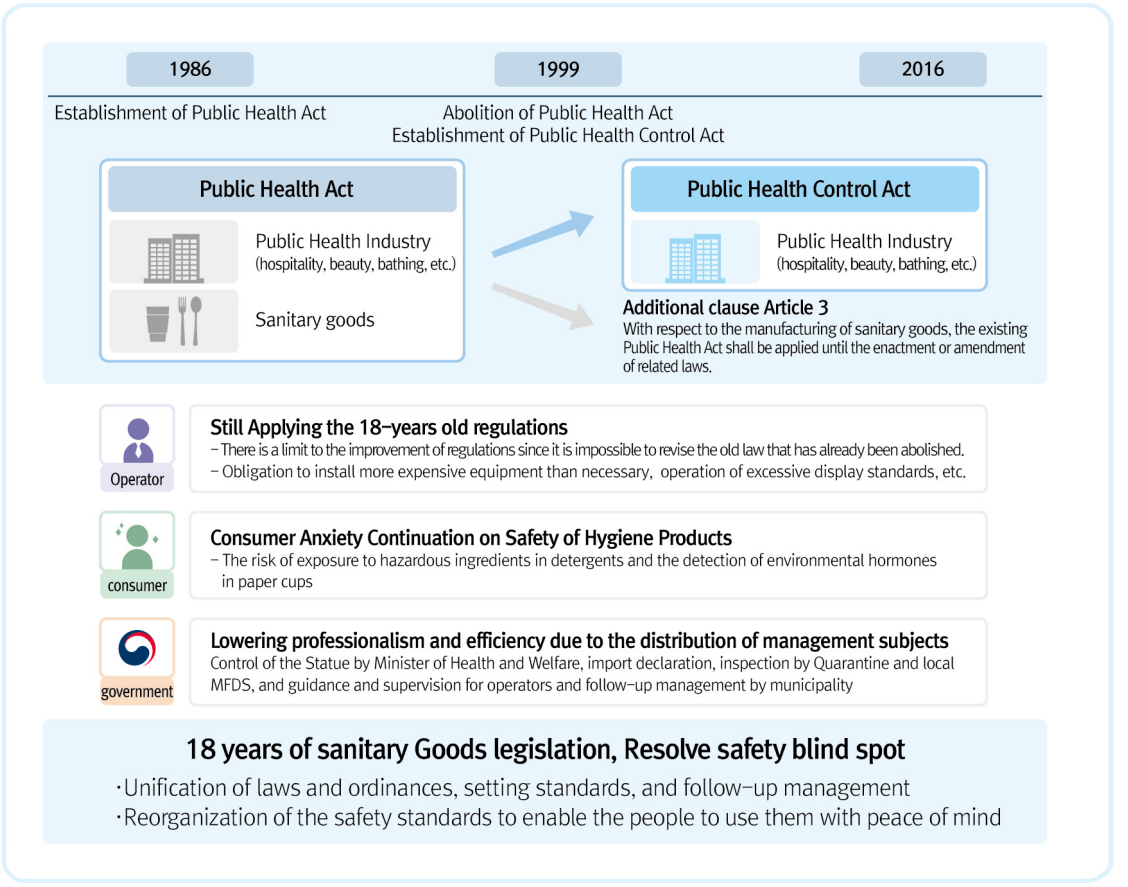
4. Establishment of Safety Management System for Sanitary Goods

As the Public Health Act was abolished in 1999 and the "Public Health Control Act" was enacted, in accordance with Article 3 of the "Public Health Control Act," the sanitary articles, which are closely related to the daily lives of citizens such as detergents, wet tissue for restaurants, was to be applied to 「Public Health Act」 until the enactment or amendment of the law. However, until now, new law related to this has not been enacted or revised, and it is still subject to the (former) Public Health Act. Due to the lack of legislation, unreasonable regulations such as unnecessary facilities obligation continue in the hygienic industrial environment, and there is a management blind zone for newly emerging sanitary products such as paper towels (hand paper).

Therefore, MFDS is enacting separate legislation for hygiene products in order to improve the management system of sanitary products and improve the hygiene level and improve public health. In 2016, the MFDS announced the "Sanitation Goods Management Law" ('16.3.18~4.27)), which stipulates that the "Public Health Act" should be put into practice to provide a legal basis for sanitary goods management, (Oct. 16, 2001, Proposal No. 2003111). In addition, lawmaker Il-Jong Sung also initiated the "sanitary goods management bill" (October 16, 2010, bill number 2002612) under the same law name. The main content of this policy is to strengthen safety management by including personal hygiene products, such as paper towels and diapers, which has been not subject to the jurisdiction or lack of management, in the scope of hygiene products. Currently, two "Sanitation Goods Management Law" is being pending in the parliamentary bill.

In order to minimize the safety management gap and social disruption caused by changes in the prefectural departments before and after the establishment of the 「Sanitation Goods Management Law」, the MFDS has been working with the Ministry of Health and Welfare, the Ministry of Industry and Trade (National Institute of Standards and Technology), and composed the "TF for Cooperation of Sanitation Safety Management Department" in July 2016. MFDS maintains a close cooperation system between the related ministries such as conducting a joint survey on sanitary products distributed on the market. In 2017, the 「Sanitation Goods Management Law」 alternative (two pending sanitary goods management measures) prepared by the Subcommittee on Bills of Law will be merged and reviewed.

[Table 4-1-2] Status and Problems of Sanitary Goods Management



5. Strengthening the Cooperative System on Food and Drug Safety Issue Between MFDS - Korea Consumer Agency

A. Background

As consumers' interest in health-related food·pharmaceuticals·cosmetics·medical devices have been increased rapidly, various organizations including Korea Consumer Agency and consumer groups have made its effort to carry out campaigns on consumer safety and provide damage relief services.

In particular, Korea Consumer Agency actually collects and analyze consumer complaints and consumer risk information, and announces information on the safety of a product to the public after conducting research·study, if needed.

MFDS signed an MOU with Korea Consumer Agency in 2009 and started cooperative relations by sharing consumer injury information and conducting joint research·investigation on the safety of food and drugs. The MOU was renewed in 2015 to have advance consultation meeting prior to any public announcements related to food and drug safety to prevent confusion from inaccurate information. The two organizations also announced plans for joint investigation on agenda which can attract consumers interest, established a communication channel for cooperation between the two and built a constructive cooperative relationship through regular meetings and joint workshops.

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Section 2 Creating Consensus on the Food and Drug Safety through Strengthened On-site Communication

1. Expanding Communications with the Public

In order to communicate with people from all ranks and sectors and help them to participate in policies related to food and drug safety, MFDS established reciprocal communication channels between the public while providing food & drug information on-or offline that can be helpful in daily life.

It also analyzes surveys, consumer counselling cases, and the atmosphere in the press to identify consumer complaints and interest regarding the safety of foods and drugs. Based on the analysis, major agenda are selected and a management committee is established to actively respond and provide feedback on the agenda in various ways by collaborating with the relevant governmental bodies: providing guidance·inspection, conducting surveys to investigate actual condition, improving or correcting the relevant system, providing useful information.

In addition, MFDS holds Consumer Forum every year to communicate with the public, encouraging participation of the consumers, collecting opinions and creating social consensus on the food and drug safety issues. The Consumer Forum was held four times in 2016 as same as the previous year to listen to various opinions of the persons concerned.

Moreover, MFDS not only provides the communication channels regarding the food and drug related policies but also strives to find and share customized information on food & drug safety to help people's daily lives.

With the two-way communication channels to give and receive feedbacks to/from the public, MFDS will continue its effort to establish safety consensus among people on food and drugs. And it will continuously provide seasonal and age-specific practical information on food and drug safety for personalized communication with the public.

2. Building and Facilitating Communication Network

MFDS has operated 'Public-Private Communication Committee for Food and Drug Hazards' (consisting of 9 ministries and 37 members from private sector) to share information and build/have

cooperative communication system in the occurrence of food and drug safety issues.

In 2015, it came up with collaborative measures by sharing experiential programs provided by each Ministry regarding the free semester program, discussed the topics such as 'how to improve the function of the control tower for food safety management' and 'food safety management that can meet the expectations of customers', and had consultation with the relevant organizations to prepare practical food safety management policies, for example, for the foods sold nearby schools, which are very closely connected to people's lives. In 2016, discussions were held on ways to improve the publicity of the sales policy of food products around the school, sharing the operation status of integrated food safety information netword, and collecting opinions.

Also, MFDS established and operated Communication Advisory Committee comprised of consumer groups and experts from various sectors such as communication and promotion. Topics discussed in the committee were 'Preparation of communication messages for the public' (Jun. 12), 'Review on the necessity of maintaining goals for food safety level felt by the people and the unification of investigation institutions' (Sep.1) and etc. for which it receive advices from experts as well as general housewives. In addition, MFDS receive written advices to prepare communication messages for the public on the issues of the facilitation of the HACCP system, aluminum intake, etc.

For effective communication with the public when food and drug safety issues occur, MFDS also provided education sessions to personnels from headquarters related to food & drug safety, 6 regional offices and local governments to strengthen the communication on hazards by developing communication strategy & methods and communication messages and analyzing communication cases, etc. In 2017, the Public-Private Communication Committee for Food and Drug Hazards held working-level conference to effectively responding to safety issues occurred related to food and drugs and with the Communication Advisory Committee, it will continuously endeavor to enhance communication with the people by developing communication messages regarding hazards etc.

3. Operating Experiential Programs for the Public

In order to enhance communication with the public, MFDS operates various programs for the people to involve in and experience policies related to food and drug. For example, it conducted a proactive face-to-face education through 'Food and Drug Safety Education Courses for

Consumers' by visiting those with difficulties in getting informations including elderly people and housewives, etc. to provide information needed to use food and drugs safely. A total of 64 education sessions were provided in Seoul, Gyeong-gi and Chungcheong provinces for 3,133 participants, recording 92 points of satisfaction score.

Through 'Junior Program for Food and Drug Safety', a program to give opportunities to experience the actual tasks of MFDS, 3,072 middle school students visited MFDS, provincial offices and 6 public organizations. Also, MFDS operated 'Food and Drug Young Leader' program to nurture youth communicators (of middle and high school students) who will voluntarily share food and drug safety information with people around them. In 2015, 57 teams (22 middle schooler teams and 35 high schooler teams), or 209 students, were selected for the agenda of 'Know Your Food Additives' and shared food and drug safety information with many people on- of offline for about 3 months. Their promotional activities were evaluated later and 12 teams with excellent performance received award and prizes from the Minister of the Food and Drug Safety. MFDS published a Casebook of Excellent Activities describing the promotional Activities of Young Leaders to share ther results with the Ministry of Education and consumer groups, etc.

In addition, 'Food and Drug Safety Monitor' program was also expanded to spread accurate information on the safety of foods and pharmaceuticals. Currently, 200 monitors are actively participating in the monitoring activities as 7th Food and Drug Safety Monitors (from Sep.1 to Dec.31, 2015), sharing safety information using social networking services. Also, they can participate in workshops and education sessions conducted in each region as a policy monitors. Through Food and Drug Safety Monitors, MFDS has spread and shared around 70,000 safety information on its major policies, etc.

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Section 3 Expansion of Sharing·Disclosure·Use of Food and Drug Safety Information

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

A. Background

With the expanded free trade agreements and increased trade volume with major countries, stricter safety management on foods and drugs are required. For prompt and accurate collection·analysis·evaluation of domestic and foreign food and drug safety information, MFDS has established a systematic prevention system for safety accidents. In food and drug sectors, 189 websites from 32 countries and 142 websites from 16 countries, respectively, are now monitored to collect information on hazards, and Overseas Information Reporters consisting of overseas Koreans and students studying abroad are helping MFDS to gather food and drugs safety information of foreign countries.

B. Achievements

MFDS collected 33,934 pieces of information regarding hazardous food and drug information in 2016 alone and took measures for 310 cases with such as further inspection or delay of distribution and sales, in a way to secure public happiness by providing safe foods. Among 1,402 piece of overseas information gathered by Overseas Information Reporters, 626 pieces of information were used as references for policies for departments in charge of information analysis and business operation. To prevent direct overseas purchase of adulterated foods and medical products through internet in advance, MFDS provided 349 pieces of information on them to online shopping sites including Auction and Gmarket, blocking access to 173 websites.

Meanwhile, MFDS operates 'Food Safety Information Exchange Council' and 'Industry·Academia·Government Joint Support Group For Exported Food' to strengthen export competitive by providing information from food-related businesses, encouraging food safety information sharing between businesses.

C. Implementation Plan

MFDS will continue to carry out its role as a control tower for the safety management of domestic foods·medical products by analyzing information on hazards collected from various sources to provide them to relevant governmental bodies, departments, businesses and online shopping sites where these information are necessary, and providing more customized information by sector.

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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 60 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 2016, regular and/or special inspections were conducted on testing and inspection agencies for foods (58 organizations), livestock products (28), pharmaceuticals (8), cosmetics (13) and medial devices (14). 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) remedial

action for inspection results of previous year, (2) non-compliance with test methods and standards, and (3) appropriate testing and inspection record management using MFDS-developed Laboratory Information Management System(LIMS).

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 2015 and 45 agencies in 2016.

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 26 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 2017. 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 2017, MFDS will be conducting proficiency testing for 213 testing and inspection agencies on 23 items including contaminants and residual materials, 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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2017 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. Advancement 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-longterm master plan for research and development projects, carried out a preliminary planned 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 81.86 billion won in 2017, being managed over 6 areas: 'food safety management(28.08 billion won)', 'pharmaceuticals safety management(24.09 billion won)', 'medical device safety management(8.52 billion won)', 'safety evaluation technology research and development(12.53 billion won)', 'advancement of safety technology(3.44 billion won)', and 'livestock and marine product safety management(5.20 billion won).'

In 2016, MFDS' major achievements include a large-scale survey and on the quantity of intake of hazardous substances such as heavy metal and the hazard evaluation expanded from 1 item of mercury in 2014 to 41 items including perfluorinated compounds in 2015 and to 110 items including heavy metal in 2016 for securing safety level of highly consumed food and a report on integrated risk assessment by materials including heavy metal.

To present safety standards of consumers' life-relevant products such as cosmetics and household chemical products, MFDS conducted a series of risk assessment on 30 items of sunscreen in 2014 and 60 items of disinfectant and 69 items of restricted ingredients, and the number of testing method development such as authenticity testing method to identify fake sesame oil and ginseng(red ginseng) mixed with balloon flower root and high-tech testing method for eradication of food containing hazardous substances like pesticide residue has been increasing year by year: 88 cases in 2014, 121 in 2015, and 131 in 2016.

MFDS laid a scientific foundation for the national smoking cessation policy by analysis, monitoring and disclosing of the smokable's hazardous gas ingredients and prepared 45 and 13 ingredient analysis methods, each for the general cigarette and the electronic cigarette to

prevent the public from the damage of smoking. Also, MFDS has been building its analysis capacity as it joined the WHO Tobacco Laboratory Network(TobLabNet) (March 2016) and international laboratory accreditation scheme. On top of that, MFDS has established a systematic and efficient R&D business operation foundation through the improvement of R&D project management regulations in order to develop the R&D business and prepare the institutional basis for the future, and set up a basic plan for MFDS R&D safety technology for the next five years from 2017 to 2021, establishing mid- to long-term development direction and road map. In order to strengthen the development of safety technology for the people, such as preemptive response and investment enhancement for the future environment, MFDS will invest primarily in the safety field of foods and pharmaceuticals, which are closely related to daily life of the people. And then to solve the problem urgently, MFDS will make the best investment in securing advanced analysis technology for prompt response to red and processed meat, reduction of harmful substances, illegal food safety management, and adulterated food.

In livestock and fisheries sector, MFDS will reinforce investments in the advancement of the chemical and microbiological hazard safety management technology of livestock and marine products' all stages of importation-production-processing-distribution-consumption and will operate and expand the management system which is able to respond immediately and effectively to the occurrence of Avian Influenza(AI).

In the field of medical products, MFDS will strengthen the foundation for preemptive safety evaluation as technology development and support for new promising fields such as new drugs, medical devices and stem cell therapy and biopharmaceutical R&D will be expanded. MFDS will also establish a system for prompt approval and license for the market entry of advanced and hybrid medical products in the new industry category of the 4th industrial revolution such as bio and 3D printing.

In the field of safety evaluation, MFDS will establish a technology based on prediction and evaluation of the safety of toxic, pharmacological, clinical and high-tech analysis technologies, laboratory animals and alternative test methods to analyze and promptly respond to health-threatening substances. In doing so, MFDS will strengthen a preemptive investment in future technology and environmental changes.

Kim Mi-jung, Director of Research Planning & 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 systematically manages the planning, notification, selection and final evaluation of research projects and their performance management through a research management system. MFDS also provides various services such as briefing sessions and brochures so that researchers can carry out researches and administrative work of the projects, fully understanding the laws and regulations for executing and managing MFDS' research funds which are general accounts such as research fund and outsourced R&D fund and contributions according to the Act on the Promotion of Technology for Ensuring the Safety of Food, Drugs, etc.

In 2016, through 10 sessions of selection evaluation process, a total of 285 new research projects have been selected. Among them, 87 MFDS' self-research projects and 191 outsourced research projects, and 7 funded research projects. In 2015, final end-of-year/continued next year on research or not an 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.

For your reference, an agreement was signed as 7 funded R&D projects were selected through the safety technology advancement project with the budget for contribution fund pursuant to the Act on the Promotion of Technology for Ensuring the Safety of Food, Drugs, etc. The first funded R&D projects of MFDS in 2016 were 4 undesignated projects based on private demands and researchers' creativity in addition to 3 designated projects.

MFDS has strengthened the functions of planning and performance management and advanced the connection between research fund and card system in order to improve convenience and accessibility of R&D system which has been established and operated since 2004 to manage the overall R&D activities of MFDS in a systematic and transparent manner.

In addition, MFDS published and distributed the 「Easy Outsourced R&D Project Guide for Researchers, the 2nd edition: Research Costs」 that reflects revised R&D management guidelines including clarification on estimation standard of severance pay and standards of settlement and use and held a briefing session for R&D cost settlement for research directors and other related researchers.

MFDS will continue to strive to conduct a fair and transparent evaluation. As part of this effort, MFDS plans to revise the R&D project evaluation guidelines to expand research participation by outstanding researchers. In addition, MFDS will provide accurate information

on the MFDS' R&D performances by continuously updating the 'Easy Outsourced R&D Project Guide for Researchers', hold a 'Visiting Briefing Sessions for the Use of R&D costs by MFDS,' and carry out an on-site inspections for commissioned settlement of R&D expenditures and management to encourage researchers to appropriately execute the research funds and thus create a transparent and reliable environment for the research fund management.

Park Ki-suk, Director of Research Management TF
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3. Effective Outcome Management for Research and Development Projects

The performance of the research and development of MFDS are focused on policy utilization rather than technology development concerning the academic aspect or economic effect, and it finally turns out to be contributing to people's quality of life such as health improvement. To this end, the R&D performance indicators of MFDS for performance management are as follows: the deduction of food and pharmaceuticals safety standards(number of development of test methods, number of suggested guideline, and number of manufactured standard products) and the policy application rate(rate of policy reflection to the number of policy proposal(%)) and thesis index. The results for each of the indicators exceeded the 2016 target by more than 100%. In particular, according to the recommendations of the Ministry of Science, ITC and Future Planing for qualitative performance indicators, the thesis index applied the relative Modified Rank Normalized Impact Factor(mrnIF) and the standardized Modified Rank Normalized Impact Factor(mrnIF) by SCI thesis to set performance indicators, and by adding policy application rate, the rate of qualitative performance indicators was raised to up to 60% compared to the overall performance indicators.

In 2016, MFDS conducted a mid-term (self-assessment) evaluation on the two projects, 'Safety management of pharmaceuticals' and 'Safety management of livestock and fisheries.' And all of these received the 'Normal' rating at meta evluation conducted by the Ministry of Science, ITC and Future Planing, and this was reflected in the budget and business plan for the following year.

In 2017, as the integrated evaluation of the financial program has been made, the self-evaluation is being carried out for the evaluation of the integrated financial program for

the ‘food and pharmaceuticals safety R&D.’ The detailed projects for 2017 are ‘safety assessment technology development and research’ and ‘safety technology advancement.’ Also, and comprehensive analysis of the project details for 2018 will be carried out to improve and set performance targets and indicators that meet the characteristics of the project and guidelines for evaluation, and the ‘MFDS Self-Evaluation Committee’ will be established to carry out professional and comprehensive performance analysis in order to enhance the reliability of self-evaluation of the ‘performance indicators and indicators(draft).’

As the performance-based management of national R&D projects is strengthened and efforts to create, use, and disseminate the excellent achievements are required, the logical linkage between strategic and performance goals will be made possible by determining the type and nature of projects and considering the characteristics of the project based on the project environment, the contents of the work and performance analysis of each research project, and the logical model analysis of the project. These performance targets will be designed to provide challenging and reasonable targets so that the way in which the project is conducted can be matched and they will also be made possible for specific, qualitative and quantitative measurement based on the appropriateness between the performance indicators, the validity of the measurement methods, the rationality of the target values.

Kim Mi-jung, Director of Research Planning & Management Division
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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 harmful substances in potentially hazardous food, establishes a risk assessment for preventive and follow-up safety management, and develops new assessment methods.

Also, with the establishment of the Monitoring Information Management System (MIMS)/ Monitoring Database and Assessment Program (MAP), MFDS secured a large-scale data of 45.75 million cases including the hazard substance information, monitoring data, the quantity of food consumption, etc. and strengthened the basis of risk assessment by setting up maximum permissible exposure limits for hazardous substances and food additives and establishing a method for analyzing hazardous substances in human biological specimens. Moreover, 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 will strengthen cooperation with foreign risk assessment organizations and other relevant international organizations and run customized risk assessment training programs to expand the risk assessment infrastructure in Korea.

Koo Yong-eui, Director of Food Safety Risk Assessment Division
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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)[9]

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 testing methods and relevant researches are being constantly demanded to minimize food safety blind spots that are expanding due to changes in consumers' food choices and purchasing patterns and in the market structure. Accordingly, MFDS carried out analysis on consumer reports and complaints, gathered opinions and suggestions from businesses, and then developed and improved testing methods for food and alcoholic beverage labeling. Also, MFDS plans to prepare a regulatory instrument so that safer and healthier food products can be distributed in the market.

Lee Gyu-sik, Director of Pesticide and Veterinary Drug Residues Division
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9) Positive List System (PLS): A system for applying a standardized limit (0.01ppm) to pesticides and animal drugs that do not have maximum residue limits established

3. Strengthening the Scientific Basis for Reducing Hazardous Contaminants in Food

Due to environmental pollution, abnormal climate changes and changes in eating habits, the likelihood of human exposure (hazard level) to harmful pollutants (heavy metal, dioxin, mycotoxins etc.) has gradually increased over the years. In this regard, to reduce the amount of exposure to harmful contaminants, the current status of contaminant exposure must be examined at all stages including the consumption stage and, safety evaluation must be carried out on those pollutants.

According to the 「Reevaluation of the Standards and Specifications on Unintentionally Generated Contaminants」, MFDS investigated harmful contaminants such as heavy metal, mycotoxins, dioxin, radioactivity, etc. in foodstuffs (46,470 items including agricultural products) and carried out the risk assessment on the amount of contaminant exposure based on food intake data. The results of risk assessment on 8 kinds of mycotoxins and 5 kinds of heavy metals in food were used as a basic data for determining the health risk through food intake and as a policy material for preparing management standards for safety of harmful contaminants.

In addition, MFDS will continue to carry out a joint research with multiple government ministries to solve major social issues to jointly respond to reduce contaminants through cooperation among departments and agencies and to carry out educational training programs and public campaigns in order to promote and spread risk assessment of hazardous contaminants and relevant technologies. To reduce the total amount of exposure to harmful contaminants such as heavy metal and dioxin from food consumption in order for Koreas to have safe food items, MFDS will continuously monitor harmful contaminants in foods and carry out the risk assessment to prepare basic data for food safety management standards.

Kang Gil-jin, 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 accuracy and reliability through improvement of microbial testing

methods, it is required to continue to conduct researches including comparison and review of Korea's microbial testing methods with those of foreign countries. Accordingly, MFDS compared and analyzed the microbial testing methods with the methods(AOAC, etc.) not only internationally used but also used in foreign countries such as Japan and the US and conducted research and development on the management system for the overall restructure of the official microbial testing method in Korea. Then MFDS selected items required to improved, and among these items, 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 completed. To enhance the accuracy and reliability of the microbial testing methods that use advanced new technologies, MFDS will continue to compare and review 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 the continuous increase in large-scale food poisoning due to increasing in group meal services and handling of unsuitable food, 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), applied mobile and environment-friendly sterilizing equipment on the site and secured a quick Norovirus detection kit using copper and light amplification technology.

MFDS also developed a test kit that can distinguish and simultaneously analyze more than 45 key food poisoning bacteria genes and is planning to develop and verify a test kit which simultaneously detects both food poisoning like Norovirus and protozoan. Also, metagenome[10]and genomic information[11] of food poisoning bacteria in 'potentially hazardous foods that are very likely to cause food poisoning'[12] will be analyzed

10) 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.

11) 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)

12) High-risk foods: fish and shellfish (oyster, clam, gizzard), livestock (chicken, raw beef), agricultural products that

continuously and be stored in a database.

Chung Gyung-tae, Director of Microbiology Division
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5. Strengthening Safety Management of Food Additives, Utensils, Containers and Packaging

Due to modernization of dietary life and advancement of food processing technology, 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 for the people's health.

So in 2017, MFDS is carrying out risk assessment on food additives (27 items including color fixing agents) in food utensils, containers and packing (Polyethylene, Polypropylene, and polylactide) and in foods and on transferable substances (7 substances including 1-hexene).

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 will carry out researches on improvement of the testing methods through cross validation between laboratories which are mentioned in 「Food Codes」 and 「Analysis Methods for Food Additives in Foodstuffs」, improvement of testing method of ingredient specifications in food additives code, and improvement of leaching test on food utensils, containers, and packaging. In addition, MFDS is developing a simultaneous analysis method for standard -unestablished additives (5 additives including advantame), developing testing method for fransferable substances in food utensils, containers, and packaging (bisphenol and mineral oil)and conducting monitoring on them.

MFDS is also planning to investigate the content of naturally derived food additives in vegetables and carry out technical review considering whether to recognize naturally derived

are consumed raw (sprouts, cabbage, lettuce) and foods with high food poisoning risk

food additives as food additives and regarding the use of raw materials of cleaning product to prepare scientific evidences.

Kim Mee-kyung, Director of Food 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 needs to continue to conduct a research for establishment of scientific evidence. In this regard, MFDS continues to work on conducting a research on Korea-customized eating pattern to reduce the possibly hazardous nutrients, a research on socio-economic benefit analysis and impact assessment of sugar reduction policy, and a research on nutrient database construction to establish scientific basis for setting nutrition management and nutrition safety policies for all walks of like. MFDS also developed a method for testing nutrients and functional substances in milk formulas and contributed to the advancement of substance testing methods.

Oh Keum-soong, Director of Nutrition and Functional Food Research Team
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7. Strengthening Scientific Surveillance of Food Alteration 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 fake sesame oil, raw material of Korean Jerusalem sage and product of Garsinia Cambogia . In addition, to strengthen the safety of imported food, MFDS collected and analyzed 484 food items sold on foreign websites and

requested the cease and customs clearance of 72 sexual performance enhancing products and dietary products that contain illegal compounds. Also, genetic analysis methods for animal and vegetable ingredients from 22 types of visually indistinguishable food such as king crab and red king crab. 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 150 foreign objects including metal and hair and, provided this data to local governments, relevant testing organizations and food manufacturers. As a result, MFDS estimated the exposure amount of each hazardous substance and prepared a risk assessment report based on the amount of hazardous substances of 61,296 items in total and the amount of food intake estimated by the national health nutrition survey.

Kwon Ki-sung, Director of New Hazardous Substances Team
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Section 3 Supporting Research and Commercialization for Medical Products Safety Management

1. Advancement of the Basis of Medical Products Safety Management

The pharmacopeia provides the least quality standards that pharmaceuticals being distributed in the market need to comply with. The Korean Pharmacopeia has been revised around every 5 years since it was published in 1958, and it is now preparing for the 12th revision(scheduled to be published in 2018) after the 11th revision (for 2014). In 2016, MFDS proposed a series of revisions for 198 items of pharmaceutical, 6 items of biopharmaceutical, and 71 items of Chinese medicine(herbal medicine) and published the Korean Pharmacopeial Forum twice to collect internal and external comments. MFDS will continue to make the following versions of revision considering the modified Pharmacopeia after integration of official compendiums, advancement of scientific technology, the expedient reflection of international harmonization, and the conditions of the pharmaceutical industry.

A reference standard is directly linked to the quality of medical products and public health as a standard material used for quality verification of pharmaceuticals. MFDS has steadily secured and distributed the reference standard of medical products starting with that of chemical pharmaceuticals since 1991, and now it distributes a total of 462 reference standards including 182 items of chemical pharmaceuticals, 26 items of biopharmaceuticals, 222 items of herbal medicine, 31 items of IVD medical devices, and 1 item of quasi-drugs. Also, to secure quality reliability of the reference standards, MFDS has conducted the stability test on the reference standards in storage periodically and published and distributed the '2016 MFDS Comprehensive Guide for Reference Standard.' Moreover, MFDS will continue to increase and provide the reference standards of medical products in the future, reflecting the demands of the field.

In addition, to secure the quality of distributed pharmaceuticals, MFDS conducted testing and inspection of 51 items of chemical pharmaceuticals, 15 items of biopharmaceuticals, 561 Chinese (herbal) medicine, 83 items of cosmetics and quasi-drugs, and 56 items of medical devices. Since MFDS achieved accreditation from an international official accreditation institute(ISO17025) in 2014, it has now expanded the area and been accredited for 12 test items in 2 areas in order to ensure objectivity and reliability of the testing and inspection

results. In 2016, MFDS integrated quality assurance systems which had been individually and separately operated in the areas of chemical and herbal pharmaceuticals and biopharmaceuticals, and it will continue to expand accreditation test items and enhance the reliability and capability of testing and inspection with a designated national standardized laboratory in the future.

Shin Won, Director of Drug Research Division
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2. Research on Pharmaceutical Safety Management

In order to respond to the rapidly changing environment such as the changes in people's interest from treatment to health care, illness prevention and health promotion, costumer-tailored safety management according to life-cycle by all walks of life, consideration of information vulnerable group, the strengthened collaboration between countries for pharmaceutical safety management, and international harmonization of pharmaceutical quality standards, MFDS preemptively conducts researches for enhancement on pharmaceutical policies, systems, etc. and provide safety pharmaceutical information. MFDS has published and distributed Braille/visual materials, information in sign language videos and information booklet translated into multiple languages on the safe use of medicines for the visually/hearing impaired and multi-cultural families who are not able to have an easy access to pharmaceutical usage information since 2010. Further, in 2016, MFDS published the 「Medication Information on Frequently Used 'Over-the-Counter' Drugs(II)」 and reproduced it in the form of braille book with braille, mute letter, and voice output code inserted for the visually impaired and provided 「Guide to Proper Usage of Pharmaceuticals for Would-be Mothers」 in 5 different languages including Korean to multi-cultural families.

In addition, in order to introduce ICH Medical Dictionary for Regulatory Activities(MedDRA), MFDS made 12 kinds of Korean pharmaceutical dictionary and guidelines(draft), the guideline for integrated analysis of stability data and safety management foundation after scientific review and commercialization of the pharmaceuticals, the plan for reduction of medication error, and the detailed countermeasure of pharmaceutical industry to the Nagoya Protocol which is now in effect, all of which are made to be utilized for policy-making.

On top of that, MFDS has strengthened international cooperation by reviewing and sending

comments on the revised international pharmacopeia organized by World Health Organization(WHO), continuously participating in international drug proficiency testing and many international meetings including WHO's International Meeting of World Pharmacopeias. Furthermore, MFDS made an effort to identify information through human resource exchange as 1 expert is seconded the European Directorate for the Quality of Medicines(EDQM) and 5 and 1 domestic experts participate in the expert groups of EDQM and the U.S. Pharmacopeial Convention(USPC), respectively.

MFDS will not spare its effort to conduct a research on safety management on the unmet demands such as drugs for chronic diseases and orphan drugs, a preemptive development research on evaluation techniques supporting new technology development and product commercialization, and a research on consistency and scientific evidence for approval and evaluation of pharmaceuticals.

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3. Research on Biopharmaceutical Safety Management

In our efforts towards achieving the national self-sufficiency of vaccines in preparation for national health crisis such as an outbreak of a new infectious disease, MFDS has established a roadmap for developing evaluation methods for vaccines against new infectious diseases and strategies for rapid licensing of products in responding to emergency situations. Based on this, in 2016, MFDS conducted researches on the development of test methods for quality control of new vaccines and clinical testing methods for emerging diseases such as MERS, ZIKA and CHIKUN GUNYA, as well as establishment of biological reference standards. In addition, MFDS has carried out researches on testing methods for quality assurance of vaccines such as the potency assays for BCG, HPV, diphtheria, and tetanus toxoid vaccines and immunogenicity test methods. Standard sera have been developed for HPV, B-type streptococci, meningococcus, shingles, and pertussis vaccines. By doing so, MFDS aims to improve the national self-sufficiency in essential vaccines and to ensure the quality and safety of vaccines against new infectious diseases. MFDS signed an MOU with the National Institute for Biological Standards and Control (NIBSC), UK on October 17, 2016, to promote mutual collaboration in the establishment and management of biological reference standards through joint studies, information sharing, and short-term staff

exchange.

As the global and domestic markets for biosimilars and new biopharmaceuticals are expected to grow with the expansion of investments by the government and private companies, MFDS has committed to researches to ensure the quality and safety of products through developing advanced evaluation technologies, etc. The key objective of these researches is to set up an advanced regulatory system for biological products (vaccines, blood products, etc.). MFDS also has performed studies for the advanced therapeutic products (recombinant protein products, cell therapy and gene therapy products) on 1) the development of policies and regulatory systems 2) establishment of national guidelines and testing methods for evaluation of safety, efficacy and quality of products and 3) safe use and management of biopharmaceuticals. The major research projects include the risk assessment of next-generation stem cells therapy products such as adult stem cells, induced pluripotent stem cells, and comparison and analysis of domestic and international regulations to devise a new safety management system suitable for the control of 'advanced biopharmaceuticals'.

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4. Research on Chinese (Herbal) Medicine Safety Management

To strengthen pre- and post-quality safety management from raw materials to finished products of Chinese medicine (herbal medicine), MFDS developed technology for differentiating herbal medicines with the possibility of forgery and falsification, established the generalized basis for research on herbal medicine resources in response to Nagoya Protocol, and conducted international cooperation activities.

In order to prevent the 'Fake Cynanchum Wilfordii' incident (2015), which used Cynanchum auriculatum that is not listed in the Official Cynanchum and can not be used as a raw material for pharmaceuticals as Cynanchum Wilfordii, MFDS developed an advanced differential discrimination method that includes DNA barcodes and chemical profiles for a total of 29 cases(until 2016), including 'Cynanchum Wilfordii and Cynanchum Auriculatum' which is not verifiable with sensory test and 'Seok Changpo and Suchangpo' which can be confused with similar names. Also, in order to respond positively to the international situation of Chinese

(herbal) medicine resources such as the Nagoya Protocol, MFDS opened the Herbal Medicine Resource Preservation Center in the 'Okcheon National Herbal Resource Management Center' and secured a feasibility study budget for the establishment of the 'Jeju National Herbal Medicine Resource Center' to establish the basis for the conservation, management and research of (sub)tropical herbal medicine. In addition, MFDS led two international conferences, including the sharing of the technology of manufacturing reference standards at the Forum for the Harmonization of Herbal Medicine(FHH), based on accumulated know-how in the field of quality control in Chinese (herbal) medicine. MFDS also signed an ODA agreement with WHO WPRO and complete the training program for civil servants of Laos(6 months) and Cambodia(3 months), respectively.

In 2017, MFDS will expand the testing and risk assessment of Benzopyran to the raw materials used in the manufacture of natural pharmaceuticals, and will continue to prepare differential discrimination methods that synthesize and apply research techniques such as morphology, ingredient profiles, and DNA barcodes for Chinese medicines which is likely to be forged and falsified. Furthermore, MFDS will establish a comprehensive response system for leading the international standardization work of Chinese medicines(ISO/TC249) and will lead the international standard of Chinese (herbal) medicine's quality control and safety management by establishing the expanded basis of the National Herbal Medicine Resource Management Center.

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5. Research on Cosmetics and Quasi-Drugs Safety Management

Recently, as Korea's economic and cultural levels have improved to that of advanced countries, consumption of life-friendly products such as cosmetics and quasi-drugs has been increasing. Particularly, cosmetics and quasi-drugs are recognized as essential products for our daily life. The National Institute of Food Drug Safety Evaluation has been carrying out the research required for "safety management of cosmetics" so that the public may use safe cosmetics. On the other hand, quasi-drugs are advantageous in that they can be easily purchased compared to pharmaceuticals, but because they have efficacy and are used directly to the human body, strict quality and safety management is required. To this end, MFDS is

conducting research to ensure safety and efficacy, along with the implementation of an 'approval' system through pre-screening of quasi-drugs.

MFDS conducted a risk assessment for safety concerns among cosmetics and quasi-drugs and adjusted the limit of 19 ingredients such as Triclosan and Paraben. MFDS has also prepared revised guidelines and notices(draft) for the 'cosmetic labeling and advertising test method', and 'efficacy evaluation method' to improve the screening system such as support for approval and review.

MFDS has published a series of test methods and materials in order to establish an expedient testing and inspection system for unintentional hazardous substances and prohibited ingredients in the distributed products. In order to understand the safety management system for cosmetics and quasi-drugs and to create a public consensus, MFDS held a briefing session on the 'Plan for Sharing Cosmetics Risk Assessment' and published a booklet for right and safe use of cosmetics and quasi-drugs.

In 2017, MFDS plans to establish a network of international experts on risk assessment of cosmetics and hold a symposium through the 'Research on Enhancement of Cosmetic Risk Assessment Technology' and to propose safety standards(draft) through risk assessment of substances causing safety issues such as surfactants. For quasi-drugs, MFDS will provide safety management policies by conducting research for the prevention of harmful factors in accordance with changes in the policy environment with the provision of the 「Safety Management Measures for Household Chemical Products」. Also, MFDS will continue to develop guidelines for the efficacy evaluation of cosmetics and quasi-drugs, as well as the development and monitoring of hazardous substance test methods, and plan to develop safety evaluation technologies such as standards and specifications in the future.

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6. Research on Medical Devices Safety Management

The Korean medical device industry is one of the major growth engines due to the accelerated population aging, increased life expectancy, and diversification of diseases of Korean society. Korea's aging population is forecast to reach 14% in 2018 and 20% in 2026, leading to an expansion of the medical device industry. The domestic medical device market has already

reached 5.3 trillion won by 2015, and recently, such medical device technology has been used as a personalized base implantable device utilizing 3D printing technology, a high technology-based therapeutic device utilizing robot technology, and ICT such as IoT, AI, and Big Data are applied to the new medical device technology. The medical device industry, which plays an important role in prevention, diagnosis and health care services, is expected to expand in the future. These medical devices are developing into a new concept based medical device technology development with self-measurement (Quantified Self) technology and medical technology based on the development of the smart device and sensor technology and with the convergence among IT(information technology), BT(biotechnology), NT(nanotechnology). In 2016, medical device safety management research has laid the basis for establishing medical device safety policy with preemptive policy support and developed fairness and objectivity of manufacturers and certification institution by developing guidelines for advanced approval and inspection of the medical device. In particular, MFDS has contributed to the advancement of the medical device industry and the enhancement of global competitiveness by preemptively developing evaluation technologies for medical devices that respond to the future medical environment through the industry-academia-government cooperation forum. Through the joint cooperation activities of the International Organization for Standardization(ISO), MFDS has developed internationally harmonized standards and prepared standard working guidelines and it has also utilized them for safety management to strengthen the testing and inspection capability. In 2017, MFDS will predict the possible changes in the future medical environment through the research on the advanced basis of safety management and the research on scientific evaluation, and in connection with the research and development projects being pursued by all the ministries and agencies, MFDS will also conduct a research on international harmonization of medical devices, scientific evaluation, and the latest safety management standards in order to contribute to public safety and development of the national medical device industry with the support of rapid commercialization.

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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

With the emergence of new chemicals every year and increasing interest in health, there is a growing demand for safe management of ingredients and related products, such as pharmaceuticals, and for providing rapid toxicity information.

To this end, MFDS operates a toxicity information providing system (Tox-info) for providing information to the public. To date, 1,477 toxic information, 570 addiction information, and 29,957 product information have been constructed. In order to improve the readability of toxic information, MFDS is improving the information providing style and updating the existing construction materials sequentially. MFDS will also promote linkage of toxic information in the life and safety information system of the Ministry. Also, as part of national toxicology program (KNTP), MFDS constructed safety evaluation data through 11 toxicological tests of natural products such as windshields, the effect of ionization of nanoparticles on toxicity, and development of evaluation method of carcinogenicity using stem cells. In the future, MFDS will expand the toxicity assessment for social issues that are expected to have safety problems for preemptive safety management such as pharmaceuticals, establish a preliminary response system to solve the problem of national unrest and work with the Korea-US National Toxicology Program (NTP). Through the conclusion of the agreement, MFDS will strengthen the international cooperation system and provide accurate information to the people through the toxic information providing system.

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2. Development of Alternatives to Animal Testing and Advancement of Non-Clinical Trials

There is a growing need to develop alternative test methods for the safety evaluation of cosmetics as the European Union has banned animal testing. In response to this move, Korea revised the 「Cosmetics Act(No. 14027, Feb. 3, 2016)」 in 2016 with a view to prohibiting the distribution and sale of animal-tested cosmetic products.

The Ministry of Food and Drug Safety (MFDS) founded the Korean Center for the Validation of Alternative Methods (KoCVAM) in 2009. KoCVAM has actively participated in international collaboration on the development of alternatives to animal testing since it signed a Memorandum of Cooperation (MoC) with EURL ECVAM, ICCVAM, JaCVAM and Health Canada in 2011 to join the International Cooperation on Alternative Test Methods (ICATM). In 2016, the MFDS worked on the development of alternative test methods such as a 'in vitro phototoxicity test using cell lines' and a 'developmental toxicity test using embryonic stem cells' and on the validation of an 'eye irritation test using a human cornea model'. In addition, the 'Local Lymph Node Assay Using Flow Cytometry (LLNA: BrdU-FCM)' proposed by the MFDS was adopted as an official project by the OECD. It has also been committed to introducing OECD Test Guidelines including TG 492 (Reconstructed Human Cornea-like Epithelium (RhCE) Test Method) and TG 442C (In Chemico Skin Sensitization (DPRA)). KoCVAM will constantly accept OECD TGs so that those can be used in evaluating the toxicity of cosmetics.

The global advancement of domestic pharmaceutical companies requires the production of reliable non-clinical trial data and the training of non-clinical trial personnel in compliance with OECD Good Laboratory Practice (GLP) principles. The MFDS has operated non-clinical expert training programs for new drug developers and non-clinical workers since 2008. In 2016, it held a total of 8 workshops including the 'Non-Clinical Education Aiming to Enhance Expertise' and the 'Nonclinical-Clinical Linkage Education'. Furthermore, a working group including industry, academia and research institutes was established to analyze the latest ICH and OECD guidelines and to prepare an internationally harmonized amendment to the 「Standards for Toxicity Testing for Pharmaceuticals」. The MFDS will remain committed to strengthening the foundation for non-clinical trials.

Lee Jong-kwon, Director of Toxicological Screening and Testing Division
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3. Research on Predictability of Drugs and Assessment of Pharmaceutical Dependence

In the field of drug interaction and safety assessment technology, there is an increase in the use of pharmaceuticals and foods due to an increase in interest in healthcare, such as population aging and chronic diseases, and concomitant use of medicines and health foods (herbal medicines). Also, MFDS has been conducting the combined use of medicines and health foods (herbal medicines) and evaluating drug interactions by intestinal microorganisms.

In the field of narcotics-related business, there is a tendency that the domestic inflow of new kinds of drugs is increasing rapidly as the drugs are easily traded through the Internet. Therefore, the necessity of national control is required and the designation of drugs and system improvement and in order to support this scientifically, MFDS is carrying out pilot researches such as policy support such as designation of drugs and system improvement (draft), development of technology for assessing dependency and toxicity of temporary drugs and rapid prediction of new drugs. In addition, MFDS is participating in international drug conferences, sharing information on domestic and foreign new drugs through the synthesis and sale of standard materials used in national institutions, and strengthening the collaboration system between drug control departments.

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

As the development of clinical safety prediction technology has led to the emergence of drug safety prediction program technology using computer modeling and simulation techniques, recently, with the paradigm shift of the international drug market, investment and research are being expanded in the field of innovative clinical evaluation technology and drug genetic information utilization technology for the safety and efficacy of pharmaceuticals led by advanced countries.

In Korea, customized new drug development technology and genomic information utilization technology have been selected for five major technical fields of national research, and early

clinical research and development and genome biomarker development are being promoted as key technologies. As part of the establishment of a basis for innovative clinical trial and evaluation technology, MFDS has developed a quantitative pharmacological integrated model, prepared guidelines for bio-imaging standards, and provided information on safe use of medicines for women. As part of the establishment of a basis for innovative clinical trial and evaluation technology, MFDS has developed a quantitative pharmacological integrated model, prepared guidelines for bio-imaging standards, and provided information on safe use of medicines for women. In order to effectively provide drug genetic information related to the safety and efficacy of drugs, MFDS has also reorganized the contents of the DB, including the menu reorganization of DB and update of the publication data such as the kind of drug gene. In addition, MFDS has contributed to institutionalization by securing policy-based data for the introduction of clinical trial and Human Research Protection Program (HRPP) and clinical sample analysis management standards to enhance international clinical ethics and system improvement.

Based on this, MFDS is planning to establish a Korean clinical trial infrastructure project that incorporates regulatory science, and to establish an optimal pharmacotherapy evaluation method through in-silico technique and quantitative pharmacological evaluation technology. Furthermore, MFDS plans to establish a scientific basis for safe use of medicines in pediatric and rare diseases, and to establish the basis for prevention of adverse effects through the verification of Korean causative genes for drug adverse reactions of specific drugs.

Choi Seung-eun, Director of Clinical Research Division
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5. Preventing Adulterated Food and Drugs through an Advanced Analysis System

MFDS is developing testing and testing methods for unwholesome and illegal drugs in order to carry out the national adulterated food eradication task. In particular, MFDS presented the results of the analysis on 660 samples to the Adulterated Food Eradication Council, Among them, Isopropyl N-Tadalafil, a new type of erectile dysfunction drug, and APINAC, a new synthetic hemp ingredient, were listed for the first time in the world and 11 papers were published in the Science Citation Index (SCI). In addition, in order to ensure the reliability

and accuracy of the test results, ISO / IEC 17025 has been acquired and operated by the Korea Laboratory Accreditation Scheme (KOLAS).

In particular, the results of the analysis of 660 specimens were submitted through the Adulterated Food Eradication Unit and the Risk Investigation Center in 2016.Among them, Isopropyl N-Tadalafil, a new type of erectile dysfunction drug, and APINAC, a new synthetic hemp ingredient, were listed for the first time in the world and MFDS published 11 papers in internationally prestigious journals (the Science Citation Index (SCI). In order to ensure the reliability and accuracy of the results of the test analysis, the MFDS acquires the International Accreditation Scheme (KOLAS) from the Korea Accreditation Scheme (ISO / IEC 17025).

In order to establish the domestic infrastructure for the measurement and disclosure of tobacco ingredient contents in accordance with the Framework Convention on Tobacco Control (FCTC), MFDS is required to test and analyze 45 harmful components such as nicotine and tar in tobacco smoke And 13 volatile organic compounds in electronic cigarette smoke. In March 2016, MFDS joined the World Health Organization TobLabNet as an analytical member and became internationally recognized for its ability to analyze tobacco components.

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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 for development of new drugs and evaluation of safety, efficacy of medicines. However, laboratory animals and disease models used in Korea entirely depend on foreign countries. In addition, the biological samples such as blood and tissue of the laboratory animals which have been administered with drugs for a long period are useful resources for research, so it is necessary to establish a system to utilize them. Therefore, MFDS is promoting the 'BIOREIN (Laboratory Animal Bio Resources Initiative)' project for the purpose of realizing scientific animal preservation and bio-resource sharing.

In 2016, two species of Korean strain mice (Korl:ICR, C57BL/6NKorl) were obtained and the founder resources were distributed to the laboratory animal breeders so that they could be utilized by domestic researchers. MFDS's 「Center for Mouse Models of Human Diseases」 developed 19

disease model mice including metabolic disease, circulatory disease, and immunodeficiency.

In addition, MFDS promoted the construction of the 'Laboratory Animal Resource Bank', an infrastructure for securing and utilizing laboratory animal resources. Future studies will further secure DBA/2 mouse resource and plan to develop 14 disease models In addition, MFDS is building an laboratory animal resource bank with the goal of completion in October 2017. MFDS intend to acquire Korean laboratory animal resources through the BIOREIN project and establish the biological resource utilization system.

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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

Biologics such as vaccines and blood products are in the process of being approved by the Food and Drug Safety Assessment, a member of the MFDS. As of December 31, 2016, a total of 68 products and 208 items subject to national shipment approval are to be approved.

In 2016, a total of 2,375 lots were shipped nationwide, 41 lots more than last year (Table 4-5-1). It is expected that applications for shipment approval will steadily increase due to the increase in the share of domestic manufacturing vaccine and the expansion of production facilities of blood drug manufacturers.

[Table 5-5-1] National Lot Release Statistics in the Last 6 Years

(Ref: 2016 Annual Report on National Lot Releases, unit; lot, as of Dec. 31, 2016)

Category \ Year	2011	2012	2013	2014	2015	2016
Bacterial vaccines	383	304	327	243	186	194
Virus vaccines	558	596	668	679	670	691
Botulinum toxin (BoNT) products	92	152	242	471	536	597
Blood products	739	955	1,018	976	942	893
Total	1,772	2,007	2,255	2,369	2,334	2,375

MFDS has introduced and operates the 'Biological Drug Delivery System' based on the hazard analysis from April 1, 2016. MFDS will establish the risk stage for 208 items in 2017 and conduct a certification test and review manufacturing and quality control data.

In order to improve the clarity and efficiency of the national shipping approval process, MFDS is in the process of revising the national shipping approval manual starting from 2015. MFDS has established and revised seven business manuals by 2016 and plans to enact three items, including the 「Notification procedure for national shipment approval test and test method」 in 2017. In addition, MFDS plans to prepare a checklist of manufacturing and quality control summary review items to improve the consistency of reviewing data such as national

manufacturing approval and quality control summary (SP) and MFDS will run test records from 2017, which will record the material, equipment, and process. As such, MFDS intends to steadily increase the efficiency and reliability of the national shipment approval system.

2. Strengthening Cooperation and Communication through the Operation of Public-Private Consultative Group

The MFDS has formed a public and private consultation body to promote quality control efficiency and international harmony through information exchange and technology exchange between laboratories. There are 13 manufacturers and 2 quality inspection agencies participating in the "Vaccine Quality Control Laboratory Network (Lab-Net)". In 2016, joint research on the establishment of national reference standards was conducted on five themes. Through these activities, MFDS has achieved such as the manufacture and establishment of candidate substances for various national standards, and the proficiency level of the test method for influenza vaccine hemagglutinin. MFDS also held a workshop on the "Network of Biological Quality Control Laboratories(Lab-Net)" for internal and external experts in the field of vaccine and blood product.

In the field of blood products, MFDS is operating the 「Civil-governmental association For Blood product quality study」 with 8 manufacturers and importers and 3 blood centers. As a network activity of blood product quality control laboratories, a joint research was carried out on improvement of test methods and establishment of standards. Three trials were conducted to check the competence of the organ for immunoglobulin of the anti-tetanus and the manufacturing and import companies.

In 2017, MFDS will continue to cooperate with the manufacturers, quality inspection agencies, and blood centers to jointly produce and establish national standards, conduct training on quality control testers, operate proficiency programs, and visit the manufacturers' sites.

3. International Cooperation Activities

In order to strengthen the capacity for biological safety management and to discuss and exchange information on regulatory issues, the MFDS is carrying out various cooperation with foreign national regulatory labs in the Western Pacific, including the World Health Organization (WHO), the European Directorate for the Quality of Medicines and Healthcare (EDQM), Germany's the Paul Ehlich Institute (PEI), Japan's the National Institute of Medical Sciences

Infectious Diseases (NIID), and National Regulatory Labs in the Western Pacific.

Since 2006, MFDS has signed a contract to carry out the WHO's Technical Service Agreement (TSA) and has been tested for the WHO delivery vaccine. In 2016, MFDS signed an additional contract test for 6 lots of Japanese encephalitis live vaccine, 10 lot of BCG vaccine and 10 lotus pertussis vaccine for two years by the end of 2017. In 2016, two trials of Japanese encephalitis virus vaccine and 5 BCG vaccine vaccines among the contracted vaccines were carried out, and the results were sent to the World Health Organization to carry out the fiduciary testing work. In the future, the proportion of fiduciary exams from the World Health Organization is expected to increase gradually.

As MFDS was designated as a cooperation center in the field of standardization of the World Health Organization in 2011, MFDS has been carrying out various cooperation activities between them. And during the last four years, from 2012 to 2015, the 'Hands-on Training', which was operated as a vaccine quality management self-education, was officially designated as the 'Global Learning Opportunities for Vaccine Quality (GLO / VQ)' in 2016.

In addition, the "Western Pacific Lab-Net International Workshop" was held between September 1 and 2, 2016 in order to strengthen the cooperation between national regulation laboratories in the Western Pacific region. Quality control experts from China, Japan, Vietnam, Philippines, Australia, and WHO Regional Office of the World Health Organization participated in the international joint research activities for the sharing of the quality control studies of vaccines and blood products by inviting countries.

MFDS conducted collaborative studies with Japan's the National Institute of Medical Sciences Infectious Diseases (NIID) to establish and the National Reference Standard for snake venoms and with UK National Institute for Biological Standards and Control (NIBSC) to establish international standard for tetanus immunoglobulin.

The major international cooperation activities planned in 2017 are to operate the World Health Organization's International Training Center for National Shipment Approval/ Examination for 10 days (August 30 - September 8) for developing countries around the world. And an international workshop on National Regulatory Labs in the Western Pacific region will be held on September 20th and 21st with quality experts in the Western Pacific region. In addition, a WHO commissioned test for Japanese encephalitis live vaccine, BCG vaccine, and pertussis vaccine will be conducted, and WHO-sponsored international collaborative research for establishing international standard product of meningococcal polysaccharide, joint research for the development of alternative test method for exothermic with the German Paul Ehlich Institute (PEI) and joint research with the UK National Institute for Biological Standards

and Control (NIBSC) for the identification of thrombin production in immunoglobulin are planned be conducted.

4. Strengthening the Quality Management Function in National Testing and Operation of Proficiency Program

In order to ensure the retrospective and international credibility of the test results, MFDS established a systematic quality control and quality assurance system for the test and analysis tasks, and in December 2004, the International Standardization Organization (ISO / IEC 17025) was recognized as an authorized testing institute. In addition, in order to ensure objectivity and reliability of the test capability, MFDS continuously participates in the international proficiency program and operate the proficiency program to check the quality control of domestic manufacturers.

MFDS operates an internationally accredited testing institute for a total of eight products and six test items by newly recognizing five products and two test items in 2016. In order to maintain international accredited testing laboratory accreditation, Month internal review and external update evaluation in September. In addition, she participated in three programs including the low-molecular-weight heparin content measurement color development test method among the international proficiency programs hosted by the European Medicines Quality Committee, and was recognized for the quality inspection ability at the international level.

MFDS will continue to operate new / old training, internal auditors and evaluator training for internationally accredited testing laboratories for shipment approval testing personnel, and will continue to expand the test items for international standardization bodies. In 2017, MFDS will participate in four programs, including the European Pharmacopoeia Quality Committee and the UK Pharmacovigilance Standardization Research Institute International Expertise Program, which tests the human blood coagulation factor VIII factor. MFDS will further develop its ability to test and analyze internationally in the field of vaccines and blood products, thereby providing more reliable test analysis and research facilities.

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VI

Special Edition

Special Edition 1

MFDS' Achievements of the Last 4 Years

1. Enhanced Safety Assurance of Food and Drugs in Daily Lives

A. Increased Scope of Products for Safety Management including Agricultural·Livestock·fishery products, Alcoholic Beverage, Cigarette, and Wet Wipes, Etc.

For more effective and systematic safety management of foods in all stages from production to consumption, the Ministry of Food and Drug Safety (MFDS) was newly inaugurated in March 2013, and since then, the safety management tasks that had been distributed to various departments by food type and field have been unified. As a result, the function of safety management of agricultural·livestock·fishery products at the production stage was transferred to the MFDS from the Ministry of Agriculture, Food and Rural Affairs to reinforce the function. In particular, a systematic sanitation·safety management has become available for eggs that have been poorly managed even though they are one of the most commonly consumed foods by preparing comprehensive measures such as sharing standards for cleaning·distribution·storage and enhanced administrative disposition for collecting·storing·selling·using of defective eggs (June 2016).

Also, in 2013, the MFDS established a basis for safety management of alcoholic beverages as it required to manage alcohol manufacturers as food manufacturers·processors and introduced 'Sanitary Management Grading System' to regulate alcohol manufacturers differentially according to their sanitary level. The amendments of Tobacco Business Act are under deliberation by the National Assembly, which were made to measure and disclosure harmful ingredients of tobacco and to ensure safety management by assessing risks to humans.

Meanwhile, in 2015, wet wipes, which had been managed as industrial products, were classified as cosmetics and the safety management for them were enhanced as the existing 22 items were divided into and managed as 1,020 unavailable ingredients and 159 restricted ingredients. In April 2017, the Hygiene Products Management Act was established to systematically manage 17 products for daily use including disposable chopsticks and wet wipes

for restaurants, etc. providing legal·institutional basis for thorough management of hygiene products that were in the blind spot since 1999 when the Public Health Act was repealed.

B. Ensured Safety of Products Being Distributed·Consumed

With the expanded application of HACCP, the rate of producing HACCP-certified foods was increased from 45.9% in 2013 to 68.7% in 2016. Also, GMP medical products were also increased so that the number of CGMP-certified cosmetic manufacturers were rapidly increased from 21 in 2012 to 109 in 2016 while the mandatory application of GMP on oriental medicine manufacturers was expanded from 12 businesses in 2012 to 152 in 2016. Moreover, GMP, which was voluntarily applied to health functional foods, will be made mandatory in phases to be fully introduced by 2020.

As the capabilities for tracking and managing the history of product manufacturing, distribution and use were enhanced, the number of businesses which registered the Food Traceability System were greatly increased from 46 in 2012 to 5,901 in 2016, and to prevent illegal distribution of narcotics, the 「Integrative Narcotics Control System」 was also established and applied in phases after the test operation. In addition, the number of human-implantable medical devices to be tracked, such as a heart valve prosthesis, was also increased from 19 in 2012 to 52 in 2016. And It became available to manage the entire process from the approval to use of medical devices, as it has become mandatory to add Unique Device Identifier (UDI) label on medical devices by product type by 2016.

Meanwhile, to fundamentally ensure safety of imported foods, the Special Act on Safety Management of Imported Foods was enacted (Feb. 2015) and a systematic management system was prepared for the safety management from the local site prior to import to customs and distribution stages. Approximately 48,000 foreign manufacturers were pre-registered, and the rate of finding imported foods with defect rates at customs were decreased to 0.2% in 2016 from 0.41% in 2012, and the rate of non-compliant products directly purchased from overseas were also decreased to 7% in 2016 from 27% in 2013, indicating the enhanced safety management of imported foods.

To reinforce the sales prevention of hazardous food on-or offline, 「Hazardous Food Sales Prevention System」was installed in all convenience stores and marts (about 78,000 stores) of the entire country, increasing the rate of those who benefited from the safe shopping thanks to the system from 59.5% in 2012 to 97.8% in 2016. Moreover, the 「Hazardous Pharmaceuticals Sales Prevention System」 was also installed in 79% (about 17,000 drugstores) of pharmacies,

and the monitoring on the online distribution of illegal pharmaceuticals through e-robots, etc was also enhanced to record increase in prevention of sales of unwholesome foods and illegal pharmaceuticals from 10,646 (2012) to 15,160 (2016) and from 10,912 (2012) to 18,949 (2016), respectively.

2. Created Safe Consumption Environment for Foods and Drugs

A. Expansion of the Basis for Healthy Dietary of People

MFDS improved the sanitary and nutrient condition of children's food in child care services and kindergartens which does not necessarily hire nutritionists and created a safe environment for children of couples working together for a living. The number of Centers for Children's Foodservice Management was rapidly increased from 22 centers in 2012 to 207 in 2016, raising the rate of those who benefited from the center from 9% to 60%. Also, it continued to improve children's eating habits. As a result, hand washing before meals became a daily routine (the rate of those who wash their hands before meals: 49.3% in 2011 → 95.9% in 2016), and children who eat balanced meals also increased (60.7% in 2011 → 86.6% in 2016).

In addition, in order to prevent food poisoning, MFDS supplied sterilizing equipment for ground water to food service facilities in elementary, middle, and high schools (a total of 2,868 units from 2012 to 2013), reporting that the number of patients with food poisoning caused by Norovirus were decreased to 560 in 2016 from 1,665 in 2012, and the 「Food Poisoning Early Warning System」 has been connected to and installed in schools which procure·purchase food ingredients.

On the other hand, with the movement to reduce sodium intake requiring voluntary participation of people and companies, MFDS could reduce daily sodium intake by about 20% from 4,831mg in 2012 to 3,890mg in 2016. It is quite a dramatic reduction in such a short time given that it took 30 years to reduce sodium intake by 30% for Finland, a country known for its successful reduction in sodium intake.

B. Support for Safe Use of Food and Drugs and Enhanced Public Convenience

The MFDS has provided more safety information, enhancing the right to know of the public and relieving people's anxiety over food and drug safety. It disclosed the results of scientific

risk assessment conducted to find toxic substances(1 case in 2014 → 110 cases in 2016), and provided easy-to-understand toxicity information (1,182 pieces of information in 2012 → 1,477 in 2016) through the toxicity information providing system (Tox-Info). In addition, the MFDS established the Integrated Food Safety Information Network to share·disclose·use food safety information (159 types from 12 ministries) and a portal site for food safety information to provide one-stop food safety information that can be useful in people's daily lives.

In 2015, a social compensation system was introduced to guarantee compensation for side effects caused by normal use of medicines without lawsuit. With the system, the compensation for death was paid from 2015, for disability and funeral expenses, from 2016. In 2017, The system will be completed by covering medical expenses in 2017.

Meanwhile, to ensure consumers' access to information and informed choice, the MFDS expanded and improved the labeling system to a more consumer-oriented one. It also made the nutrition labeling on coffees and sauces and allergy marks on Children's Favorite Foods including hamburgers mandatory, displayed all ingredients of pharmaceuticals and quasi-drugs, and provided drug identification information. Furthermore, the font size in food labels was increased and information contained in the labels were also reduced to improve readability.

By allowing store-within-a-store (e.g.: a coffee shop in a book store, cafe in a flower shop, etc.) and parcel delivery of instant manufactured·processed foods such as rice cakes, and by abolishing the limitation on the distance for buffet services, the MFDS responded to consumer demand.

3. Expanded Supply of Foods and Drugs in high demand

A. Increased Supply of New Food and Drugs and Rare Orphan·Essential Drugs

MFDS expanded the certification·licensing of new foods and drugs and supported the market entry of high tech medical devices. A total of 155 functional food ingredients were approved, and 206 pharmaceuticals including 138 new drugs, 62 incrementally modified drugs and 6 biosimilars were also certified and approved as new drugs. Moreover, it simplified the process to file civil complaints on high tech medical devices, and shortened the period for approval by up to 13 months through the simultaneous examination with the National Evidence-based Healthcare Collaborating Agency, increasing the treatment opportunities.

Furthermore, the MFDS established a pan-ministerial plan for stable supply of national essential drugs (Oct. 2016) and operated a council to promote stable supply essential drugs such as vaccines and orphan drugs that are difficult to be procured in the market. As a result, the self-sufficiency rate of vaccines has risen from 29 % in 2012 to 46% in 2016 and about 78.58billion won of rate pharmaceuticals were supplied to 25,064 patients.

B. Developed Country-Level Food and Drug Safety Management

Based on the perspective of 'One Health' that recognizes that the health of humans, animals and ecosystems are interconnected, the MFDS came up with 'National antimicrobial resistance management measure' to enhance the survey on antimicrobial resistance of livestock·fishery products. Furthermore, in 2016, the Republic of Korea was selected as a chair country for Codex Alimentarius Commission (CODEX) Ad Hoc Intergovernmental Task Force on Antimicrobial Resistance for resolving global antimicrobial resistance issues, leading to the establishment of international standards. Meanwhile, in order to harmonize international pharmaceutical manufacturing and quality control standards and to improve the inspection system, the MFDS joined the Pharmaceutical Inspection Cooperation Scheme (PIC/S) in which there are 46 member countries including the US and European countries and the Korean pharmaceutical exports were increased by 31.1% year-on-year to record 790.6 billion won. In addition, for the purpose of providing internationally harmonized guidelines for medicines, MFDS joined the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH), the most authoritative international organization that the United States and the EU joined, strengthening its position as a leading institution for establishing standards.

Moreover, it signed a pre-qualification (PQ) agreement on vaccines with WHO (Dec. 2016) to support the advancement of domestic vaccines overseas. When UN agencies selects vaccines that passed the WHO PQ evaluation on quality, safety and efficacy to supply to developing countries through international bidding, the eligibility of Korean vaccine safety management system was recognized and the period required for vaccine exports was also decreased from 12-18 months to 6-12 months.

4. Evaluation Results and Remaining Tasks

Since March 2013 when the Ministry of Food and Drug Safety was newly inaugurated, a systematic and efficient system was established to manage food safety from farm to table, prioritizing the food and drug safety as one of top priority tasks for the nation. As a result, the subjects for national safety management is increased and the management methods were also improved. Before the MFDS' inauguration, timely and effective safety management measures were not taken for the customs clearance of Chinese melamine milk powder and Japanese radioactive contaminated foods as the relevant tasks were scattered to several ministries. However, with the inauguration of MFDS, the task of safety management at the manufacturing stage was transferred to MFDS and it has been able to apply consistent food safety management systems such as HACCP and a history tracking system from agricultural·livestock·fishery products to processed·cooked foods. Also, with the pan-governmental Task Force for Eradicating Unwholesome Food on which the food safety management capabilities of prosecution, police and relevant departments were focused, the MFDS has promoted the eradication of unwholesome food at the production and distribution stages to find around 120,000 businesses manufacturing unwholesome products. Thanks to its all-out efforts, the degree of food safety felt by the people was significantly increased from 66.6% in 2012 to 84.6% in 2016.

As the food and drug safety had been considered as a sub-agenda for health and medical services and was mainly focused on responding to industrial incident related to food safety, introducing and promoting fundamental and consumer-oriented policies were put on the back burner until the status of Korean Food and Drug Administration was raised to ministry. Since then, the MFDS has been introducing a series of measures to improve food and drug safety management from lowering limit on penalties for food safety-related offenders, early warning service for food poisoning, Good Manufacturing Practice (GMP) to post marketing re-evaluation. In addition, the MFDS emphasized and promoted consumer-oriented polices such as reducing sodium and sugars, securing safety of children's meals, supplying essential medicines during national emergencies, and relieving drug damages.

On the other hand, prior to the inauguration of MFDS, safety issues were managed only in the fields of food, pharmaceuticals, and medical devices which were in its responsibility, so there were limitations in applying various safety management methods to products harmful to the human body, other than providing guidance or carrying out crackdowns. However, MFDS expanded the scope of products for safety management from foods and pharmaceuticals to alcoholic beverages, tobacco, wet wipes, and other products that are directly applied to

human body. And through consumer-oriented safety management measures such as the division of functions into the headquarters (policies) and regional offices (execution)*, big data-based management using the Integrated Food Safety Information (integrated 159 types of information from 12 ministries) and management of 'the person' who violated relevant laws and regulations, MFDS has raised the level of food and drug safety.

The changes in the food and medicinal environment, such as an increase in new threats due to climate change, a change in demand pattern for food and drug caused by population aging, an increase in imported products and household chemical products, and a change in food and pharmaceutical ecosystem because of the fourth industrial revolution are rapidly taking place. Therefore, the MFDS shall continuously come up with and promote new food and drug safety policies in order to help people realize a healthy and happy life in their daily lives.

Jeong, Yong Ik, Director of Planning and Finace
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Special Edition
2

1. Extension of the MFDS Headquarter Office Building

[Image 6-2-1] The front view of MFDS Headquarter Office Building

A. Background

On March 23, 2013, the KFDA (hereinafter, Korea Food and Drug Administration) was promoted to the Ministry of Food and Drug Safety (hereinafter, MFDS). With the promotion, the number of organizations and employees were increased, resulting a shortage of space. Therefore, the headquarter office building was built in order to secure more office space.

B. Overview

(1) Project expenses: KRW 18 billion
(2) Project Scale: 1 basement level, 5 aboveground level, gross floor area: 6,542㎡
(3) Project Period: 3 years (2014 - 2016)
(4) Project Implementation: Directly implemented by MFDS
(5) Department for Carrying out the Project: MFDS

C. Progress

- Dec. 2013. Reflected Public Property Acquisition Project of State-owned Asset Management Fund
- Apr. - Dec. 2014. Data survey and execution drawing
- Apr. 2015 Started the construction work
- Oct. 2016. Completed the construction work

D. Achievements

1) Secured Budget

On April 30, 2013, MFDS applied for a project to acquire a public property of the Ministry of Strategy and Finance in 2014, and in December of the same year, the project expenses of 13.5 billion won was reflected in the construction project of a 6,843㎡ office building.

Since then, MFDS has requested an increase of around 7 billion won because of the construction cost increase, etc, and secured an budget of 18 billion won by increasing the additional project budget of 4.5 billion won on January 22, 2015.

2) Data Survey and Execution Drawing

A) Data Survey and Execution Drawing

The design for MFDS headquarter office building was outsourced to Garam Architects and Associates and carried out from Apr. 4, 2014 to Jan. 27, 2015.

The building was designed as a 1st grade energy efficient building with a forward-looking exterior and safe and reasonable space, by focusing on the concept of symbolism, harmony, comfort and efficiency.

B) Management of Design Construction Project

Design Construction Management[13] was carried out from August 1, 2014 to January 27, 2015 by Jaejun Architecture Company in order to secure the excellent design quality through reviewing the appropriateness and economical efficiency of the design.

Through the construction engineering management, about 1 billion won was saved from 51 items such as reduction of underground floor space and minimization of rooftop structure, and it was reflected in the design.

C) Construction

The contracts related to the extension of MFDS headquarter office building was signed on April 20, 2015 as follows: Construction work - Shinsung Engineering Co. Ltd., Electric work - Misung Co. Ltd, Telecommunication construction - Sammi Co., Ltd., Firefighting construction - Wonbangjae Engineering, Co., Ltd.

The construction work was carried out for a total of 18 months from April 27, 2015 to October 31, 2016. In 2015, construction of earthworks, foundation work, building structure and various plumbing and piping system were completed. In 2016, exterior and interior of the building was completed, and machinery equipment and lamps were installed.

D) Construction Management Project

Construction Management was jointly carried out by both Dongil Architects & Engineers and Jin Electrical Engineering Co. Ltd., for 19 months from April 27, 2015 to November 15, 2016.

Woo Young taek, Director of General Affairs Division
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13) 'Construction Management' refers carrying out planning, feasibility study, analysis, design, procurement, contract, construction management, supervision, evaluation or follow-up management of construction work.

2017 MFDS White Paper

Ministry of Food and Drug Safety

VII

Appendix

1. Changes in the Number of staff

Mar. 21, 2017

○ Reshuffle of bureaus and divisions related to food
- Reshuffle relevant bureaus and divisions to strengthen safety management of imported food and to ensure efficiency of food safety management

* Reshuffle Food Nutrition and Dietary Safety Bureau to Food and Consumer Safety Bureau

* Reshuffle Agro-Livestock and Fishery Products Safety Bureau to Imported Food Safety Policy Bureau

Classification	Major reshuffles	
	Bureau	Division
Food Safety Policy Bureau	Food Safety Policy Bureau	· Food Policy Coordination Division → Food Safety Policy Division (changed name) · General Food Management Diviision → Food Safety Management Division (changed name) · Food Consumption Safety Division → Food Safety Labelling and Certification Division (changed name) · Health Functional Food Policy Division (transffered from Food Nutrition and Dietary Safety Bureau) · Livestock Products Standard Division → Residues and Contaminants Standard Division (changed name)
Food Nutrition and Dietary Safety Bureau	Food and Consumer Safety Bureau	· Dietary and Nutritional Safety Policy Division (Dietary Life Safety Division and Nutrition Safety Policy Division were merged) Agro-Livestock and Fishery Products Policiy Division, Agro-Livestock and Fishery Products Safety Division, (transffered from Agro-Livestock and fishery Products Safety Bureau) * Livestock Products Sanitation Division and Agro-Fishery Products Safety Division were merged Agro-Livestock and Fishery Products Safety Division, Agro-Livestock and Fishery Products Policy Division (transferred from Agro-Livestock and Fishery Products Safety Bureau) * Agro-Livestock Fishery Products Safety Division and Agro-Fisher Products Safety Division were merged)
Agro-Livestock and Fishery Products Safety Bureau	Imported Food Safety Policy Bureau	· Imported Food Policy Division (transfereed from Food Safety Policy Bureau) · Foriegn Inspection Division → On-site Inspection Dvision (changed name) · Imported Food Inspection Management Division, Imported Food Distribution Safety Division (reshuffled via merge of divisions))

○ establish R&D policy capabilities on food and drug. adjusted the number of officers
- one 5th class officer was transferred from Research Planning Management Division to Customer Risk Prevention Bureau

○ strengthen food microbiology risk analysis capabilities
- 4 researchers were transferred from the HQ to Food Microbiology Division

○ adjustment in director general level open position system
- designated director general of Food and consumer Safety Bureau as open position system and director general of Food Nutrition and Dietary Safety Bureau was excluded after reshuflle.

<table>
<tr><td>Feb. 28, 2017</td><td>- Reflected the required number for 2017 (38 persons)
• Three divisions were established (Alcoholic Beverages Safety Policy Division, narcotics Management Division, Biopharmaceuticals Review Management Division)
• 38 persons increased: (one class-4 officer, four class-5 officers, eleven class-6 officers, nine class-7 officers, two senior officers and eleven researchers)
* expanded scope of responsibility of special judicial police (3 persons), expand food traceability system gradually (2 persons), strengthen imported food safety management (4 persons), strengthen safety management of alcoholic beverage (1 person), implement restaurant sanitation grade system (1 person), strengthen safety management of livestock-fishery products (2 persons), drug approval update, etc. (5 persons), narcotics management division (6 persons), strengthen approval of health functional food (2 persons), biopharmaceutical review management division (9 persons), strengthen international cooperation (2 persons), document controller (2 persons)</td></tr>
<tr><td>Jan. 26, 2017</td><td>- 15 persons decreased: (one class-5 officer, three class-6 officers, three class-7 officers, one class-8 officer, one class-9 officer, two senior officers and four researchers
<table><tr><th rowspan="2">HQ(△5)</th><th colspan="2">Affiliated institutions (△10)</th></tr><tr><th>NIFDS(△4)</th><th>Regional Offices(△6)</th></tr><tr><td>one class-5 officer,
one class-6 officer,
one class-7 officer,
one class-9 officer,
one senior officer and
one researcher</td><td>two senior officers and
2 researchers</td><td>two class-6 officers,
two class-7 officers,
one class-8 officer and one
researcher</td></tr></table></td></tr>
<tr><td>May. 19, 2016</td><td>- 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)</td></tr>
<tr><td>Feb. 5, 2016</td><td>- Adjustment in positions in 2016: ±15 persons (two grade-3·4 officers, six grade-4·5 officers, two grade-5 officers, 5 senior officers)</td></tr>
<tr><td>Dec. 30, 2015.</td><td>- 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.</td></tr>
</table>

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 Seung Hee	Apr. 7, 2015 ~ Mar. 12, 2016
Jeong Seung	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 Yeopyo	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 Jongsei	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 Seunghee	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.
Byeon 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 coordinate policies regarding utilizing food safety information among government agencies. In charge of managing and supporting integrated food safety information network.

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 Safety Policy Division		Establish sanitation and safety management policies of utensil, container or packaging, food additive, health functional food and food. In charge of coordination of improvement of regulations.
	Food Safety Management Division		Establish comprehensive plan regarding guidance and crackdown on operation of food business. Establish and manage food collection and inspection plan.
	Food Safety Labelling and Certification Division		In charge of labeling standard of food, etc, and labeling and advertisement approval standard of infant/baby food weight control food, establish and coordinate comprehensive plan regarding HACCP, in charge of food traceability system.
	Health Functional Food Policy Division		Develop policies regarding health functional food and improve relevant regulations, establish and in charge of comprehensive safety management plan, in charge of relevant regulations regarding health functional food business approval and notification
	Alcoholic Beverages Safety Management and Planning Division		Establish and coordinate comprehensive plan on policies regarding alcoholic beverage safety management, improve and amend relevant laws and regulations, educate and promote alcoholic beverages safety management, impose administrative penalty.
	Food Standard Planning Office	Food Standard Division	Establish and execute total plan for improving food standard and specification
		Residues and Contaminants Standard Division	Establish and implement comprehensive plan to improve standard and specification of hazardous material in food.
		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
Imported Food Safety Policy Bureau	Imported Food Policy Division		Establish comprehensive plan on safety management of imported food and enact and amend act aims to improve regulation and notification.
	On-site Inspection Division		Establish comprehensive plan on safety management of manufacturers located in foreign countries and conducts import sanitation assessment.
	Imported Food Inspection Management Division		Establish and coordinate inspection plan on imported food. Designate products subject to inspection.

Department		Main Functions
	Imported Food Distribution Safety Division	Establish comprehensive plan on guidance and crackdown on business related to imported food. Establish and manage plan on collecton and inspection of imported food. etc.
Food and Consumer Safety Bureau	Nutruition Safety Policy Division	Establish and in charge of food nutrition safety policy and comprehensive plan. in charge of children's food safety management and and matters related to nutrition and safety policy of children's favourite foods.
	Agro-Livestock and Fishery Products Policy Division	Manages sanitation and safety control scheme for domestic agro-livestock and fishery products and establishes countermeasures.
	Agro-Livestock and Fishery Products Safety Division	Establish and manage safety manage plan on safety research, collection, inspection of agro-livestock and fishery product. Establish guidance and crack down plan.
	Foodborne Diseases Prevention and Surveillance Division	Establish and implement comprehensive plan on food poisoning prevention Operate pan-governmental committee for responding outbreak of foodborne diseases Educate, promote and evaluate food poisoning prevention.
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
	Narcotics Management Division	Establish and pursue comprehensive narcotics safety management plan. In charge of operation of Narcotics Information Management System. Establish and coordinate basic plan on distribution and surveillance of narcotics and raw materials of narcotics, etc.
	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

Department		Main Functions
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.
	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 March 21, 2017 (Unit : persons)

Position / Agency, Division	Total	State	General Posit											Management Operation Post		
		Minister	General·Research	3·4	Class 4	4·5	Class 5	6	7	8	9	Senior officer	Researcher			
Total	1,797	1	23	12	48	31	206	310	312	138	52	158	471	9	2	24
HQ	589	1	10	10	35	20	119	126	113	6	7	36	86	7	2	11
Agency	1,208	-	13	2	13	11	87	184	199	132	45	122	385	2	-	13
NIFDS	418	-	7	-	5	1	28	13	11	19	5	107	219	2	-	1
Regional FDA	790	-	6	2	8	10	59	171	188	113	40	15	166	-	-	12
Seoul Regional Office	122	-	1	1	1	2	9	28	29	11	7	5	23	-	-	5
Busan Regional Office	206	-	1	1	4	-	17	43	50	42	7	2	37	-	-	2
Gyeongin Regional Office	263	-	1	-	3	2	17	57	54	31	13	5	76	-	-	4
Daegu Regional Office	52	-	1	-	-	2	4	11	14	9	3	1	7	-	-	-
Gwangju Regional Office	72	-	1	-	-	2	7	14	20	11	5	1	10	-	-	1
Daejeon Regional Office	75	-	1	-	-	2	5	18	21	9	5	1	13	-	-	-

2) History of Change in Prescribed Numbers

Feb. 28, 2017 1,797 persons (38 persons increased)

► required person for 2017 : 38 persons

- expanded scope of responsibility of special judicial police: 3 persons
- expand food traceability system gradually: 2 persons
- strengthen imported food safety management: 4 persons
- enhance alcoholic beverage safety management: ±1 person
- implement restaurant sanitation grade system : 1 person
- strengthen safety management of livestock-fishery products : 2 persons
- in charge of pharmaceutical approval update, etc 5 persons
- enhance safety management of narcotics : 6 persons
- enhance approval capability of health functional food : 2 persons
- medical product approval and review: 9 persons
- enhance international cooperation : 2 persons
- document controller : 2 persons

Jan. 26, 2017 1,759 persons (15 persons decreased)

► reduced 17 persons according to integrated operation plan of MOPAS (13 June)

- HQ: △5
- NIFDS : △4
- Regional offices : △6

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(16)	Enforcement Ordinance(19)	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	Enforcement Decree of the 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 / Contents	ICT Management and Statistics Office/ Moon Kwang-kyu	Kim Jong-Wook Lee Woo-Sun Jang Min-hee Lee Gyeong-Min
I. Outline		
1. Vision, Objectives, and Core Strategies	Planning and Finance/ Jeong Yong Ik	Lim Hyung Ho Namkung Jong Hwan
2. Organization·Affiliated Organizations	Organization and Management Innovation Office/ Cho Dae Sung	Im Chang Geun
3. History		Lim Rock Joung
II. Food		
Chapter 1. Strengthening of the Food Safety Management System		
1. Cooperation between Government Bodies to Eradicate Unwholesome Food	Food Integrity Bureau/ Kang Daejin	Shin Yongjoo Jeong Mihee Han Taehee
2. Strengthening Safety in Food Production and Manufacturing Safety		
1) Establishment of a Basis for Food Manufacturing Safety	Food Safety Labelling and Certification Division/ Jwa Jung Ho	Kim Se-hwan Kim Mi Ja Jeon Dae-hoon
	Food Safety Management Division/ Kim Myeong Ho	Kim Sung Il Sun Nam Kyu
2) Safety Management of the Production and Distribution of Agricultural, Livestock and Fishery Products	Agro-Livestock and Fishery Products Safety Division/ Yang Chang-sook	Cho Tae-Yong Yu Mungyun Cho SoungHun Lee Moon-hong
3. Enhancing the Safety Management of Foods Being Distributed·Consumed	Food Safety Management Division/ Kim Myoung Ho	Kim Sung Il Sun Nam Kyu
	Food Safety Labelling and Certification Division/ Jwa Jung Ho	Kang Seung-keug Jeong Jinmok
4. Strengthening the Safety Management Systems of Imported Foods		
1) Strengthening Inspection and Management of Imported Foods	Imported Food Policy Division/ Kim Sung-Gon	Oh, Jae Joon Kim, Myung Hee
2) Strengthening of On-Site Inspection in Exporting Countries for Precautionary Safety Management	On-site Inspection Division/ Choi Soon-Gon	Jung Young-Ae Park So-Young
3) Reinforcing Safety Management of Novel Foods including Genetically Modified (GM) Foods	Novel Food Division Kang Yun-sook	Lee Woo-young Jang Mi-ran Shin Ji-eun
	Imported Food Policy Division/ Kim, Sung-gon	Jang, Hwa-jong Min, Seon-mi

Contents	Division / Director	Contributors
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 Kim Chun Soo
	Residues and Contaminants Standard Division/ Son Seong Wan	Byun Seong Keun Yune So Young
2. Improving and Reinforcing Standards and Specifications on Food Additives, Equipment, Containers and Packaging	Food Additives Standard Division/ OH Jae-Ho	Park Sung Kug Lee Jisun
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1. Strengthening Food Safety Management		
1) Expansion of the Management of Meal Service Sanitation and Nutrition	Life Safety Division/ Jung Jinee	Hwang Sun-soon Choi Woo-Jeong Lee Sung-Hak
2) Strengthening Safety Management of Children's Food		Lim Ji-Yeoun Jeong jeong-soon
2. Reduction of Food Poisoning through Development of a Safe Eat-out and Meal Service Environment	Foodborn Disease Prevention& Surveillance Division/ Kim, Yong-Jae	Kim, joo-Won Kim, Hack-Su
3. Improving the Regulation of Health Functional Foods and Invigoration of the Market	Health Functional Food Policy Division/ Hong, Heon-woo	Shin Seung Chul Hong, Jeong-Mi
4. Strengthening of Safety Management of National Nutrition		
1) Expansion of National Movement to Reduce Sodium and Sugar Intake 2) Induction of Proper Sodium Intake 3) Expansion of Nutrition Labeling and Provision of Nutrition Service	Nutrition Safety Policy Division/ Jung Jinee	Yoon Eun Gyeong Lee Soon Ho Yoon Tae Hyeong Lee Si Young Shin Yeong Hee
Ⅲ. Medical Products		
Chapter 1. Medicine		
1. Introduction and Stabilization of GMP that is in Harmony with International Standards	Pharmaceutical Quality Division/ Chung Myeong-Hun	Park Yeon Sim 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 Eun-hee Song Ju-kyoung
2) Efforts for International Harmonization of Pharmaceutical Evaluation	Pharmaceutical Policy Division/ Sang-Bong Kim	Pan-soon Kim Sun-im Park Mi-Kyoung Kim
3) Advancement of Pre-and Post-Management System of Clinical Trials	Clinical Trials Management Division/ Lee Nam-hee	Lee sung-doo Nam Tae-kyun Jeong ho Lee Cheol-seung

Contents	Division / Director	Contributors
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	Lee Sun-Hee Kim Min-woo
2) 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
3) Adverse Drug Reaction Relief System		Kim Sang hyun Lee Kyeo re
4. Strengthening the Competitiveness of the Pharmaceutical Industry by Stable Operation the Patent-Regulatory Approval Linkage System	Pharmaceutical License and Patent Division/ Ok Gi-Seok	Kang Yeong A Kim Min jo Heo Kyung moo
5. Establishment of a Management System for Preventing Abuse and Misuse of Narcotic Drugs	Narcotics Policy Division/ Kang Seok-youn	Kim Kwang-jin Seong Dong-cheon Kim Ik-sang Park Gong-soo Kim Bok Yeon Shin Myung-in
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2. Safety Management of Herbal and Natural Medicine Background	Herbal Medicine Policy Division/ Kim Young-woo	Hwang Sun-yi Seo Dong-hoon Yoon Hae-seok
3. Consumer-Centered Safety Management of Cosmetics and Quasi-Drugs	Cosmetics Policy Division/ Kwon Oh Sang	Lee Seung Chul Lee Jung Hwa
	Quasi-Drug Policy Division/ Ahn young jin	Sung Joohee Kim Dae-Ki
4. Realizing the Creative Economy to Support Korean Biopharmaceutical Industry's Advancement into the Global Market	Biopharmaceutical Policy Division/ Kim Young-ok	Kim Namsoo Chae Jooyoung
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2) Improving the Approval·Evaluation System and Leading the International Standards for Biopharmaceuticals and Herbal Medicine·Cosmetics, Etc.	Biologics Division/ Chung Hye-joo	Jee Seung-wan Lim Jong-mi
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2. Strengthening Consumer-Centered Medical Device Safety Management System	Medical Device Management Division/ Ju Seon-tae	Lim Jae-gwi Ko Joon-young
3. Establishment of a Safety Evaluation System for Medical Devices	Medical Device Safety Evaluation Division/ Yu Hee-sang	Park Joo-hwan Kim Se-jung

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IV. Risk Prevention		
Chapter 1. Establishment of a Basis for Consumer-Focused Preemptive Risk Prevention and Crisis Response System		
1. Establish Roadmap for R&D on Safety Technologies for Food and Pharmaceuticals	Customer Risk Prevention Policy Division/ Jang Min-su	Moon Byeong-ho Lee Geum-yong
2. Establishing a Basis for Preventing Safety Accident		Jang In-seong Im Yeong-in
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5. Strengthening the Cooperative System on Food and Drug Safety Issue Between MFDS - Korea Consumer Agency		Kim Jeong-han
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1. Expanding Communications with the Public	Communication and Cooperation Division/ Ahn Gwang-su	Park Nam-Su Park Na-Young
2. Building and Facilitating Communication Network		Baek Nami
3. Operating Experiential Programs for the Public		Lee Ju-Kyung Lee Hai-Eun
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V. Research and Development for Food and Drug Safety		
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1. Advancement of Food and Drug R&D	Research Planning and Management Division/ Kim Mi-jeong	Mun Chun-sun Kang Jin-wook Kim, Mi-ra
2. Impartial Research Management and Provision of Services for Researchers	Research Management TF/ Park Ki-suk	Lee Seon-hwa Kim Min-sik
3. Effective Outcome Management for Research and Development Projects	Research Planning and Management Division/ Kim Mi-jeong	Roh Hye-won Lee Min-hwa 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/ Koo Yong-eui	Moon Gui-im Cho Yoon-jae Suh Jin-hyang

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3. Strengthening the Scientific Basis for Reducing Hazardous Contaminants in Food	Food Contaminants Division/ Kang Gil-jin	Kim Sheen-Hee Kang Young Woon
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/ Kim Mee-kyung	Choi Jae-chon Lim Ho-soo
6. Establishing a Basis for Managing the Safety of Food Nutrition, Dietary Life and Functional Health Foods	Nutrition and Functional Food Research Team/ Oh Keum-soong	Lee Hwa-jung Kang Yoon-jung
7. Strengthening Scientific Surveillance of Food Alteration and Food Fraud	New Hazardous Substances Team/ Kwon Ki-sung	Choi Jang-duck Kang Tae-sun
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1. Advancement of the Basis of Medical Products Safety Management	Drug Research Division/ Shin Won	Lee Kwang-moon Kim Sun-hee
2. Research on Pharmaceutical Safety Management	Drug Research Division/ Shin Won	Lee Kwang-moon Kim Sun-hee
3. Research on Biopharmaceutical Safety Management	Biologics Research Division/ Chung Ja-young	Kim Byung-guk Kang Hyun-kyung
	Advanced Therapy Products Research Division/ Ahn Chi-young	Eom Joon-ho Baek Joung-hee
4. Research on Chinese (Herbal) Medicine Safety Management	Herbal Medicine Research Division/ Lee Hyo-min	Shim Young-hun Hyeon Seong-ye
5. Research on Cosmetics and Quasi-Drugs Safety Management	Cosmetics Research Team/ Choi Ki-hwan	Min Chung-sik Lee Rhee-da Kim Sang-seop
6. Research on Medical Devices Safety Management	Medical Device Research Division/ Park Chang-won	Lee Seung-ro
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2. Development of Alternatives to Animal Testing and Advancement of Non-Clinical Tests	Toxicological Screening and Testing Division/ Lee Jong-kwon	Kim Joo-hwan Ahn Il-young
3. Research on Predictability of Drugs and Assessment of Pharmaceutical Dependence	Pharmacological Research Division/ Kim Hyung-soo	Kim Young-hoon Shin Ji-soon
4. Securing Public Health and Safety through Advancement of Clinical Evaluation and Reduction of Adverse Events	Clinical Research Division/ Choi Seung-eun	Oh Woo-yong Lee Jong-gu
5. Preventing Adulterated Food and Drugs through an Advanced Analysis System	Advanced Analysis Team/ Baek Sun-young	Park Sung-kwan Park Hyoung-joon

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