보다 나은 정부

2018
Ministry of Food and Drug Safety
White Paper

Ministry of
Food and Drug Safety

Foreword

The Moon Jae-in administration which came into office in May 2017 makes the safety and health of the people its highest priority. The Ministry of Food and Drug Safety also gives its best efforts to protect food and medicine which serve as the basis for people's lives.

A Cyber Investigation Team was created to combat the illegal sales of food and medicine online. And the Ministry of Food and Drug Safety introduced the National Petition Safety Inspection System under the catch phrase of "If the people want, the Ministry of Food and Drug Safety will perform an inspection".

Through the Women's Health Reassurance Project, the safety of women's items such as tampons and other women's sanitary products is enforced and more information is provided, which in turn results in a concensus from women and civic groups.

Also, to enable advanced bio medicine and converged medical devices to quickly make their way to the market we have streamlined regulations not related to safety and actively listened to the opinions of consumers, business professionals and others. We are overcoming obstacles and striving for the pharmaceuticals and medical device industry in Korea to position itself as a growth engine in the 4th Industrial Revolution.

Moving forward, the Ministry of Food and Drug Safety promises to do its utmost to secure the health and safety of the people. I hope that this white paper can become useful material in understanding policies for food and drug safety.

July 2018

Minister of the Ministry of Food and Drug Safety, RYU YOUNG JIN

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Outline

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1. Vision·Objective·Core Strategies

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

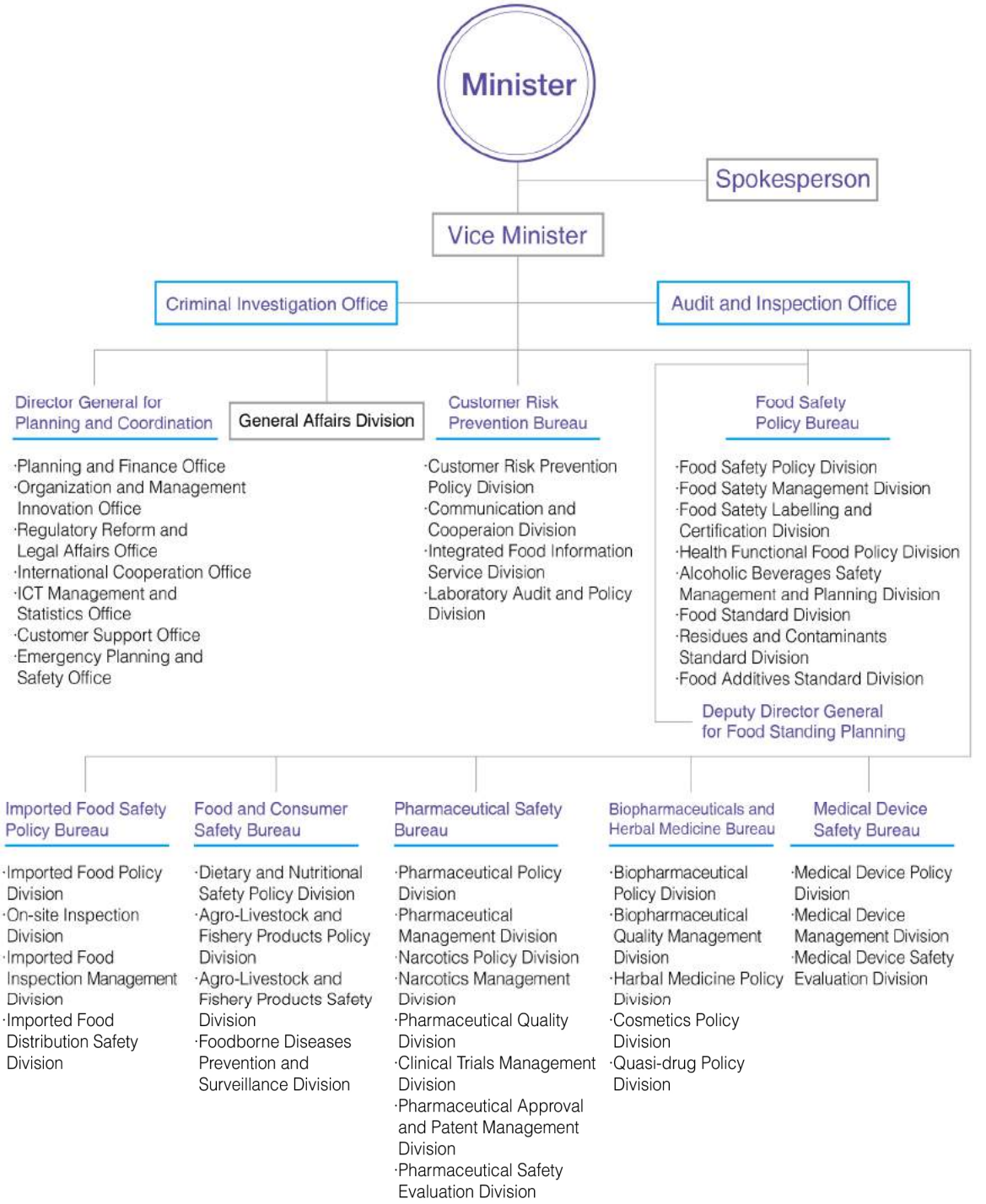
Customized Promotion

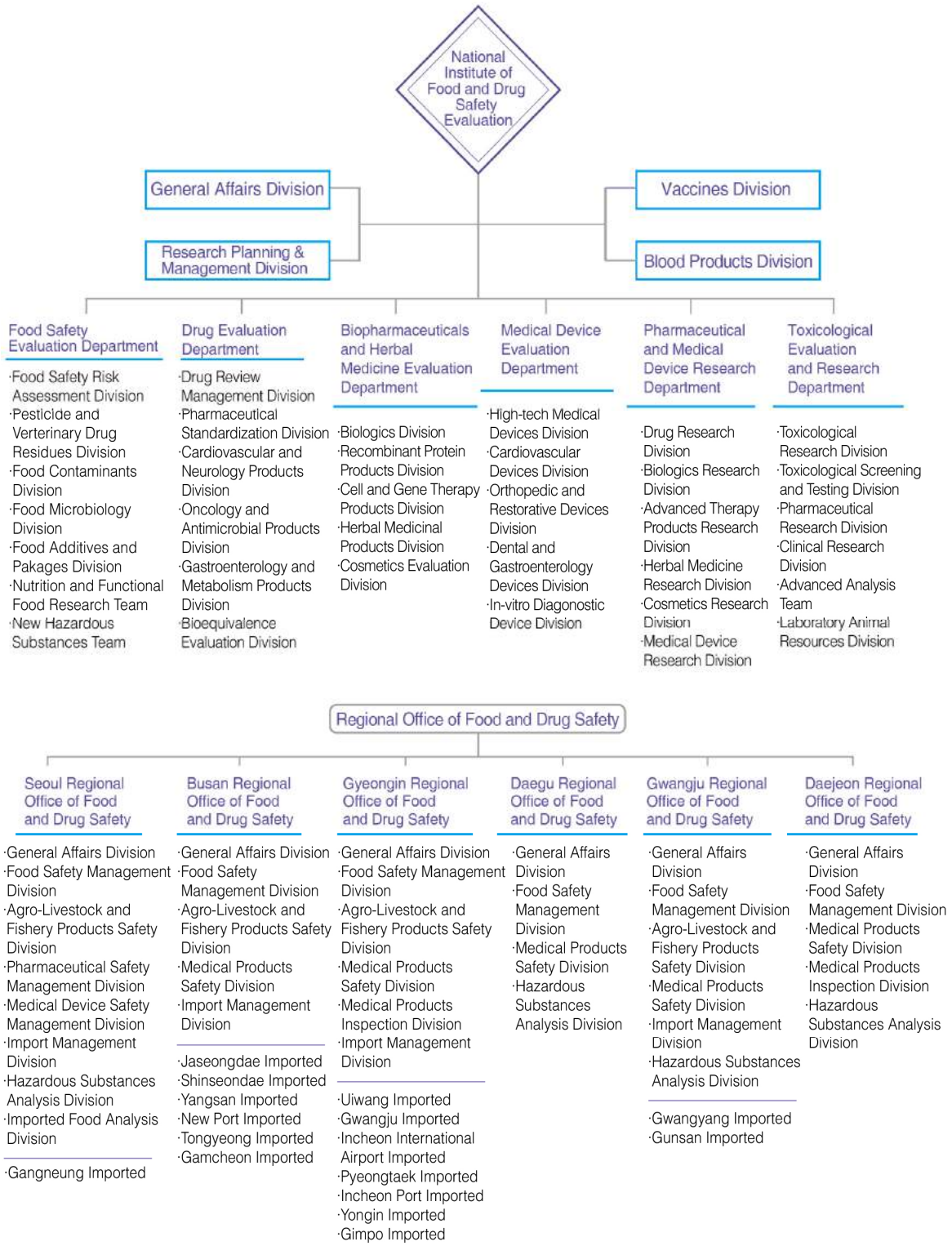
Experiential Marketing

Participatory Promotion

Implement a Government-guaranteed food safety system	01 Proactive safety management for agricultural, livestock and fishery products 02 Enhance management of changes in food trends 03 Improve food safety management system
Prevent anxiety factors in daily life	01 Establish management system for hazardous substances and products 02 Strengthen safety management of food and medicine for the vulnerable 03 Expand the public participation and communication
Improve the publicity of medicine, etc.	01 Improve the publicity through user-centered safety management 02 Strengthen safety management for from ingredients to side-effects 03 Improve the safety management system for drugs and medical devices
Lead innovative growth with customized regulations	01 Create an innovative regulation ecosystem for the 4th industrial revolution era 02 Provide strategic support for global market entry

2. Organization·Affiliated Organizations




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

3. History

2018.03 Establishment of Gimpo Imported Food Inspection Center

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 Planning, 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 Fool (transferred of 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 Dicision 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 Pyeongteak 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 Establishment 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 Airprt (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

2018 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 a Pan-governmental System for Eradicating Unwholesome Food

1) Background

With the increased need for recognizing 'food management' as a core value in order to safeguard people's lives and their right to pursue happiness, the government has designated food safety as a core governmental task to realize a 'safe community where people lead a happier life'.

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

The Ministry of Food and Drug Safety (MFDS) has effectively carried out governmental tasks to build a safe ecosystem for food, remove blind spots within through communications between departments of the government, and expand public participation to strengthen continuous monitoring. By doing so, MFDS has actively improved the system in order to prevent recurrence of and solve the root cause of issues related to unwholesome food. MFDS is striving to boost the collaborative system for information sharing and feedback between departments through 「Pan-governmental Council for Eradication of Unwholesome Food」. MFDS, as a control tower of food and drug security in Korea, strives to provide a sense of security to individual citizens through focused and centralized management of department-wise capabilities pertaining to health and wellness.

B. Achievements Related to Pan-governmental Eradication of Unwholesome Food

1) Implementation of Pan-governmental Joint Planning Surveillance and System Improvement

A) Operation of a Pan-governmental Joint Monitoring System

The MFDS Task Force for Eradicating Unwholesome Food considers food safety-related issues as problems of public safety, the basis for public happiness. Hence the Task Force collaborated with other ministries and came up with a comprehensive plan in order to root out 'unwholesome food', which has been a factor of anxiety for people over the last five years. In order to prevent any blind spots in the management for hazardous factors in all stages from production, to manufacturing·processing·import, and to distribution·consumption, the Task Force had to secure the driving force for rigorous management of the virtuous cycle in the same direction as prevention of vulnerable factors in safety. For this purpose, it conducted pan-governmental joint planned surveillance in the areas of national concern and social interests such as areas related to hygiene and vulnerabilities by analyzing clients and tracing and cracking down on serious offences including violation of expiration dates.

B) System Improvement for Eradicating the Root Cause of Unwholesome Food

In order to eradicate unwholesome food, it is necessary to identify the cause of frequent illegal activities and prevent recurrence through fundamental system improvement. Therefore, based on the results of planned surveillance, MFDS identified and carried out system improvement tasks such as amendment of laws and ordinances to solve the root cause of unwholesome food.

In view of the increasing incidence of deceptive behaviors such as attempts to sell inedible food and presenting imported agricultural products as local produce, Korea Customs Services revised the 「Notification on Management of Distribution Track Record after Customs Clearance」. Based on several requests, three items including inedible imported anchovies (executed on Aug.1, 2017), oilfish, and inedible bee pollen (executed on Oct.1, 2017) were listed and managed in the Management of Distribution Track Record after Customs Clearance.

C) Advanced Information Analysis for Food Safety Issues

Through monitoring sales trends by food purchase route, items with increased consumption, and consumption patterns, MFDS identified 20 cases having potential hazardous factors (frozen marine products with suspected illegal weight, non-edible plants fraudulently presented as edible items, etc.). It also designated staff in charge of analyzing civil complaints through 1399 reports (calls made to 1399 to report fraudulent/illegal foods) and information from media at home and abroad and had them report the analysis results on a daily basis to utilize about 3,000 cases as clues for planned surveillance.

In addition, MFDS dispatches monthly and yearly analysis reports (through collection and analysis of information on a total of 39,992 cases) to relevant institutions (41 institutions) by analyzing and assessing occurrence pattern and trends related to unwholesome food, cause of occurrence, hygiene blind spots and areas of high consumer interest. It also conducted six rounds of interviews to collect opinions from personnel in charge of sanitary inspection for convenience foods during the production and distribution stages as well as inspection of ingredients and half-finished goods supplied to convenience stores.

In addition, MFDS set up a hotline for governmental bodies to ensure a one-voice communication with people, to avoid confusion from different opinions between departments, amplification of issues or spreading of rumors.

D) Resolving public inconvenience with an effective central crackdown system

Since July 2013, MFDS has integrated the Defective Food Call Services (1399), which had been operated separately by 17 municipalities nationwide, into the 'Integrated Unwholesome Food Reporting Center' in order to quickly and accurately identify adulterated food and conduct investigations. By doing so, it was possible to eliminate the cause of unwholesome food and establish a system to prevent the distribution of hazardous food.

From Aug. 2016, in an effort to deal more strictly and thoroughly with the complaints received by the Integrated Unwholesome Food Reporting Center (1399), the central crackdown team under Task Force for Eradicating Unwholesome Food was significantly strengthened and expanded (9 → 24 persons). The team operates a one-stop support platform offering services from field survey to the recovery of hazardous food based on the complaints and reports from people to address five major issues including whistleblowing, forgery of expiration date and false hypes. As a result of these efforts, the period for processing those reports have been drastically shortened (25.3 days/case on average in 2015 → 7 days/case in 2017) compared

to the past when the local governments were in charge, thereby securing public trust in the reporting window. At the same time, the detection rate of violations has also increased to 46.3% in 2017 from 16.7% in 2015, revitalizing public participation through increased reports on adulterated food, etc.

E) Public relations activities for food safety that people can relate to

Through various public relations media, MFDS carried out campaigns for encouraging people to report unwholesome food and creating an atmosphere of safe food. MFDS also organized low-cost high-efficiency promotional activities in cooperation with other governmental departments (Ministry of Culture, Sports and Tourism, Ministry of Agriculture, Food and Rural Affairs, Korean National Police Agency, and etc.). In addition, through a private-public cooperative 「Safe Food」 campaign, MFDS has also provided information closely related to people's diet, contributing to developing a sense of confidence in food.

F) Practical education tailored for producers and customers

MFDS has implemented integrated and customized practical safety education for producers and customers on how to select safe food and reduce sugar and sodium. The training covers topics such as eradication of unwholesome food, false advertisement·hype, prevention of food poisoning, HACCP, etc.

In addition, MFDS regularly conducts nation-wide joint crackdowns (MFDS with police, local governments, and citizen watchdogs) and actively helps senior citizens to report illegal real estate brokerage activities focusing on false advertisement·hype. MFDS also operates booths to track real estate transactions of those illegal brokers (in 278 senior's welfare centers and 245 branch offices of The Korean Senior Citizens Association).

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2. Strengthening of Safety of Food Production·Manufacturing

A. Establish Safe Food Manufacturing Infrastructure

1) Facilitation of the Standards of Food Safety Management Accreditation (HACCP)

A) Background

Korea established the regulation on Hazard Analysis and Critical Control Points in 「Food Sanitation Act」 in 1995 and introduced the HACCP system by through enactment of the 「Hazard Analysis and Critical Control Point」 in 1996. Furthermore, in August 2003, six items including fish cakes were designated as mandatory HACCP-applied items[1] (Kimchi cabbage was added in Dec. 2006), and the HACCP system was enforced from 2006 to 2014 in multiple phases, based on annual sales and the number of employees in business entities.

In May 2014, 8 items including kids' favorite foods were added in the list of mandatory HACCP-applied items[2] and mandatory HACCP application on these items is being implemented phase-by-phase from 2014 to 2020, based on the annual sales and number of employees as determined in 2013.

HACCP application became mandatory for livestock slaughter business in January 2001, milk collection and diary processing business in 2014 (in 4 stages from Jan. 2015 to Jan. 2018), and processed egg industry in 2016 (in 2 stages from Dec. 2016 to Dec. 2017). In 2017 when pesticide-tainted eggs were detected, MFDS newly established an edible egg packaging system and designated it as a mandatory HACCP-applied item in order to enhance sanitary quality of egg distribution & management system. Further, mandatory HACCP application on processed meat product businesses dealing with ground processed meat (such as hamburger patties, etc.), etc. will be enforced from 2018 to 2024 in multiple phases based on annual sales.

B) Achievements

The Korea Institute for Food Safety Management Accreditation (KIFSMA) was established (Feb. 13, 2017) by integrating individually operated HACCP certification organizations, to unify

1) Processed fish products (fish cakes), Frozen marine products (fish, invertebrates, flavor-treated processed products), Frozen food(pizza, dumplings, noodles), Ice-creams, Non-pasteurized beverages, Retort food products, Kimchi cabbage

2) Snacks·Candies, Breads·Rice cakes, Chocolates, Fish sausages, Beverages, Instant foods, Noodles, Instant fried noodles, Special purpose foods

the HACCP certification process, efficiently carry out HACCP-related tasks, and alleviate inconveniences to businesses.

[Table 2-1-1] Management system including HACCP certification of food and livestock products and follow-up management

(As of Dec.31, 2017.12.31, Unit: 100 million/business entity, Ref: Food Safety Labelling and Certification Division)

Category	Certification	Follow-up Management
Food HACCP	(Mandatory and Voluntary) KIFSMA	(Mandatory and Voluntary) Regional FDA
Livestock HACCP	(Mandatory) Certified when approved by local governments as is required by the HACCP system	(Mandatory) Regional FDA Quarantine Agency
	(Voluntary) KIFSMA	(Voluntary) KIFSMA

※ Tasks including HACCP certification on livestock slaughter businesses, milk collection businesses, and farms were commissioned to the Ministry of Agriculture, Food and Rural Affairs.

In order to stabilize HACCP certification of food and livestock manufacturing businesses, expand voluntary participation in HACCP application and support smooth HACCP certification of small businesses, the Korea Institute for Food Safety Management Accreditation provides various supports including customized technical assistance for businesses that are willing or are required to apply HACCP, technical assistance for HACCP operation, training and promotion. As a result, the number of HACCP-certified businesses has significantly increased from 4,487 in 2010 to 17,152 in 2017.

☆ Manufacturers: Food (Food manufacturing and processing businesses), Livestock(Livestock processing businesses, milk processing businesses, meat processing businesses, egg processing businesses, and meat packing businesses)

[Table 2-1-2] HACCP Certification Status

(As of Dec.31, 2017; Unit: business entity (cumulative), Ref.: Food Safety Labelling and Certification Division)

Category	2010	2011	2012	2013	2014	2015	2016	2017
Total	4,487	5,851	8,161	10,461	12,024	13,991	15,566	17,152
Food	797	1,163	1,809	2,408	3,029	3,734	4,358	5,031
Livestock	3,690	4,688	6,352	8,053	8,995	10,257	11,208	12,121

In order to strengthen follow-up management of HACCP, with the revision of the 「Food Sanitation Act」 in August, 2015, MFDS introduced a regulation that allowed immediate cancellation of HACCP certification for businesses that either received less than 60% in the

periodic inspection/assessment, don't abide by the food safety standards, acquired HACCP certification by unlawful means. After the regulation was introduced, MFDS canceled HACCP certification of 35 businesses by the end of June 2017.

Also, after the revision of the 「Food Sanitation Act」 in February, 2016, MFDS introduced a regulation to set an expiration date for HACCP certification and make it mandatory for businesses to undergo a re-examination every 3 years. This regulation has been effective since August, 2016 and in this period MFDS completed an examination of a total of 4,633 business entities (1,971 food items, 2,662 livestock products) for extension of certification,

In addition, MFDS conducted TV publicity and events for terrestrial and cable broadcasting, and increased the number of broadcasting exposures while determining the method of publicity by age. MFDS also continues to actively promote the HACCP system with consumer groups and food-related associations.

[Table 2-1-3] Consumer Awareness of the HACCP System

(As of Dec.31,2016, Unit: %, Ref.: Food Safety Labelling and Certification Division)

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

※ As per the National Assembly's comment (the awareness survey is conducted every 2 years), the survey was not carried out in 2013, 2015.

C) Implementation plan

(1) Expansion of Mandatory HACCP Application and Strengthening of Certification Management to Promote the HACCP System

Starting from 2018, mandatory HACCP certification will be applied to edible egg packaging businesses (enforced in April 2018) and meat processing businesses in a phased manner. In view of the detection of pesticide-tainted eggs in August 2017, veterinary drugs (pesticides, etc.) and agricultural pesticide (herbicide, etc.) will be added* in the HACCP evaluation items, and more evaluation items for other animal species (cows, pigs) will also be added for strengthening HACCP certification management.

☆ Chicken & Duck HACCP Farms: evaluation items were added to check the use of pesticides and determine whether there are residual substances (MFDS Notification No.2017-80, Oct.27, 2017)

[Table 2-1-4] Mandatory HACCP Application Status of Foods with Expanded Mandatory HACCP Application

(As of Dec.31, 2017; Unit: business entity, %, Ref.: Food Safety Labelling and Certification Division)

Plan for Expanding Mandatory HACCP Application

Category	Enforcement Date	Size of Industry Subject to Implementation	Number of Businesses
Convenience foods, 8 categories of kids' favorite foods (7,698 businesses)	Dec.1, 2018	With annual sales more than 100,000,000 won and number of employees more than 6	984
	Dec.1, 2020	With annual sales less than 100,000,000 won or number of employees less than 5	5,620
Meat packaging industry (2,276 businesses)	Dec.1, 2018	With annual sales more than 2,000,000,000 won	114
	Dec.1, 2020	With annual sales more than 500,000,000 won	348
	Dec.1, 2022	With annual sales more than 100,000,000 won	697
	Dec.1, 2024	Other businesses	1,117

◈ Edible egg packaging business (The Livestock Products Sanitary Control Act was amended on Oct.24, 2017, Enforcement date: Apr.25, 2018) has been newly established as a business and HACCP-certification made mandatory

(2) Enhancing HACCP Follow-Up Management (periodic inspections·assessment)

In order to strengthen the management of HACCP farms, which are commissioned by the Ministry of Agriculture, Food and Rural Affairs, MFDS plans to introduce random assessments without notice throughout the year and establish grounds for immediately canceling the certification of farms that violate specifications on residual material.

(3) Strengthening HACCP Support Projects

To ease the burden of small manufacturing enterprises that are subject to mandatory HACCP-application, MFDS provides technical support for HACCP certification and operation of those businesses through the Korea Institute for Food Safety Management Accreditation (KIFSMA). In addition, MFDS will do its best to enhance the role of KIFSMA and strengthen HACCP examiners' competence in order to ensure the reliability of HACCP certification.

(4) Strengthening Public Relations to Improve Customer Awareness of the HACCP system

For proper implementation of the HACCP system, it is necessary that the general public to recognizes the superiority of HACCP-certified food and purchase it directly, thereby inducing the voluntary participation of the food manufacturing/processing industry. As there are

increasing needs to promote the HACCP system to the public, the government will expand its customized advertising not only for TV commercials but also for consumers and industries.

2) Management of Foreign Substances in Food

In order to promptly take measures as necessary to investigate and deal with consumer complaints regarding foreign objects in food and to resolve distrust disputes between food businesses and consumers, it is mandatory to report any foreign substances detected in food to the Ministry of Food and Drug Safety and to the Si/Gun/Gu office having jurisdiction over the area where the complainants are located at the time of reports.

In 2017, there were was 3,236 reports on foreign matters found in food, and the foreign substances reported included worms (29%), mold (11.5%), metals (9.4%) and plastics (8.5%).

[Table 2-1-5] Foreign Substance Report Status by Year

(As of Dec.31, 2017, Unit: Case(%), Ref. : Food Safety Management Division)

Year	Total(Number of cases)	Reported by businesses	Reported by customers
2013	6,435	3,407 (52.9%)	3,028 (47.1%)
2014	6,419	3,178 (49.5%)	3,241 (50.5%)
2015	6,017	2,993 (49.7%)	3,204 (50.3%)
2016	5,332	2,346 (44.0%)	2,986 (66.0%)
2017	3,236	1,048 (32.4%)	2,188 (67.6%)

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

1) Background

As there is only a limited number of ways to reduce or eliminate hazardous elements associated with agricultural, livestock, and fishery products at the production and distribution stages, chances are high that hazardous elements are delivered to the end consumer if it is

not blocked at the production stage including cultivation, breeding, farming, etc.

Therefore, preventive safety management during the production stage is very important to eliminate hazardous elements at the production stage. Furthermore, safety inspection on lands, water, and materials that are used for agricultural, livestock, and fishery products should be conducted in a systematic way.

2) Achievements

A) Safety Management of Agricultural Products

As part of efforts towards safety management of agricultural products conducted in 2017, 135,156 commonly consumed items that were frequently found to be not compliant, and transacted in the public wholesale markets, were inspected for pesticide residue and heavy metals, etc. Among the inspected items, 2,134 cases (1.6% of the total number of inspected items) were found to exceed the permitted limit. Measures such as deferment of shipment and disposal of those products were taken on those items.

Also, 52,828 commonly consumed agricultural products that were frequently found to be not compliant during distribution·sales stages were investigated for pesticide residue, heavy metals, sulfur dioxide, etc. and 599 non-compliant items (1.1% of the total number of inspected items) were identified and disposed of.

MFDS has concentrated its safety management efforts on hazardous items in food such as agricultural products to be supplied to children' meal services when the schools begin, local specialty agricultural products, agricultural products for holidays and gifts, seasonal agricultural products that are commonly consumed, etc. In particular, inspection of agricultural products in the public wholesale market, which is the distribution channel of agricultural products, was strengthened to prevent the distribution of inappropriate agricultural products in advance.

In addition, to prevent illicit distribution of agricultural products that cannot be used as food, MFDS also intensified its safety management on the blind spots by conducting inspection of 397 places including food retailers in the top 5 herb medicine markets in Korea and monitoring 1,138 online distributors and sales companies such as online shopping malls, blogs, etc.

To relieve the rising public anxiety over Japanese products as well as domestic foods in the aftermath of the nuclear disaster in Fukushima, MFDS inspected radiation level of 503 agricultural products such as green onions and cabbages grown outdoors at production stage and 3,203 agricultural products distributed in domestic markets, such as onions and carrots at distribution·sales stages to find none with excessive levels. Information on agricultural

products with a trace of radiation below the standard level were also transparently provided to the public through the MFDS website and mobile apps, etc.

On the other hand, regular and planned safety inspection during the production stage, which was commissioned to the Ministry of Agriculture, Food, and Rural Affairs, was conducted on a total of 82,328 non-conforming agricultural product items to detect pesticide residue, heavy metals, and fungi toxins. As a result, 1,535 (1.9% of the total number of inspected items) non-conforming agricultural products with excessive levels were blocked from distribution·sales through measures such as postponement of shipment, change of use, and disposal.

In addition, information on non-complaint agricultural products at production and distribution stages were analyzed and shared with relevant organizations such as the Ministry of Agriculture, Food and Rural Affairs and the local governments on a monthly basis. This information was used to provide safety management and guidance·training for producers (groups), contributing to creating a safe environment for agricultural products.

B) Safety Management of Livestock Products

Safety inspections·investigations on livestock products were carried out for a total of 396,702 items including 370,838 items in the production stage and 25,864 in processing·distribution stages. For items in the production stage, inspections were focused on slaughterhouse (meat) and dairy farms (raw milk).

Residual substance tests on meat were also carried out by 17 cities (Si) and provincial (Do) level livestock testing·inspection agencies for a total of 148,542 livestock products including beef, pork, chicken, duck, lamb (goat meat) and horse meat to check for a total of 156 toxic substances including 41 types of antibiotics, 58 synthetic antibacterial products, 3 hormone drugs, 7 other medicinal products, and 47 types of agricultural pesticides. The tests revealed that 522 out of 148,542 livestock products had residual substances at levels in excess of the allowed range (the violation rate of residual substance was 0.35%). Preventive measures such as restriction of shipment and postponement of release were imposed on the non-compliant farms in question.

Also eggs from 7,377 farms (including overlapped farms) were collected and inspected for 78 residual substances including antibiotics, synthetic antibacterial products, pesticides, etc. A total of 40 cases including quinolones (8 cases) and pesticides (32 cases) such as fipronil were detected (the violation rate of residual substance was 0.05%) and preventive measures such as postponement of release were taken.

Along with investigations on the hygiene management of livestock facilities, microorganism tests on meat products were carried out at slaughter houses (111,483 cases), meat packing facilities (2,097 cases) and meat stores (4,002 cases) in order to examine the sanitary status of meat. The inspections identified 117 cases (0.1%) exceeding the recommended level. Safety management measures such as cause analysis and technical guidance for reducing microbial contamination were taken for facilities that failed to meet the recommended standards. MFDS also collected and inspected 19,216 items at distribution stage including processed livestock products; 87 cases (0.5%) were found to be non-conforming to standards and specifications, and measures such as withdrawal·disposal of the products and administrative measures against the concerned business operators were taken.

In particular, since insecticides were detected in edible eggs, lot tests were conducted for all egg farms (1,239 cases), and eggs (1,337 cases) at distribution stage were collected and tested. As a result, 76 non-compliant farms that violated residual substance standard were identified, and follow-up surveys were carried out to withdraw·dispose of the inedible eggs. Furthermore, pre-shipment inspection was conducted for eggs produced at the non-conforming farms, securing the safety of eggs being distributed.

C) Safety Management of Fishery Products

In 2017, a total of 26,814 commonly-consumed fishery products (by producing area, item, and season) that have a history of non-compliance were tested for animal medicines, heavy metals, shellfish toxins, Vibrio parahaemolyticus, Norovirus, etc. and 260 items were found to have exceeded standards. Measures such as restriction·postponement of shipment, withdrawal·disposal and administrative measures were taken on the non-compliant products to secure food safety.

At the distribution·sales stage, 13,038 domestic aquatic products with high consumption and frequent non-compliance histories were collected and inspected. As a result, 68 cases with excessive animal medicine and heavy metal content were found and appropriate measures including withdrawal and disposal of those products were taken. Especially, in order to strengthen management of radiation-related safety for marine products distributed in the domestic market, MFDS selected the items that are commonly consumed or frequently raise safety concerns as the main target for safety management. Radiation tests were carried out on 6,431 fishery products such as pollack, mackerel, Pacific saury, hairtail, Japanese Spanish mackerel, and seaweeds. All test results were confirmed to be safe, and were shared transparently through the MFDS website and mobile apps.

Also, MFDS 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. In addition, in an effort to protect people from food poisoning, MFDS has established a Vibrio vulnificus prediction system that predicts the occurrence of Vibrio vulnificus using marine environment factors.

Furthermore, MFDS commissioned safety inspections during the production stage to the Ministry of Maritime Affairs and Fisheries. Accordingly, 13,776 items including flatfish, eels, blue mussels, sharks, catfish, etc. were tested for heavy metals, antibiotics, toxins, vibrio parahaemolycius, dioxins and radioactivity. As a result, a total of 192 cases, including 121 cases of non-conforming marine products with excessive levels of hazardous substances and 71 cases having excessive shellfish toxins, were detected and measures such as postponement of shipment, prohibition of change of use·disposal·shipment (collection), etc. were taken in order to prevent their distribution·sales in advance.

3) Implementation Plan

A) Safety Management of Agricultural Products

In 2018, MFDS will carry out safety inspections on 113,580 agricultural products including hazardous·concerned·vulnerable items.

In an effort to safely manage agricultural products at distribution·safes stages, MFDS will designate top 15 hazardous·troublesome items that are most commonly consumed and have repetitive histories of non-compliance as subjects for special management. A total of 45,000 items distributed in the public wholesale markets will also be collected and tested.

For management of safety from radiation, which is a major concern for the public, MFDS plans to conduct radiation test on 2,400 items that are being produced·distributed in Korea including the most commonly consumed items such as rice and potatoes, and agricultural products cultivated outdoors such as chili peppers, cucumber, etc.

MFDS will also provide guidance·inspection to prevent the illegal distribution of agricultural products that cannot be used as food, and continue its education drive to protect consumers. As more and more fresh agricultural products are being distributed·sold online, MFDS is going to intensify guidance·inspection of the distribution centers belonging to online shopping malls.

Meanwhile, for managing the safety of agricultural products at production stage, which has been commissioned to the Ministry of Agriculture, Food and Rural Affairs, a total of 68,580 items will be tested for heavy metals, pesticide residue, pathogenic microorganisms, and

radiation, including 16,200 items for preventive safety survey according to vulnerability·period and occurrence of safety issues occur. Further, 15,930 items will be subjected to residue inspection to evaluate their safety level and toxic substance survey for their agricultural and growing conditions.

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 in order to re-evaluate the overall inspection subjects, volumes, and items. MFDS engages in consultations with these entities and reflects the results in the safety inspection plan for 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 the domestic market, with special focus on the items that have been reported non-compliant many times. Meanwhile, with regard to regulatory inspections on meats with high possibility of violating the permissible limit of residual substances, MFDS plans to increase the number of inspection items from 29,300 to 30,000 taking the violence rates into account. MFDS will also carry out a pilot survey to introduce and operate the National Residue Program (NRP) for milk.

In addition to the regular product collections·inspections, MFDS will focus its monitoring on livestock processing facilities that have non-compliant histories based on their own self-quality tests, and carry out special monitoring for false advertisements and hypes on the internet in order to preempt food accidents caused by hazardous substances.

C) Safety Management of Fishery Products

In 2018, in an effort to guarantee sustainable management of the safety of fishery products in poor sanitary conditions, MFDS will strengthen its safety survey, guidance·training for fish farms with a history of non-compliance or of being detected for safety issues on account of using banned medicine. MFDS will carry out 23,000 tests including heavy metal testing for commonly consumed fishery products that are sold·distributed by auction in joint fishery markets, a distribution channels for marine products, and monitor products with high non-compliance rates such as sharks, etc.

For fishery products at distribution·sales stages, MFDS will designate 21 items with repetitive

records of being unfit for consumption as subjects for priority management, and monitor 40 items of the most commonly consumed products including mackerel·short-neck calm·squid. MFDS will collect and carry out inspections for a total of 10,000 marine products being distributed including 4,000 products for antibiotics and heavy metals, etc.; 3,000 products for antibiotics, heavy metals, contents, and radioactivity; and 3,000 products (by producing area, item, and season) for shellfish toxins, Vibrio parahaemolycius, norovirus, etc., in order to block distribution and sales of hazardous aquatic products.

Meanwhile, the Ministry of Maritime Affairs and Fisheries(National Fishery Products Quality Management Service) will carry out safety inspection during the production stage on a total of 13,000 products for heavy metals, animal medicine, dioxine, shellfish toxin and radioactivity, including 16 items for special management; 4,430 products of 75 categories that are the most commonly consumed; 1,420 domestic fishery products from near and deep sea for radiation tests; 6,350 certified or exported marine products; and 500 products under 10 categories 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 food facilities that have a large impact on the public when accidents occur or facilities in poor sanitation conditions. These crackdowns are carried out along with the periodical inspections or seasonal necessities. In 2017, 9 joint crackdowns were carried out on 44,915 businesses including facilities supplying holiday·summer foods, school cafeterias preparing for a new semester, and youth training centers. The inspections identified 1,227 businesses (violation rates: 2.7%) that had poorly managed sanitation, to which administrative and improvement measures were applied.

[Table 2-1-6] Results of National Joint Crackdown by Year

(As of Dec.31, 2017, Unit: Business entities, %, Ref. : Food Safety Management Division)

Year	Number of Inspected Businesses	Number of Detected Businesses	Violation Rate (%)
2013	25,203	1,038	4.1
2014	28,528	995	3.5
2015	32,829	740	2.3
2016	31,492	780	2.5
2017	44,915	1,227	2.7

B. Reinforcing Collection·Inspection of Foods Being Distributed

In order to secure food safety and promote public health, MFDS, local food& drug safety administrations, cities and provinces (Si/Gun/Gu) collect and inspect foods being distributed in the domestic market.

Reflecting the consumption trends and overseas information on customized seasonal (periodic) collection·inspection, MFDS regularly carries out planned collection·inspection on commonly consumed foods whose consumption increases in summer or during the holidays such as New Year's day, Korean Thanksgiving day, etc.

Last year, 168,096 items of agricultural·livestock·fishery products and processed foods were collected and inspected, and 1,064 cases that were non-compliant with food safety standards and regulations were seized or disposed of. The non-compliance rate remains unchanged from the last year's rate reported at 0.6%.

[Table 2-1-7] Result of Collection·Inspection by Year

(As of Dec.31, 2017, Unit: cases, %, Ref. : Food Safety Management Division, Health Functional Food Policy Division, Imported Food Distribution Safety Division, Agro-Livestock and Fishery Products Safety Division

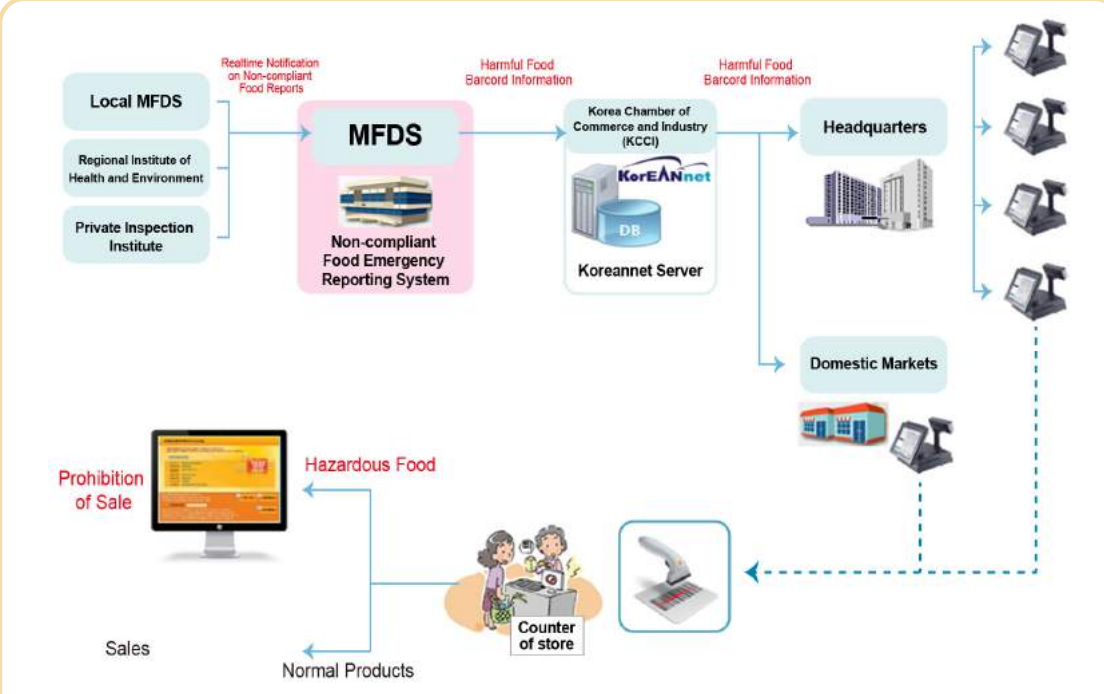
Year	Cases Collected	Non-Compliant Cases	Non-Compliance Rate (%)
2015	210,592	1,455	0.7
2016	189,198	1,176	0.6
2017	168,096	1,064	0.6

C. System for Prohibition of Sale of Harmful Foods

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

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

As of 2017, the "Harmful Food Sales Prohibition System" has been used in a total of 88,722 (cumulative) stores nationwide including major supermarkets, department stores, small and medium-sized distributors, convenience stores, Nadeul stores (small-sized supermarket), and stores run by TV shopping channels (including online shopping stores), etc.



※ After foods are collected and inspected nationwide, all the information on non-compliance products are reported to MFDS and sent to counters of each store through the computer network of large (small and medium-sized) distributors enlisted in the Koreannet of the Korea Chamber of Commerce and Industry, protecting end-consumers from buying those hazardous products using products' barcodes at the counter.

[Image 2-1-1] Flow Chart of the Harmful Food Sales Prohibition System

D. Operation of the Food Traceability Management System

MFDS operates a "Food Traceability Management System" through which it manages information on food traceability from the manufacturing·processing stages to the sales stage in order to rapidly take measures such as cause analysis, recalls, etc. when food safety-related problems occur, providing more accurate food traceability information to consumers.

The system has been mandatorily applied from 2014 to businesses manufacturing and processing (including import and distribution) baby food products and health functional foods since these products can be especially hazardous when food safety problems occur. The system also monitors other food retailers that sell foods to the customers in person. It is being made mandatory for businesses processing milk formulae to register with the "Food Traceability Management System" in a phased manner from 2016 to 2018. The system enforcement on manufacturers·importers of infant foods and other food retailers was completed in 4 phases (Dec.2017), and, as a result, a total of 6,493 food-related businesses are now registered in the system as of 2017. In addition, MFDS conducts inspections·evaluations every 2-3 years to ensure that the information is correctly linked even after the system registration of the businesses.

E. Establishment of Hazardous Food Recalling System and Reinforcement of Information Sharing with Consumers

In order to reduce consumer damage related to food safety incidents, measures to promptly recall and cut off distribution and sales of nonconforming food are required. For this, MFDS is providing information regarding hazardous foods in real-time to relevant organizations, distributors, and consumers by means of its website and sharing portal sites for food safety information.

MFDS notifies information on foods subject to recall on the MFDS website and the food safety information portal sites for promptly withdrawing hazardous food from stores, etc. and providing consumers with information. In 2017, MFDS actually took measures to recall 202 hazardous foods, etc.

[Table 2-1-8] Recall Status of Nonconforming Processed Food by Year

(As of Dec. 31, 2017; Unit: number, Source: Food Safety Management Division, Health Functional Food Policy Division, Imported Food Distribution Safety Division)

Year	Recall Status		
	Food	Health Functional Food	Total
2013	316	36	358
2014	269	18	287
2015	310	14	324
2016	252	31	283
2017	169	33	202

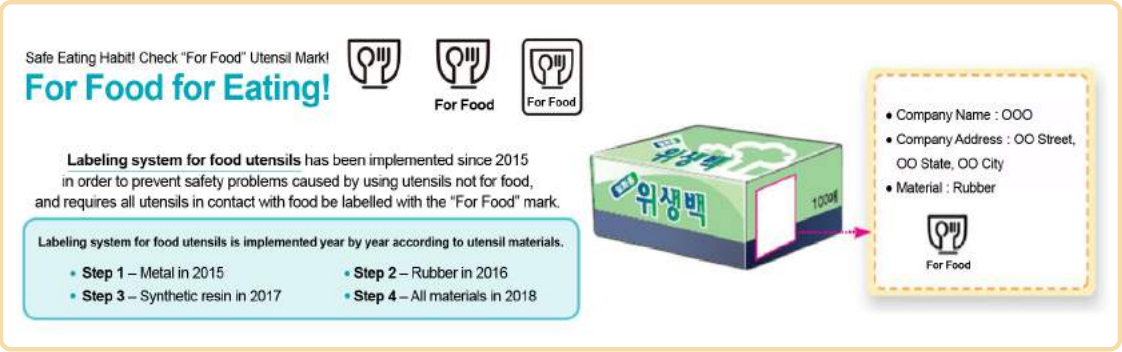
F. Improvement of the Food Labeling System to Provide More Information to Consumers

1) Background

MFDS is making great efforts to provide accurate information on foods, food additives, utensils, and containers·packaging through labels so that consumers can select appropriate products and enjoy healthy consumption. Thanks to these efforts, notifications in 「Food Labeling Standards」 have been improved for providing more information to consumers and securing their rights to know.

2) Achievements

MFDS introduced a labeling system for food utensils in phases to ensure that the food containers or utensils consumers use are safely manufactured according to standards defined in the Food Sanitation Act. In 2017, this labeling system was fully implemented on synthetic resin products so that consumers could verify the “For Food” mark on packaging materials before purchase. MFDS also promoted this system to the public on TV and in movie theaters to allow the system take roots.



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

Further, a precaution labeling system for consumer safety has been reinforced. Intake precautions and the content of flaxseed are required to be indicated on products containing flaxseed that may cause concerns of cyanosis in the case of excessive intake. In addition, an amendment has been prepared for 4 food additives including liquid nitrogen that makes it compulsory include to precautions for users in the wake of the "Yonggari snack" (nitrogen snack) accident in South Korea. The new amendment also has directions for adding "pine nut" to the list of contractants.

Since 2013, MFDS has been operating the 「Consultative Body on Standards of the Food Labeling System」, which is composed of consumer groups, industries, academia, relevant organizations, etc. for drawing reasonable results through improvements of the food labeling system and social issues among stakeholders. In 2017, 5 meetings with a total of 77 participants were held for reviewing 19 issues in total and collecting stakeholders' opinions. In addition, presentations on 「Standards of the Food Labeling System」 were held for business managers and government employees in five regions in order to raise understanding on food labeling; the presentations had 1,274 participants in total.

Since 2015, MFDS has carried out annual nationwide campaigns on allergies by means of food labelling to raise allergy awareness among elementary school students, parents, and school nurses and prevent food allergy among children. In 2017, a total of 96 campaigns were implemented for 4,564 participants.

3) Implementation Plan

From 2018, a size 10 font or larger will be used on all food packaging for content intended for consumers: ingredients, expiration dates, and warnings. The list-type of label will be replaced with tables and paragraphs to make the writing more readable for consumers.

Also, pursuant to the full implementation of the label system for the classification of food preparation utensils for all materials, consumers can be rest assured when using utensils after reading the labels. Further, for content regarding allergy information would be in larger print, and education is planned to be conducted to contribute toward improving the quality of life of allergy patients. Moving forward, there are plans to improve the provision of more accurate, essential information through the operation of a consumer-centered food labelling system.

G. Monitoring of False Advertisements and Hypes

False advertisements and hypes about food, etc. must be managed to protect consumer health and prevent economic losses. The necessity to efficiently control false and exaggerative advertisements overflowing through media such as the Internet, TV, newspapers, and magazines has been growing.

In this context, MFDS caught 341 false·exaggerative advertisements in 2017 through continuous monitoring through monitoring agents, and took measures such as administrative penalties and prosecution on parties responsible for these advertisements. MFDS also requested the Korea Communications Standards Commission to block access to illegal overseas websites that contain false advertising, and operates “Information sharing on false and exaggerative food advertisement” in its website and its portal, Food safety Korea (www.foodsafetykorea.go.kr) to provide consumers with information on the scope of false·exaggerative advertising and violation cases.

[Table 2-1-9] Administrative Penalties on False·Exaggerative Advertisements of Food

(As of Dec. 31. 2017; Unit: Number, Source: Food Safety Management Division)

Year	Total	Business Suspension	Item Manufacturing Shutdown	Correction Order	Accusation /Sending	Others (Corrective Action, Sales Office Closing, etc.)
2013	567	198	15	20	320	14
2014	505	203	13	16	244	29
2015	552	246	5	26	240	35
2016	540	279	8	19	198	36
2017	341	194	12	17	105	13

[Table 2-1-10] False·Hyped Advertisements of Food by Medium (by medium)

(As of Dec. 31, 2017; Unit: Number, Source: Food Safety Management Division)

Year	Total	Internet	Newspaper	Magazine	Printed Matter	Broadcast	Others
2013	567	436 (76.9%)	111	0	8	0	12
2014	505	461 (91.3%)	35	2	1	1	5
2015	552	517 (93.7%)	11	2	2	1	19
2016	540	520 (96.3%)	16	0	0	1	3
2017	341	298 (87.4%)	13	1	0	2	27

※ Others : banner, wrapper, etc.

H. Establishment of a Private and Public Joint Monitoring System

1) Operation of Consumer Food Sanitation Supervisor

MFDS is operating "Consumer Food Sanitation Supervisor" system in order to encourage consumers' active participation in food sanitation monitoring activities and to ensure fairness, reliability, and transparency in these activities by working with experts such as leaders of consumer groups.

In 2017, 9,515 people were newly appointed as consumer food sanitation supervisors, and a total of 124,734 supervisors participated in monitoring activities on a yearly basis. Inspections were carried out on sanitation condition of 631,717 food service businesses including restaurants and cafeterias providing food service. The inspections also identified business without a license, violated labeling standards, and/ or engaged in false·exaggerative advertising activities.

[Table 2-1-11] Activities of Consumer Food Sanitation Supervisor by Year

(As of Dec. 31, 2017; Unit: Person, Number, Source: Food Safety Management Division)

Year	Appointed Persons	Active Persons in Year	Inspected Businesses	Violating Businesses	Violation Details			
					No License	Labeling	Advertising	Other Accusation
2013	13,545	147,110	736,466	13,721	536	201	59	12,946
2014	12,765	145,100	712,268	12,337	776	154	91	11,316
2015	11,895	159,730	691,142	11,775	826	164	222	10,563
2016	9,307	122,935	606,120	11,282	741	287	99	10,183
2017	9,515	124,734	631,717	7,382	292	128	33	6,929

2) Operation of Report Reward System on Unclean·Adulterated Food

In order to revitalize consumer monitoring on food safety and expand consumers' participation, MFDS operates a report reward system on unclean·adulterated food, which gives a reward in the range of 10,000 won (approximately 9.30 dollars) to 10,000,000 won (approximately 9,296 dollars) depending on details of violation of the Food Sanitation Act in accordance with the current reward payment standard. In addition, MFDS has established a system to reward a whistle-blower through active cooperation with the Anti-Corruption & Civil Rights Commission, for reinforcing compensation to the whistle-blower on unclean·adulterated food. In 2017, MFDS accepted a total of 7,885 reports on suspicious unclean·adulterated food, researched on their veracity, took administrative measures accordingly, and gave rewards of 4,340,000 won (approximately 4,034 dollars) on 78 reports.

[Table 2-1-12] Reward Payment Status by Year

(As of Dec. 31, 2017; Unit: Number, 1,000 won (0.9 dollars), Source: Food Safety Management Division)

Year	Number of Reward Payment	Amount of Reward Payment
2013	1,051	58,510
2014	535	37,500
2015	332	24,990
2016	309	18,330
2017	78	4,340

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4. Reinforcement of Safety Management System for Imported Foods

A. Reinforcement of Inspection and Management of Imported Foods

1) Reinforced Customs Inspection on Imported Foods

After analyzing country·item·hazardous substance detection history, MFDS differentiated random sample testing rates based on hazard levels and selected items subject to in-depth inspection in application of the "selection and focus" principle. For random sample testing, MFDS utilizes the preliminary prediction import inspection system (OPERA) designed for in-depth inspection of potentially hazardous imported foods.

[Table 2-1-13] Inspection Status on Imported Foods(including Livestock·Marine Products) over Recent 5 Years

(As of Dec. 31, 2017; Unit: Number, 1,000 tons, Source: Food Safety Management Division)

Classification	2013	2014	2015	2016	2017(p)
Inspected Foods (number)	494,242	554,177	598,082	625,443	672,273
Weight (1,000 tons)	15,541	16,358	17,064	17,261	18,294
Amount (million dollars)	21,552	23,112	23,295	23,438	25,088
Nonconforming Foods (number)	1,442(0.29)	1,242(0.22)	1,397(0.23)	1,250(0.20)	1,279(0.19)

※ Numbers in parenthesis ( ) indicates a non-conforming rate (%), (p) indicates an estimate.

2) Implementation of Inspection Order Policy on Importers of Potentially Hazardous Foods

Since the implementation of the Inspection order Policy for Imported Foods (Mar. 29, 2012), MFDS has applied the inspection order policy to 8 cases (snacks from Indonesia, products containing puffer fish, litopenaeus vannamei from India, etc.) as of the end of Dec. 2017.

3) Reinforcement of Importers' Responsibility for Imported Food

For securing safety and quality of imported food, MFDS issues an education order upon

finding non-conforming imported food during customs inspection or distribution inspection. Under this program, MFDS has provided a total of 1,035 people with 31 training sessions. With a view to securing the effectiveness of the food safety education order policy, MFDS improved the policy by allowing education for not only business operators but also hygiene personnel designated by the business operators.

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

1) On-Site Inspection of Foreign Food Facilities

MFDS has made it mandatory for foreign food facilities (57,624 facilities) to register their main details (company name, address, safety management system such as HACCP, export item, etc.) prior to import declaration.

MFDS carried out on-site inspections of foreign food facilities (234 facilities) that have a history of manufacturing non-conforming products or have exported a large quantity of food to South Korea, and imposed import suspension or corrective action according to results of the on-site inspection. In case of corrective action, reinforced import inspection is implemented until completion of the corrective action. In addition, MFDS partially outsources on-site inspection work (132 facilities) to foreign food sanitary evaluation agencies in order to secure efficiency of on-site inspection.

Moreover, in order to encourage importers to import safe food voluntarily, MFDS has vitalized an excellent importer registration system for nurturing excellent importers. This system supports import of food for which safety has been managed in advance.

2) On-Site Inspection of Workplaces in Livestock Product Exporting Countries, and Import Sanitary Evaluation

In the case of new imports, MFDS approves the import of livestock products from countries that have established a sanitary management system by field such as sanitary management organization of the country, sanitary management for a specific pathogenic microorganism or

residual substance etc., and is evaluating 95 livestock products from 48 countries including Finland as of 2017. In addition, MFDS has inspected sanitary management of 87 foreign workplaces in 12 countries including the US, Brazil, Thailand, and China among registered workplaces.

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

In 2017, MFDS carried out sanitary inspection on 72 processing facilities for marine products in 6 stipulated countries jointly with the Ministry of Maritime Affairs and Fisheries, and implemented inspection on in countries with generally unsanitary conditions and fishery by-products. The inspections identified 13 facilities in 3 countries, and requested correction and improvement of items such as facility renovation that were pointed out during inspection of processing facilities.

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C. Reinforcement of Safety Management in Distribution Stage of Imported Food

1) Systematization of Management Infrastructure in Distribution Stage of Imported Food

In order to rapidly and efficiently take measures against overseas hazard information and to relieve anxiety regarding imported food, in 2017 MFDS carried out 6,258 cases of collection and test (32 non-conforming cases), and guidance and examination for businessmen at 574 facilities (14 non-conforming cases) related to distribution of imported food. The number of inspections has continuously increased every year.

2) Systematization of Safety Management for Abnormal Imported Food

In order to manage directly purchased overseas food containing hazardous substances, MFDS carries out joint inspection by dispatching one dedicated employee to the Incheon Airport Customs (Mar. 1, 2017). In the case of food with the purpose of self-consumption entering

the nation through so-called “peddlers”, inspection prior to the import stage is difficult to be conducted. To overcome such safety management problems, MFDS has expanded the scope of inspections and conducted periodic inspections twice a week by port in 2017 (Incheon Port, Pyeongtaek Port, and Gunsan Port).

[Table 2-1-14] Collection·Test Status for Overseas Directly Purchased Food over the Recent 5 Years

(As of Dec. 31, 2017; Unit: Number, Source: Imported Food Distribution Safety Division)

Classification	2013	2014	2015	2016	2017
Inspection	121	255	444	902	1,002
Non-conforming	33(27.3)	74(29.0)	99(22.3)	107(11.9)	163(16.3)

※ Numbers in parenthesis ( ) indicate the rate of non-conformance (%).

[Table 2-1-15] Collection·Test Status for Food Carried by Peddlers over the Recent 5 Years

('As of Dec. 31, 2017; Unit: Number, Source: Imported Food Distribution Safety Division)

Classification	2013	2014	2015	2016	2017
Inspection	44	368	897	1,230	1,166
Non-conforming	0(0)	6(1.6)	49(5.5)	33(2.8)	22(1.9)

※ Numbers in parenthesis ( ) indicates the rate of non-conformance (%).

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D. Reinforcement of Safety Management for Novel Foods including Genetically Modified Foods

1) Safety Evaluation of Genetically Modified Foods

In 2017, MFDS approved 18 genetically modified (GM) foods in total. Since 2000, MFDS has approved a total of 186 GM foods through safety evaluations.

In addition, an administrative pre-announcement of a revision notification (MFDS Announcement No. 2017-407, Nov. 14, 2017) was made on the 「Regulations on Safety Evaluation of GM Foods」. The main details include reinforcement of safety evaluation by adding evaluation items such as base sequence analysis materials for gene stacking event, and effects of gene products on metabolic pathways.

[Table 2-1-16] Approval Status of GM Foods

(As of Dec. 31, 2017, Unit: Number, Source: Novel Food Division)

Classification	Agricultural Products	Microorganisms	Food Additives Originating from GM Microorganism
Approved Items	163	4	19

※ Agricultural Products (163): corn 83, cotton 29, bean 28, canola 14, potato 4, sugar beet 1, alfalfa 4

2) Safety Management Including Import of GM Foods

In 2017, import declaration of GM agricultural products slightly increased as a whole, compared to the previous year. Considering Korea's high dependence on imported GM agricultural products and hence the importance of safety management, MFDS has prepared publications for safety management of GM organisms (GMO). These guidance documents provide an understanding on classification and distribution management in order to strengthen the capacity of responsible government officials and employees in companies that handle GMOs. In addition, MFDS provided opportunities to share information among responsible persons through national extension services and workshops in order to thoroughly manage the safety of GMOs.

[Table 2-1-17] Import Status of GM Agricultural Products for Food

(As of Dec. 31, 2017; Unit: million tons, Source: Imported Food Inspection Management Division)

Classification \ Year		2013	2014	2015	2016	2017
Soybean	GMO	0.78(72%)	0.99(77%)	1.06(79%)	0.98(78%)	1.04(78%)
	Non-GMO*	0.31(28%)	0.30(23%)	0.28(21%)	0.29(22%)	0.29(22%)
Corn	GMO	0.94(52%)	1.10(52%)	1.11(51%)	1.13(50%)	1.18(48%)
	Non-GMO	0.86(48%)	1.01(48%)	1.08(49%)	1.12(50%)	1.26(52%)
Canola	GMO**	51 thousand tons (100%)	0.2 thousand tons (100%)	0.5 thousand tons (100%)	0.5 thousand tons (14%)	0.03 ton (8%)
	Non-GMO	-	-	0.1 thousand tons (100%)	3 thousand tons (86%)	0.4 ton (92%)

※ Including bean sprouts

※※ Since 2014, frozen canola greens have been imported.

3) Follow-up Management Including Labeling of GM Food

MFDS and local governments have carried out continued instruction and examination on labeling of GM food in manufacturing· distribution stages in order to guarantee their safety and strengthen consumer confidence. Inspection results in 2017 revealed 6 cases involving

violation of labeling standards (Table 2-1-18). In addition, inspection on labeling of GM food found no cases of labeling violation cases. (Table 2-1-19)

[Table 2-1-18] Instruction·Examination Status of GM Food Labeling System

(Unit: ton, %, Source: Imported Food Policy Division)

Year	Instruction·Examination	Collection·Test	Violation
Total	13,259	3,604	28
2013	2,995	819	-
2014	3,234	742	4 (2 no labeling, 2 false labeling)
2015	2,839	629	5 (5 no labeling 5)
2016	2,169	726	13 (13 no labeling)
2017	2,022	688	6 (6 no labeling)

[Table 2-1-19] Research Status of Labeling on GM Agricultural Products

(Unit: Number, Source: Imported Food Policy Division)

Year	Instruction·Examination	Collection·Test	Violation
Total	13,349	2,880	-
2013*	1,508	423	-
2014	3,032	886	-
2015	2,783	665	-
2016	3,007	533	-
2017	3,019	373	-

4) Operation of Labeling System for GM Foods

MFDS operates the “GM Food Labeling System Review Council” composed of consumer groups, industries, and academia in order to execute appropriate policies for the GM food labeling system and to collect opinions of people from all walks of life. The council has united GMO terms and expanded the scope of labeling. In particular, the council standardized the term ‘GMO’ as “genetically-modified,” which had been previously expressed in various ways such as “genetically recombined” and “genetically changed.” In addition, the council expanded the scope of GM labeling from 5 “major ingredients” widely used in products to “all ingredients,” newly established a Non-GMO label, increased the font size of GMO labeling from 10 pt. to 12 pt. in order to raise readability, and revised (Jan. 25, 2017) and executed (Feb. 4, 2017) 「Standards on Labeling of GMO Food」 by reflecting above improvements.

5) Education·Campaign on GM Foods

In order to provide the public with accurate information on GM foods, MFDS worked with consumer groups to carry out customized education programs for elementary school· high school· middle school· college students, office workers, homemakers, etc. In addition, MFDS developed booklets, card news, videos, cartoons, etc. so as to provide information in a way that the people can understand easily. Moreover, MFDS carried out a GM Foods knowledge sharing event on its Facebook page in order to provide accurate information on GM foods and create an opportunity for communication through comments.

6) Temporary Standards·Specifications of Novel Food Ingredients

In 2017, MFDS held 11 "supplementary discussions" that facilitate previous consulting prior to application of ingredients in order to promote approval of novel food ingredients. As a result, in 2017, 5 novel ingredients including finger lime, corn husk, and mixed extract powder of vegetable heart were approved. In addition, MFDS held 「Food Ingredient Evaluation Research Council」 and 「Food Ingredient Internal Review Meeting」 in order to strengthen new food ingredient reviewers' expertise and secure objectivity.

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E. Reinforcement of Safety Management for Alcoholic Beverages

1) Background

MFDS has actively pursued policies for safety management of alcoholic beverages in accordance with changing alcoholic market conditions and national interest and requirements for safety of alcoholic beverages. However, there are still discrepancies in safety management and technical support education for quality improvement, and hence the establishment of a systematic and professional support system is required. In addition, the alcoholic beverage management system has a diverse responsibility structure that necessitates coordination between relevant ministries and harmonization among laws and regulations related to alcohol for efficient policy formulation and implementation.

2) Achievements

In order to allow alcohol manufacturers operate a "Sanitary Management Grading System," MFDS has evaluated safety management levels of the entire alcohol manufacturing industry. MFDS has established measures to prevent alcohol safety accidents through the off-flavor autonomous management system for beer manufacturers, planned inspection by theme or season, etc. In addition, MFDS has continuously increased the sanitary level of alcohol industry by providing support to small businesses through operation of regional alcoholic beverage safety management support centers, and through introduction of an autonomous alcoholic beverage safety management nurturing system.

A) Continuous Improvement of Hygiene Level of Alcohol Manufacturers

Because alcohol manufacturers present a wide variation in hygiene level by company, MFDS operates a "Sanitary Management Grading System" that differentiates and manages companies in order to manage the companies efficiently within limited administrative resources, and conducted safety management level evaluation for the entire alcohol manufacturing industry in 2017.

Hygienic management compliance rate of the alcohol industry has been improved thanks to education and technical support for companies with insufficient hygiene level by means of priority control measures such as improvement of compliance with Food Sanitation Act. MFDS has organized continuous guidance and education in order to improve manufacturers' perception on compliance with the Food Sanitation Act.

MFDS prepared an "Autonomous Management Manual for Beer Off-flavors" that covers topics such as types of beer off-flavors, off-flavor management methods, and major management details. Thanks to the operation of an autonomous off-flavor management system by beer manufacturers, the number of reports of consumer complaints on off-flavor beer has decreased.

B) Prevention of Alcoholic Beverage Safety Accidents through Focused Inspection of Blind Spots

MFDS strengthened collection· inspection of popular alcoholic beverages in a specific class as well as national preferred alcoholic beverages by season, and carried out rapid collection· inspection of alcoholic beverages for gifts and ancestral rites that are widely distributed during specific periods such as the Lunar New Year's Day and Chuseok (Korean Thanksgiving Day). MFDS carried out analysis on hazard information and civil complaint report status at home and abroad for this purpose.

In addition, MFDS reinforced guidance and inspection reflecting commonly consumed alcoholic beverages by season and consumption trends, and strengthened management of safety blind spots through establishing an "Autonomous Inspection System". This system will allow alcoholic beverage distributors such as large mart stores and convenience stores to autonomously inspect compliance details related to storing and handling standards of alcoholic beverages.

C) Raising of Business Managers' Awareness through Customized Support for Alcohol Manufacturers

MFDS operates designated alcohol beverage specialized organizations termed regional "Alcoholic Beverage Safety Management Support Centers". This system deploys alcoholic beverage specialists to visit facilities of small and medium-sized alcohol manufacturers in order to analyze their problems and carry out customized consulting and education.

In addition, this support system provides practical hygiene and safety management related information for companies, and implements education on food sanitation laws and regulations and analysis practices.

MFDS introduced an "Autonomous Alcoholic Beverage Safety Manager" nurturing system that fosters independent specialists who carry out independent safety management activities and take measures to prevent illegal alcohol manufacturing behaviors. MFDS also implements quality· safety education specialized by kinds of alcohol beverage.

MFDS operated an excursion program for excellent alcohol manufacturers, shared best practices in order to expand HACCP coverage for alcoholic beverages, held civil complaint briefings half-yearly in order to introduce amendments, and enhanced communication with companies through listening to their issues on the spot.

D) Dissemination of a Healthy Alcohol Consumption Culture by Providing Alcohol Safety Information

MFDS reinforced life-relevant promotion through providing information people need in their daily lives, such as method for selecting homemade alcohol, information on healthy practices while drinking alone, and a safe home brewing method, and induced public participation through alcoholic beverage safety campaigns on portal sites. In addition, in view of the culture of reusing empty alcohol bottles, MFDS carried out campaigns in cooperation with the Korean Alcoholic & Liquor Industry Association in order to transform consumers' behaviors and perceptions and reduce the number of foreign substances.

3) Improvement Plan

A) Reinforcement of Safety Management in Alcohol Manufacturing and Distribution Processes

MFDS plans to classify alcoholic beverage manufacturers into autonomous, general, and priority control grades depending on hygiene level in order to improve the efficiency of alcohol manufacturing safety management, thereby ensuring the autonomy of excellent companies and strengthening hygiene management of unsanitary companies. In addition, MFDS plans to adopt measures for pre-emptive management of commonly consumed alcoholic beverages according to consumption trends by specific period or season, reinforce special inspection of companies that use underground water, and establish an advanced safety management system for companies using underground water. Moreover, MFDS is scheduled to reinforce foreign material management by conducting education on management of foreign material in alcohol for manufactures, carrying out campaigns for prevention of mixing foreign materials, and publishing guidelines on foreign materials in unrefined rice wine including prevention of drosophila inflow.

B) Support for Alcohol Safety Management and Reinforcement of Promotion

MFDS plans to reinforce its risk prevention management plan by designating and operating alcoholic beverage safety management support centers in 4 regions in support of small-sized businesses, and carry out consultations on the spot. Customized support for management of sanitation· quality· off-flavor and an autonomous inspection system for off-flavor beer are scheduled to be established to facilitate a high-quality safe manufacturing environment. In addition, education for nurturing new “Autonomous Alcoholic Beverage Safety Managers” and refresher training are planned to be reinforced to improve safety· quality management capacities of alcohol manufacturers. Moreover, MFDS will promote relevant and practical safety information on alcoholic beverages in various forms covering topics such as healthy ways to drink and safe methods to make homemade alcohol.

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Section 2

Internationalization of Scientific Food Standards and Specifications

1. Improving Food Safety Standards and Specifications

A. Management of Food Safety Standards and Specifications

1) Background

As food trade between countries has increased with a growing number of FTAs, the need for management of contaminated residues, harmful contaminants, and food poisoning bacteria is on the rise. Therefore, it is necessary to set standards for pesticides and animal medicine without existing criteria, draw up response measures to harmful environmental contaminants, and manage standards and specifications on a regular basis.

There is also the need to reflect the new realities of international trade and revise standards and specifications to promote the food industry now that multiple stages from development to production·distribution·consumption are supposed to generate new regulations.

2) Achievements

MFDS established types and standards·specifications for fish oil (criteria for manufacturing,· processing, acid value, peroxide value, etc.), permitted oak chips (bars) that can be used for fermented vinegar, fish meat semi-products and fish surimi excluded from the list of seal packing items, and baked or fried fish products with low moisture content allowed to be circulated at room temperature. MFDS permitted room-temperature beverages and fermented milk to be frozen and sold, improved preservation and distribution standards related to frozen food for home delivery, and reformed the management scheme for honey (food type of mixed honey and specifications of the carbon isotope ratio) to expand consumers' right to know and choose.

MFDS prohibited unsanitary collection of egg contents such as compression during cleavage to ensure that Koreans are provide safe eggs and processed egg products, set up criteria for sanitary egg washing, enforced chilled circulation of washed eggs and eggs in cold storage, amended standards for preserving industrial eggs to meet those for eggs for domestic

consumption, and enhanced safety management of unsterilized egg contents after cleavage by making it compulsory to be preserved under 5 ℃ and processed within 72 hours.

MFDS improved 15 standards for the quantity of staphylococcus aureus and clostridium perfringens in processed egg products, dried fish and so on.

MFDS introduced the positive list system (executed on January 1, 2018) under which pesticide residues should not exceed 0.01 mg/kg – the non-detected level - to prevent the abuse and misuse of pesticides and manage imported produce except products with preset MRLs.

MFDS set MRLs for 152 cases on pesticides such as Cyhalothrin for cotton seeds, group MRLs for 29 cases on 16 pesticides such as Novaluron for produce grown in small areas, and MRLs for 511 cases of newly registered pesticides.

MFDS re-evaluated existing standards and specifications introduced from foreign countries and revised 121 standards related to 40 pesticides such as Iminoctadine.

MFDS amended MRLs for 18 animal drug products such as gentamicin, which are used without an MRL. Based on reports on the illegal use of insecticides on chicken and eggs, MFDS enacted rapid response test methods for 30 insecticides including Fipronil. The Ministry also established rapid response test methods for 32 insecticides including two insecticide metabolites including Fipronil and two additional ones including Tetraconazole to manage eggs more safely.

MFDS monitored pollutant levels and reassessed dioxin and PCBs in 2017 to restrict Koreans' total human exposure to 19 contaminants such as lead and cadmium[3] to a safe level.

MFDS established and strengthened the standards for lead and cadmium that cause high levels of contamination in the fishery industry to reflect climate change, environmental pollution and dietary changes.

MFDS approved 10 food materials (porous head eelpout, hibiscus, wormwood stalks, ginger stalks, schoolmaster gonate squid, upogebia major, etc.) based on the needs of food development.

MFDS aims to effectively establish and revise MRLs for food materials, pesticides, animal medicine and contaminants scattered among government ministries. To that end, MFDS shared information and closely cooperated with other government entities through the 'Institutional Cooperation Council on Food Materials', 'Residual Pesticide Safety Management Council', 'Council on Animal Medicine Residue Standards' and 'Council on Pollutant Management in Foods.'

3) Heavy metals (6 kinds: lead, cadmium, arsenic, total mercury, methyl mercury, tin), filamentous fungi toxins (8 kinds; total aflatoxin, aflatoxin B1, aflatoxin M1, patulin, fumonisins, ochratoxin A, zearalenon, deoxynivalenol), 3-MCPD, benzopyrene, dioxin, PCBs, melanine

3) Implementation Plan

MFDS will reflect characteristics of microorganisms (based on possibility of food contamination, risk level, and dangerous amount) and base specifications regarding low-risk poisoning bacteria on quantity and reasonable standards and specifications. MFDS will also review the safety of fish newly introduced as a result of rising water temperatures and advanced fishing techniques and approve new concept food materials based on thorough evaluations.

MFDS will annually inspect contamination regarding 19 contaminants and assess standards and specifications for Benzo pyrene in 2018.

MFDS is preparing to introduce the Positive List System (PLS) on agricultural products in earnest (executed in Jan. , 2019) to manage pesticide residues in a scientific and safe manner, set up MRLs for farm products grown in small lots to enable them meet PLS standards, and establish MRLs for domestically unregistered pesticides found in imported foods. The Ministry plans to strictly manage the safety of farm products at the production stage by specifying their MRLs since the task has been transferred from MAFRA to MFDS.

Besides, MFDS will apply PLS to pesticide residues and veterinary medicine in animal and fish products (to be executed in 2021) and develop a draft plan for implementation. MFDS will also set up MRLs for foods (animal species) sold without any standard.

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

A. Management of Food Additive Standards and Specifications

1) Background

MFDS establishes and revises standards and specifications on food additives that are used for sweetening, coloring, bleaching, or oxidation prevention in the process of manufacturing, processing, cooking, or preservation of food.

MFDS provides consumer-oriented safety information to improve consumer perception and raise awareness on food additives through various communication channels with the public.

2) Achievements

After the Yongari snack incident[4] in August, 2017, MFDS immediately amended nitrogen standards to ensure that no liquid nitrogen exists in foods at the final stage and thus a similar accident will not occur; MFDS also collaborated to change food labels and include cautions regarding liquid nitrogen.

Steam boiler cleaners will be designated and managed from January 1, 2019 as a safe food additive (40 items) after concerns were raised that they may contaminate food through direct contact.

MFDS improved definitions related to adding synthetic flavors to water, ethanol, glycerin, propylene glycol, and triacetin as a diluent given international standards and opinions from the industry.

Four food additives were newly designated. Black carrot extracts for coloring candies, Methyl Tetrahydrofolic Acid Glucosamine for making folic acid in health supplements, and Branching Glycosyltransferase with temporary standards were designated in May, 2017 and Calcium Dihydrogen Pyrophosphate designated as a permissible leavening agent in December, 2017.

MFDS allowed three sorbates for sauces, fruit and vegetable juices and sodas and accordingly organized compatible standards for six benzoates and paraoxy benzoates. MFDS permitted Disodium 5'-Uridylate in food for patients and organized standards for propylene glycol. The ministry made efforts to meet international standards by adding potassium hydroxide as an acidity regulator in the list of food additives used to make infant and baby foods such as modified milk. The Ministry amended standards for 137 food additives to match food types mentioned in Korean Food Standards Codex.

MFDS implemented education and PR activities customized to general consumers and industries to raise awareness on food additives. Changes in teachers' awareness of food additive safety jumped from 7.1% before education to 75% after education. Awareness for parents of students reached 95.3%, representing the significant impact of education.

MFDS helped primary and secondary school students develop the correct awareness of food additives by holding a poster contest titled 'Let's Learn about Food Additives.' MFDS received 257 posters and plans to harness works; the best entries won the Grand Prize (1), Excellence Prize (3) and Participation Prize (10) as PR materials for improving public awareness on food additives.

4) Made by immersing in liquid nitrogen. The product was nicknamed 'Yongari' (dragon) as its liquid nitrogen turned into white gas and went out of the mouth like a dragon breathes fire. In the above mentioned incident, a child took in non-liquefied nitrogen at the bottom of the container and the gas made a hole in his stomach.

3) Implementation Plan

MFDS will cancel the designation of 20 hazardous synthetic flavors through a review process and delete 24 repetitively registered flavors from the list. To reflect the results of the 2017 food additives reassessment and reduce aluminium exposure, MFDS will make efforts to determine foods that are permitted to use 5 additives such as Aluminum Ammonium Sulfate and set standards for safe amounts that can be used.

MFDS will continue to provide online PR contents through Korea's top search portal Naver and SNS to improve public awareness of food additives by delivering correct information.

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

1) Background

As more and more consumers have come to care about food safety, there is growing interest in the safety of food utensils, containers, and packaging that come directly in contact with food as well as the safety of the food itself.

In addition, due to changes in eating habits such as increase in the number of people eating alone and the convenience of cooking, various types of new utensils, containers·packaging products have been developed. Accordingly, it has become vital to enhance safety management of harmful substances that can migrate into food when cooking or storing food using those products.

2) Achievements

MFDS revised the definition of hydroxybutyl polyester (HBP) and also separated and newly established the criteria·specifications for hydroxybenzoic acid polyester. The ministry also revised the name and definition of butylenesuccinate-adipate copolymer (PBSA) so that the name can include butylenesuccinate copolymer (PBS). In addition, in order to improve the reliability of test results (quantity, reproducibility, etc.), MFDS also improved the formula for solutions of migration test and also classified mass number tests into quantitative tests and confirmation tests by reflecting the characteristics of each material when analyzing phthalate. The formulae for a standard solution used for melamine test method and 1,4-butanediol test method were also improved and the description of those methods was also modified.

3) Implementation Plan

MFDS plans to re-evaluate hazardous substances (6 items) that can migrate into food from food utensils, containers and packaging, and also improve the standards and specifications for utensils, containers, and packaging in conformance with international standards and strengthen safety management in Korea. MFDS will also improve recycling standards for synthetic resins, safety standards for bisphenol A, and the list of ingredients that can be used for manufacturing sanitizing·disinfecting agents for utensils, based on the management status of foreign countries and usage at home and abroad.

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Section 3

Expansion of Healthy Dietary Environment

1. Strengthening Children's 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, safe food is essential for their health. During infancy and childhood, cognitive abilities develop dramatically along 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 spheres, the government's review of its policy of providing free child care, and increasing parental demands 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' interest in child care services has grown as a result of increase in the number of children cared in these facilities, there has also been increased anxiety among parents regarding children's meal services in view of media coverages on the usage of expired and rotten foods in the meal service industry. Most of the children's meal services are doing their best to provide children with the safest and healthiest food possible. However, the small sized providers 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 has established centers for children food service management with local governments and carries out sanitary and nutritional management of children's meal service facilities in cooperation with the experts and dietitian at the center.

B) Achievements

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

Beginning with 12 centers for children's food service management in 2011, MFDS expanded operations to have 22 centers in 2012, 88 centers in 2013, 142 centers in 2014, 190 centers in 2015, 207 centers in 2016, and 215 centers in 2017. MFDS is also supporting food safety management for a total of 32,093 children's meal service facilities catering to 117 ten thousand children.

The main roles of the centers for children's food service management include regular round visits to day-care centers and kindergartens to guide sanitation, safety, and nutritional management; supporting sanitation and nutrition management for targeted audiences (children, facility, principal, parents); development of diet plans for children; and consulting on sanitation and nutrition.

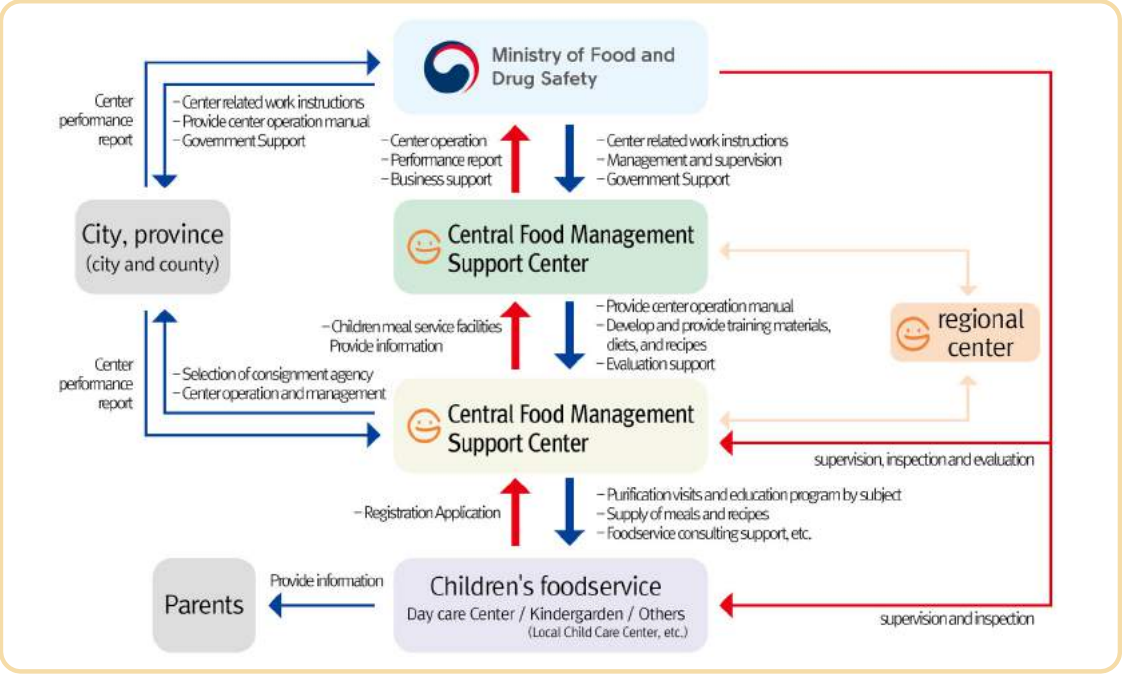
Surveys of directors and teachers at day-care centers and kindergartens that are supported by the Centers showed high satisfaction scores at 86.8 points in 2013, 89.6 points in 2014, 91 points in 2015, 91.0 points in 2016 and 90.4 points in 2017. The Centers' efforts received overwhelming parental support and positive responses of 87.0 points in 2015, 88.9 points in 2016 and 89.9 points in 2017 since more children learned to wash their hands before meals and ate balanced meals. A survey on the cost-effectiveness of the Centers' efforts showed results at around 11.1~15.7, which amounts to a volume of 1.356 trillion won.

To promote the important role that these centers for children's food service serve for the safety, sanitation and nutrition of our children's meals, MFDS developed booklets, posters, leaflets, and activity booklets for directors of day-care 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 (the numbers reached 215 in 2017), MFDS needed an exclusive supervisory organization. Also, there has been an issue of inefficiency and inconsistency in the regional centers' operations related to providing educational materials on sanitation and nutrition, meal menus, recipes and sanitary food information. To solve this issue and to improve the operations of the regional centers, the 「Special Act on Safety Control of Children's Dietary life」 was revised (Jan. 28, 2014, effective on Jan. 29 2015) and the Headquarter for Children's Food Service Management Center was established with budget for

2016 secured. With these changes, the regional centers were able to focus on field-oriented works and the headquarters management center supported and supervised the regional centers with efficient, standardized services.



[Image 2-2-1] Operation System of Children's Food Service Management Centers

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

(3) Implementation Plan

With the Centers for Children's Food Service Management established to support children at child care facilities and kindergartens and the CCFSM Headquarters established to supervise he 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 the Safety of Children's Diet

1) Improving the Food Sales Environment and Reinforcing the Foundations for Providing Healthy Food at Schools

A) Background

Obesity in children (primary and secondary school students) is ever increasing and the phenomenon may lead to obesity later in life. Hence there is need to control obesity right from childhood.

As people are expected to live longer thanks to advanced medical techniques and abundant foods, their expectations for a healthy life have created a new paradigm of food safety that encompasses both nutrition and safety.

At the same time, in view of recent incidents related to children, MFDS established comprehensive and systematic measures for children's food in its role as a control tower for children's food safety.

B) Achievements

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

MFDS aims to enable a safe and well-balanced dietary life for children by improving conditions of food sales around schools beyond parents' protection. Accordingly, MFDS designated 83 Green Food Zones around cram schools and amusement facilities to create a safe and clean environment for food sale. MFDS has so far arranged 3,086 dedicated agents to instruct cafeterias and shops in 8,537 Food Safety Zones that sell children's favorite foods to prepare, display and sell clean and safe food.

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

In Korea, snacks high in sugar, fat and sodium are replacing healthy eatables like fruits and milk and such change in dietary patterns has resulted in a growing number of overweight and obese kids since 2008.

To guide children in making the right choices, MFDS prohibited from schools and exemplary shops from selling 'high-calorie·low-nutrition food', which refers to children's favorite foods that may cause obesity or nutritious imbalance.

MFDS operates an application named 'New Notice for High-calorie, Low-Nutrition Food' and a program (web-version) to determine high-calorie, low-nutrition food on the 'Food Safety

Korea' homepage at http://www.foodsafety korea.kr. MFDS has made continued efforts to promote healthy eating habits to children.

MFDS prohibited the manufacturing and sale of alcohol bottle-shaped foods that might promote drinking or foods with pictures or phrases that may harm children's sound mind by stirring up a speculative drive or sexual curiosity; the ministry also staged a national campaign to inform the side effects of excessive consumption of caffeine before school test periods when many students intake high caffeine drinks such as coffee.

MFDS operates the 'Quality Certification System for Children's Favorite Food' to manufacture, process, circulate and sell safe and nutritious food for children and offer consumers information on certified products through logos and letters on their containers and packages.

(3) Restrictions on Advertising Related to Children's Favorite Foods

South Korea has recently intensified ad restriction to prevent children's obesity and protect consumers' right to choose good food.

The country limits and forbids TV commercials for high-calorie, low-nutrition food and high caffeine food as well as advertisement likely to lure children to buy goods according to the 'Special Act on Children Dietary Life Safety Management.' TV commercials are restricted and prohibited from 5 p.m. to 7 p.m. and furthermore commercial breaks are banned for children's TV shows. The term 'ads likely to entice children to buy goods' refers to broadcast or online advertising that offers toys at no charge or giveaways other than food, which are banned.

(4) Survey of Children's Dietary Safety Index and Dietary Safety and Nutritional Assessment

MFDS has established Children's Dietary Safety Index by objectively monitoring and assessing efforts and environmental improvement of local governments to manage children's diets more safely according to Article 23 and 24 of the 'Special Act on Children's Dietary Life Safety Management.' The Act is employed to find measures to conduct policies for the safety of children's dietary life.

The nation's statistical indices, surveyed every three years, are based on 29 review indicators in three areas of safety, nutrition, and recognition·practice of children's dietary life. These indices are helpful in understanding children's eating habits and serve as an assessment tool for safety and nutritious levels managed by local governments.

According to the 2017 survey results, children's diet safety and nutrition levels generally improved (scores: 67.54 in 2014, 73.27 in 2017) nationwide and especially in rural areas. Considering the narrowing differences between large and small cities and rural areas, it may be stated that the policy environment for children's dietary life is better than before.

(5) Education and Promotion for Safety Management of Children's Diet

Since children lack knowledge in food and nutrition and do not recognize the importance of health, they tend to choose their favorite snacks rather than healthy and safe foods. In that eating habits in childhood have a crucial impact on their future life, it is crucial to provide education on food safety and nutrition for children to cultivate the right eating habits.

Article 13 of the 「Special Act on Children's Dietary Safety Management」 prescribes the requirements for education and publicity campaigns relating to children's favorite foods so that all children may develop a healthy and safe dietary lifestyle. Under the Act, the heads of elementary schools shall regularly conduct education on safety and nutrition as necessary for managing children's dietary lifestyle.

In support of the educational drive, MFDS has been providing elementary school nutritionists (nutrition teachers) with 'nutrition and dietary life' materials from 2011; the scope of this policy was expanded to middle and high schools from 2014. In 2016, MFDS developed new elementary school materials centered on student activities by reflecting curricula amended in 2015 and helped students engage more actively in classes by deploying those materials from 2017.

In 2017, MFDS operated a pilot program titled 'Participatory Schools for Food Safety·Nutrition Education'. The program ran a school-wide campaign along with the existing theoretical education. School nutritionists (nutrition teachers) showed high satisfaction levels regarding the various contents that were handy and easy to use.

MFDS operated a professional course to reinforce school nutritionists' (nutrition teachers') capabilities and skills to heighten the quality of food safety and nutrition education and identified best classes by holding the 6th Best Class Contest in order to facilitate, and promote dietary lifestyle education and motivate participants.

MFDS continues to educate the general public through exhibitions and hands-on experience pavilions to help children and their parents understand safety policies for children's diet. The initiatives are taken with a view to encourage children develop sound eating habits and select food wisely.

C) Implementation Plan

(1) Reinforcement of Safety Management for Children's Favorite Foods

MFDS as a control tower of children's food strives to protect them from safety incidents and reinforce a safe and healthy food sale environment through stronger hygiene and safety control. To that end, the Ministry plans to implement multiple policies from the perspective

of children in conjunction with local governments, strengthen supervision of business establishments susceptible to poor hygiene, and guide the owners to strictly comply with food safety management.

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

MFDS will encourage establishments to voluntarily participate in the Quality Certification System for Children's Favorite Foods, stage promotional activities through customized public campaigns to support children obtain information and buy certified foods, and reasonably amend certification standards.

MFDS has also expanded the scope of high caffeine foods to prevent children from excessive consumption and will, in 2018, impose a ban on high caffeine foods like coffee in school.

(3) Restriction and Prohibition on Advertisement and Sale of Children's Favorite Foods

MFDS instructs companies manufacturing children's favorite foods to improve the ingredient mixture ratios and manufacturing processes so that they offer safe and nutritionally balanced foods; constantly monitors the sales prohibition and ad restriction of high-calorie, low-nutrition food and high caffeine food; and is designing a high-calorie, low-nutrition food labeling system to allow consumers make the right food choices and enhance sellers' convenience.

(4) Survey of Children's Dietary Safety Index and Assessment of Dietary Safety and Nutrition

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

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

MFDS will continue to proactively educate and promote the safety of children and adolescents' diets by strengthening support through materials and tools for food safety and nutrition education to make sure that children and adolescents can choose safe and healthy foods for themselves.

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

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

1) Background

The pattern of food poisoning outbreak has recently changed according to climate change factors such as abnormally high temperature and changes in Korean people's dietary lifestyle such as increased use of eating-out and meal services. Food poisoning most frequently occurred in restaurants while the highest number of patients with food poisoning was reported in schools. Hence, in 2007, MFDS established a pan-government food poisoning countermeasure consultative body to prevent and manage food poisoning, with participation from 32 institutions including the central government, local governments, and private organizations. Since then, the entity has been working on prevention of food poisoning outbreaks by means of comprehensive joint prevention measures for food poisoning through holding regular meetings three times a year.

2) Achievements

In order to reduce incidence of food poisoning caused by school meals that increased in the summer of 2016, MFDS carried out spot and special checks as well as joint checks targeting group meal service facilities including schools. MFDS performed consulting activities for preventing food poisoning, thereby reducing the number of patients with food poisoning caused by school meals by 29.2% in 2017. It also reduced the incidence of food poisoning caused by restaurants by carrying forward projects to strengthen the hygiene management of restaurants with many food poisoning cases. MFDS conducted a project for providing warning information to reduce the occurrence of food poisoning on the spot and offered "Card News about Food Poisoning Cases" and "Food Poisoning Prediction Information of My Town" in the form of a map at all times.

MFDS prepared for the occurrence of food poisoning by conducting a mock exercise on quick reporting and response in the field where food poisoning occurred. This initiative was taken in order to strengthen a quick reporting system, disseminate knowledge and capabilities

to the relevant institutions, and let institutions understand their responsibilities in the early stages of food poisoning outbreak.

In addition, to prevent the occurrence of food poisoning, MFDS analyzed information on the occurrence of food poisoning for the past five years (2012~2016). It also extracted the areas, facilities, and causative bacteria that presented a high risk of food poisoning outbreak and shared relevant information with 17 cities and 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 on a monthly basis. It continues to send text messages such as food poisoning precautions to school nutritionists nationwide every day.

Since many cases of food poisoning in schools occurred at the start of school term after a vacation, MFDS supervises and inspects the schools and food suppliers in cooperation with the local offices of MFDS, the Ministry of Education, education offices, and local governments in March and September of each year at the start of school terms.

School canteens were subjected to thorough inspections to improve related matters including the storage of foods that passed self-life and violations of hygienic handling standards of foods and so on. MFDS also made efforts to prevent food poisoning outbreaks at schools by conducting specialized training for school principals and dieticians on the prevention of food poisoning. The trainings are being held nationwide twice a year so as to prepare for the start of school terms when many incidents of food poisoning occur.

In addition, as a high volume of field studies and outdoor learning activities of elementary, middle, and high school students occurs in April, MFDS conducted sanitary supervision and inspections targeting 3,528 restaurants and food processing companies that make Kimbab and boxed lunches to prevent the occurrence of food poisoning. MFDS also held inspections at canteens in youth training centers used by many students in times of outdoor school activities. Further, MFDS enforced improvement measures on 150 companies that violated the 「Food Sanitation Act」.

In order to maximize preventive measures for food poisoning, MFDS encouraged people to practice “Hand Washing, Cooking and Boiling Food”, which are the three main points in the prevention of food poisoning. It also strengthened ways to promote the prevention of food poisoning customized for individual causes of food poisoning. In particular, MFDS broadcasts promotional videos for preventing food poisoning by season via TVs, radios, subway media, etc. according to the daily schedule of the cooks. It also encourages the public to get relevant information at anytime and anywhere by means of outdoor advertisement, the Internet, railway (KTX), newspapers, magazines, etc.

In addition, MFDS provides mobile food poisoning test vehicles at various local events and international events to prevent any food poisoning outbreaks. It prepared a consulting manual for the prevention and diagnosis of food poisoning and a manual for the prevention and management of food poisoning and distributed these manuals to be used for hygiene management in the fields where meal services are offered. In particular, in June 2017, MFDS prepared a manual and handbook for reducing pathogenic coliform bacillus to prevent food poisoning and distributed them to group meal service facilities.

Particularly, in 2017, MFDS prepared card news including tips for preventing food poisoning, thereby working on preventive activities via SNS, Facebook, blogs, etc. The cards were prepared after analyzing the statistics of food poisoning outbreaks for the past five years.

MFDS needed genetic information about various food poisoning bacteria to identify root causes of food poisoning and prevent spread of food poisoning. Therefore, it conducted various monitoring and exploratory surveys, for food items including agricultural, livestock and marine products, processed foods, and so on, starting from 2017. A total of 12,333 cases were examined, and 1,659 cases of food poisoning bacteria were obtained. MFDS made a database of genetic information on relevant food poisoning bacteria through analysis methods such as PFGE and jointly used the relevant information owned by other departments. In addition, it established the "Resource Center for Food Poisoning Bacteria" for systematic storage management of food poisoning bacteria in November of 2017.

3) Implementation Plan

In 2018, MFDS set a goal for reducing the occurrence of food poisoning by 20%. It has established a preliminary screening and on-site safety management plan for the prevention of Norovirus food poisoning during PyeongChang Winter Olympics and reinforced the operation of a pan-government food poisoning countermeasure consultative body. Further, as food poisoning caused by school meals harms many students, MFDS has scheduled food poisoning in schools to be managed as a top priority. It plans to supervise and check meal service facilities of all elementary schools, junior and high schools, and special schools nationwide in cooperation with local governments before starting school. The ministry will also conduct food poisoning prevention and diagnosis consulting for schools with a history of food poisoning outbreaks throughout the year.

Since the occurrence of food poisoning depends on the season and the facility, it is essential to prevent food poisoning outbreaks before it occurs. Accordingly, MFDS conducts preventive

activities such as pre-emptive guidance and inspection, education and promotion that analyze the characteristics of food poisoning by season, facility, and cause. It plans to make a promotional video for preventing three major categories of food poisoning by June 2018. MFDS will promote the promotional video via media such as TV, radio, and subway channels throughout the year, thereby ensuring that more people will watch.

MFDS has been promoting a system for preventing food poisoning based on guidance and inspection, preventive education and promotion, and conducting follow-up checks for well-known food poisoning pathogens. However, in view of the recent changes in types of pathogenic microorganisms and increased frequency of food poisoning caused by rapid climate change from four seasons to two seasons (summer & winter), the ministry plans to carry out a search for food poisoning bacteria at all stages ranging from production environment (soil, water, seawater, farm households, etc.) to distribution and consumption stages. In addition, it will introduce NGS equipment for introducing the next generation genome analysis technology and establish an integrated system for tracking the cause of food poisoning connected with "Environment-Pathogenic Organism- Food·Agricultural, Livestock, and Marine Products-Human Infection", thereby ensuring a pre-emptive response system.

B. Establishment of Hygiene Management Foundations for a Safe Eat-out Environment

1) Background

Due to the recent changes in dietary patterns stemming from the increase of nuclear families within social structure, female participation in economic activities, and one-person households, the number of people who eat out on a daily basis has increased considerably; 1 out of 3 Koreans eats out at least one meal per day (National Health and Nutrition Survey, 2014).

While the number of people eating-out is increasing, food poisoning most frequently occurs in restaurants. Among consumer complaints about restaurants, poor hygiene accounted for 35%, compared to unkindness for 21% and complaint about food quality for 14%. Therefore, the social demand for safety management of restaurants is increasing (2016, The Anti-Corruption & Civil Rights Commission).

[Table 2-2-1] The Occurrence of Food Poisoning at Restaurants

('17.12.31. Standard, Unit: %, Source: Foodborne Disease Prevention& Surveillance Division)

Division	2014	2015	2016	2017
The Occurrence of Food Poisoning at Restaurants	61	64	62	66

Therefore, MFDS has been implementing a sanitary grading system, starting from May 19, 2017 in order to raise hygiene levels through autonomic competition among restaurants and thereby improve customer satisfaction and prevent outbreaks of food poisoning.

2) Achievements

In order to secure evaluation personnel for smoothly introducing a sanitary grading system for restaurants and for settling the system in early stages, MFDS developed a systematic education system for evaluators and conducted theoretical education and practice of 14 hours over one night and two days. Further, MFDS trained 482 evaluators through a competency evaluation test targeting hygiene related public officials from local governments and customer food sanitation supervisors, thereby establishing a rational and fair evaluation basis for restaurant sanitary grading system.

In addition, MFDS held a total of 25 briefing sessions (3,455 participants) that informed general restaurant operators of the implementation purpose of the sanitary grading system, application method, designation procedure, and evaluation areas. It cooperated with Korea Agency of HACCP Accreditation and Service, a sanitary grading evaluation agency, to conduct 122 sessions of field-based mock evaluations (1,721 sites) for places that want to participate in the sanitary grading system, ensuring that more restaurant operators can easily understand the system.

3,138 general restaurants applied for sanitary evaluation to be assigned the sanitary grade for about 8 months from May 19 2017 to December 31 2017. As a result of the evaluation targeting 2,395 restaurants, 710 restaurants were assigned a sanitary grade. Among the 710 restaurants assigned a sanitary grade, 262 restaurants were rated “Excellent (★★★)”, 205 restaurants rated “Very Good (★★)”, and 243 restaurants rated “Good (★)”.

In order to stimulate the restaurant sanitary grading system and smoothly implement a project for improving the kitchen culture, MFDS formed a consultative body composed of public officials from local governments, experts from relevant associations and academia, and held three meetings sessions, strengthening collaboration and communication and gathering on-site

opinions by area to reflect them to relevant policies.

MFDS held a meeting for presenting best cases of food and kitchen culture improvement to share these cases among cities·provinces, cities·counties·districts nationwide and discuss measures for improving food and kitchen culture. In addition, it distributed the best casebooks so that restaurant operators can actively use them and adapt to local situations.

MFDS conducted a pilot project to improve the kitchen culture, which supported installation funds incurred for remodeling and repairing open kitchens and sanitary facilities and equipment for 40 small-sized general restaurants in food service business. It selected the pilot restaurants considering the distribution by the type of industry and business scale. It also preferentially selected and supported restaurants with an area of 100㎡ or less. The survey, which was conducted on restaurant owners and customers after completing the pilot project, showed improved satisfaction levels for both restaurant owners and customers. It was because the remodeled open kitchen ensured that the cooking process can be seen from the outside. This in turn not only contributed to securing the transparency of kitchen hygiene and enhancing the reliability of customers, but also increased restaurant sales.

MFDS made a leaflet and promotional video for promoting a restaurant sanitary grading system to Korean people. It produced 21,000 copies of leaflets and distributed them in 17 cities and provinces and relevant institutions in order to enhance the awareness of business owners, customers, and relevant public officials. It also made a promotional video in the form of movie trailers and promoted the restaurant sanitary grading system via TV (tvN, YTN, Yonhap News TV, etc.), KTX channels, and so on to attract customers and business owners' attention.

In addition, MFDS held SNS events to build public consensus on the restaurant sanitary grading system. For instance, it held an event where a photo with the sign of the restaurant assigned the sanitary grade was taken and posted as proof shot with reviews via Facebook and Instagram. A total of 5,303 people participated in the event, and 2,130 people won prizes in the event.

MFDS promoted "Cooking Talk Show" via SNS to spread best cases for improving the open kitchen culture. It also created the "Cooking Talk Show (Open Kitchen Talk Talk Talk)" that introduces hygiene rules while cooking Korean·Japanese·Chinese·Western foods in the open kitchen and promoted it via SNS such as YouTube, Facebook, etc. It prepared a cookbook, titled "Cooking Special Time", which presents hygiene rules for the open and clean kitchen and distributed 1,000 copies to cities·provinces and related associations, spreading the "Open and Clean Kitchen Culture".

3) Implementation Plan

In 2018, MFDS plans to consign the sanitary grading evaluation related works to the Korea Institute for Food Safety Management Accreditation to establish a stable restaurant sanitary grading system. Based on this, it also plans to grade and monitor restaurants that applied for the sanitary grading system through on-site hygiene assessment.

To improve the hygiene level of restaurants and stimulate the restaurant sanitary grading system, MFDS plans to conduct one-to-one customized technical support(consulting) by checking the hygiene level of 1,500 small-sized restaurants (with an area of 100㎡ or less) that desire to apply the sanitary grading system.

It also plans to hold a series of briefing sessions for business owners to encourage their participation in the sanitary grading system, raise customer awareness, and operate a consultative body composed of customers, business owners, and experts from individual areas

To strengthen the restaurant sanitary grading system and improve food and kitchen culture, MFDS plans to promote the message of "Choosing a Hygienic Restaurant" via mass media and SNS. As part of efforts in this direction, MFDS will make a promotional video containing the message of "Hygiene is the Key to Success" in the form of web-documentation and show the video to business owners when providing hygiene education programs.

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3. Improving the Regulations on 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 that stem from dietary habits, 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 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 manufacturing industry grew 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; 1 trillion and 823 billion won in 2015; and 2 trillion and 126 billion won in 2016, showing continuous growth every year.

B. Achievements

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

A) Advancement of the Health Functional Food Certification System

(1) Restructuring of the Screening System for 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 class of functional raw materials, maintain the existing disease risk reduction function, and unify the 1st and 2nd grades of physiologically active function as 'can help 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 test evaluation section was newly established to strengthen the verification of data on human body testing. MFDS expanded the pool of specialists to include doctors, pharmacists, oriental medicine experts/practitioners, 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 was amended to introduce a reassessment system for the safety and functionality of previously recognized functional ingredients. The re-evaluation process 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 the Self-quality Inspection System and Establishment of Basis for Inspection of Authenticity of Raw Material

In February 2016, an amendment of the Health Functional Food Act, made it mandatory to report non-conformity of self-quality test results and carry out authenticity testing on raw materials that are difficult to distinguish visually or deemed necessary by the Minister of Food and Drug Safety.

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

In February 2016, the Health Functional Food Act was amended to require gradual application of Good Manufacturing Practice (GMP). Existing manufacturers have stepped up to 20 years, and new manufacturers have expanded their coverage to receive GMP certification at the time of business licensing. In order to facilitate early settlement and participation in the system, starting 2016 MFDS has been providing on-site technical support and consultations for companies preparing to acquire GMP designation.

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

(1) Establishment and Operation of the Abnormal case-response System

In December 2015, MFDS made efforts to communicate information pertaining to abnormal cases by using text messages or e-mails and investigate the contents of administrative investigation measures. A system was organized and operated to review data such as on-site inspection and toxicity. In order to ensure smooth operation, MFDS prepared the “Abnormal Case Investigation and Management Manual” that stipulated the criteria, methods, and follow-up measures for abnormal cases, and established a cooperation system with experts to handle abnormal cases. In February 2016, the Health Functional Food Act was revised to increase responsiveness to the public’s voice by introducing a consumer administrative inquiry request system that allows consumers (more than 20 people) suffering the same damage to request collection and inspection of samples from such companies.

(2) Enhanced Management of Monitoring System for Internet Health Food Sales Sites

MFDS is conducting thorough follow-up management such as collecting, inspecting, and monitoring health functional foods that are being distributed online. This has become important in view of various risks posed by drugs for sexual dysfunction, blood pressure enhancers, and new harmful substances. The illegal Internet trading sites that have been identified are cooperating with related organizations such as the Korea Communications Commission.

(3) Reevaluation

In 2017, MFDS re-evaluated 9 functional materials that had caused controversy over their safety. As a result, changes were made to: manufacturing standards (1), specifications (2), daily consumption (2) and dietary warnings (8).

C. Implementation Plan

1) Stronger Management of Abnormal Events

To collect, analyze and assess abnormal cases related to health functional food more systematically, MFDS will lay a legal foundation on abnormal cases (by December, 2018) and regulations on the management of related information since they are subject only to guidelines as of now.

2) Specifications of Approval Standards for Health Functional Foods

To establish a clear and predictable approval review system, MFDS plans to come up with standards (November, 2018) by analyzing materials submitted for review and supplemented, as well as review results between 2004 and 2017; classify approved functional materials into large, medium and small categories; and design detailed guidelines on functions of health food.

3) Reevaluation of Functional Materials

In 2018, MFDS will reassess 19 kinds of oligosaccharides selected for periodical reassessment in 2017 and 7 kinds of glucosamine selected for frequent reassessment in 2018. The stages will be as follows: notice (Feb.), evaluation (Mar.-Oct.), reading and feedback (Nov.) and confirmation and notification (Dec.)

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4. Strengthening of Safety Management of National Nutrition

A. Leading Koreans to Moderately Consume Potentially Hazardous Nutrients

1) Leading Koreans to Moderately Consume Sodium

A) Background

There is well-established evidence on the link between excessive intake of sodium and chronic diseases like obesity and high blood pressure. For Koreans, daily average sodium intake decreased by more than 20% from 4,878 mg in 2010 to 3,669 mg in 2016 but it still crosses more than 2 times the WHO's recommended amount of 2,000 mg. Therefore, MFDS has worked to reduce sodium intake by continuously performing initiatives to cut sodium consumption.

B) Achievements

MFDS helps Koreans easily learn how to reduce excessive nutrient intake through public service ads on mass media. In 2017, MFDS actively employed familiar media such as news, TV, apartment elevators, and supermarkets to build national consensus. MFDS also communicates with the general public via Facebook and blogs in an effort to raise awareness of the need to reduce sodium intake.

In 2017, MFDS operated 705 sessions of the 'Strong Eating & Drinking Exploration Team', a field experience classroom program, training 18,165 children to participate in the practice of reducing sodium and sugar while cooking.

For group meal services, MFDS manages "Sam-sam (not salty) Cafeteria", which provides a meal (lunch) with less than 1,300mg of sodium. As of the end of 2016, MFDS operated 167 Sam-sam Cafeterias including 84 designated ones.

MFDS established guidelines on restaurants that practice reduced sodium intake in January, 2015 and designated 518 practicing restaurants as of 2017.

MFDS has been supporting franchises to develop and spread menus with less sodium starting from 2013 based on the analysis of sodium content and professional consulting. MFDS has also been assisting fried chicken shops to cut sodium used for water immersion.

In the area of processed food, MFDS has guided food companies to reduce sodium voluntarily and until 2016, they cut sodium content from 332 products of nine food groups.

In addition, MFDS holds policy briefing sessions for civil servants by providing guidance to cooperate with local governments more closely, and operates commissioned programs for nutrition practitioners and experts.

C) Implementation Plan

In 2018, MFDS will expand the existing sodium reduction policy and execute key projects by target areas such as manufacturing, processing, eat-out, and meal services, considering market situations and changing eating patterns. MFDS will develop a sodium reduction guideline for ready-made meals like lunch boxes and support the head office of franchises to thoroughly manage their stores so that they come up with less salty menus.

MFDS will enable public participation through public events and idea contests to cut down sodium amounts in food and publicize how to reduce sodium using apartment elevator screens, outdoor electronic signs, and big supermarket monitors.

2) Induction of Proper Sugar Intake

A) Background

Excessive sugar intake increases the possibility of obesity and dental caries, and in turn, obesity is closely related to chronic diseases such as diabetes. According to MFDS' survey, the total sugar intake per calorie intake increased from 70.0g in 2010 to 76.9g in 2015, and sugar intake of people aged 3 to 29 through processed foods exceeded WHO criteria that specified the intake should be within 10% of daily calories.

Therefore, MFDS announced the first comprehensive sugar reduction plan with the goal of controlling the amount of sugar from processed foods to 10% of daily intake by 2020 for the whole nation. MFDS is striving to establish a base for promoting dietary habits to eat less sweet foods, create an environment for people to select foods with less sugar, and promote sugar reduction policies.

B) Achievements

MFDS has developed and distributed a sweet taste assessment tool to check the degree of individuals' preference for sweetness from 2013 through simple tests and also published "Story of Sweet Taste" and guidebooks for teachers as an educational material to help reduce sugar intake of elementary school students. About 100,000 guidebooks were distributed to 1,175 schools in 2017.

To make promotions customized for children and adolescents who tend to choose a high intake of sugars, MFDS came up with a character named “Loshubee” to reduce sugars, and developed rap songs and card news that were released to both online and off-line media including 193 highway rest areas, franchise stores, and Youtube, etc. For parents, five online educational video clips were produced to raise awareness on reducing sugar intake. Further, online training programs for reducing sugar were added in the online supplementary education for nutritionists; about 17,000 nutritionists watched and participated in the education in 2017.

In addition, MFDS regularly investigates sugar intake through whole foods, and conducts consumer awareness surveys to identify the main source foods and policy acceptance level.

C) Implementation Plan

In order to promote successful implementation of the comprehensive sugar reduction plan, more practical sugar reduction policies should be put in place. To this end, MFDS will continue to induce changes in eating habits through targeted and customized promotion and education, and support the reduction of sugar in cooked and processed foods so that the market for low-sugar products can be vitalized. In addition, MFDS plans to monitor changes in consumers' perception on the proper level of sugar intake and their efforts to reduce the amount of sugar, the amount of sugar consumed by each class, and the major source food of sugar.

B. Expansion of Nutrition Labeling and Provision of National Nutrition Service

1) Background

We now live in the era of healthy centenarians with significant increase to the average life expectancy thanks to the advances in medical technology. On the other hand, the number of eat-outs has rapidly increased due to changes in dietary habits with increased income and increased number of couples working together. Due to over-nutrition or nutritional imbalance caused by changes in Korean's dietary patterns including westernized diet, chronic conditions such as obesity and cardiovascular diseases are emerging as the major cause of death. Therefore, public interest in health and the demand for personalized nutrition and dietary information for self-health care are increasing day by day.

In order to enable the public select healthy food and guarantee consumers' right to know about nutritional information of foods, MFDS has expanded the scope of nutrition labeling to not only processed foods but also foods served in restaurants, and provided reliable nutrition information through mobile apps and the MFDS website by establishing a nutrition analysis system for foods people eat when they dine out.

In addition, MFDS helps people select healthy foods by providing nutrition information through a reliable national nutrition database.

2) Achievements

A) Nutrition Standards and Labeling of Processed Food

The nutrition labeling system enables displaying nutrition information of processed food on the packaging of foods in accordance with certain standards. The ultimate goal of this system is to contribute to public health by helping consumers select suitable healthy foods based on nutrition information.

Since the nutrition labeling system was first introduced in Korea in 1995, the types of foods that are required to have nutrition labels have been gradually expanded. According to the Enforcement Rule of the Food Sanitary Act, currently, 13 food groups including retort foods, confectioneries (snacks, candies and sweetened ice), breads and dumplings, chocolates, jams, edible oils, noodles, beverages, special purpose foods, fish sausages and instant foods (gimbap, hamburger and sandwich), coffee (excluding roasted coffee and instant coffee), and pastes (excluding Korean Meju, Korean traditional soy sauce, Korean Doenjang and Cheonggukjang) are the subjects of food nutrition labeling. In addition, according to the Livestock Products Sanitary Control Act, it is mandatory to label nutrition contents and values on milk and dairy products (milk formula, raw milk, fermented milk, processed oil, ice cream, powdered milk, natural cheese, and processed cheese) among processed livestock products; sausages and ham among processed meat products; as well as livestock products. In 2006, 4 nutritional components (sugars, saturated fats, trans fats, and cholesterol) were added as subjects for mandatory nutrition labeling to prevent chronic diseases caused by dietary habits, and a regulation on serving size was newly established so that consumers can easily get information about their calorie and nutrition intake. As a result, people now can check the serving size and nutrition facts on the 9 nutritional components of calories, carbohydrates, sugars, proteins, fats, saturated fats, trans fats, cholesterol, and sodium per 100g(ml) of each food product.

In 2012, the 「Food Labeling Standards」 was amended to label the nutrition information of foods that are packaged and sold for one meal as a serving per container, so that consumers can more clearly understand nutritional information of the food they eat. Furthermore, MFDS introduced a "Serving Size Notification System" online in order to help businesses more conveniently set the serving size of their food. Also, based on international references and Dietary Reference Intakes for Koreans (amended in 2012), MFDS amended the "Nutrient Reference Values," which is used in food labeling.

MFDS had a meeting with relevant businesses and conducted site visits in order to expand the mandatory nutrition labeling to pastes such as Doenjang and coffee. In order to promote and raise awareness on nutrition labeling, MFDS carried out a campaign named 'Reading Nutrition Labeling' by distributing publicity leaflets through a number of events such as Food Safety Day and Youth Expo that many people participate in. In addition, in an effort to reduce intake of hazardous nutrition such as sugar and sodium that are closely related to high blood pressure and obesity, MFDS has actively promoted the use of nutrition labeling.

In 2015, the Enforcement Rule of 「Food Sanitation Act」 was revised to make nutrition labeling of pastes and coffee mandatory; set the serving size for some types of food such as pastes and sugar etc. that hadn't until then provided serving size; and change the serving size of foods such as coffee and teas whose intake has changed greatly in recent years (Notification of Amendments of 「Food Labeling Standards」).

On the other hand, although "Serving size" has been used as a reference for nutrition labeling since 2006, many people were confused due to many similar foods with different "Serving sizes" and businesses that intentionally reduced the serving size of their food in order not to be classified as high-calorie, low-nutrition food. In order to address these problems and improve the utilization of nutrition labeling system, the unit and format used in labels were revised to make it easier for consumers to understand nutrition labels. Specifically, based on the results of the 2015 Nutrition Label Recognition Survey covering 2,000 people, the unit was modified to nutrient content value per total content (as 85% of consumers preferred) and, as for the design of labels, the order of nutrients such as sodium and sugar was changed by reflecting consumers' interests. Moreover, MFDS organized a design team to provide consumer-oriented labeling design that meets the needs of people, the policy users.

Further, as the "Korean Nutrient Intake Standard" was revised in Nov. 2015, nutrient standards were changed to reflect people's nutritional status as follows: vitamin D (5 ㎍ → 10 ㎍), chromium (50 ㎍ → 30 ㎍), carbohydrate (330g → 324g), and fat (51g → 54g) and

the daily reference intake of sugar(100g) was newly set so that consumers can easily understand the sugar content of products.

In December 2017, nutrition labeling was applied to ready-to-eat (cook) foods, cereals, and processed cocoa products, etc. to reflect the consumer trends considering the increased number of people who eat alone. The amendment aimed to reduce unnecessary social costs through public health management by helping consumers to select the best food, and enabling businesses to develop and distribute healthier food. (to be executed in Jan. 2020)

In addition, in order to provide nutrient information on alcoholic beverages through voluntary nutrition labeling, 「Guidelines on Voluntary Nutrition Labeling of Alcoholic Beverages」was prepared and released (May 2017). The guidelines include the label design that should be displayed in the table considering each product's area for labels and tolerance for nutrients.

MFDS also enabled the sodium content comparative claim for commonly-consumed foods high in sodium such as noodles, cold noodles, fried noodles, hamburgers and sandwiches among ready-to-eat·convenience foods, so that consumers can select foods suitable for them. The 「Detailed Standards and Methods for Sodium Content Comparative Claim」 were also improved to display the sodium contents in the graph and enable QR codes when the area on the food package is less than 50㎠.

B) Nutrition Labeling on Children's Favorite Foods

As part of the Comprehensive Measures for Children's Food Safety, MFDS implemented voluntary nutrition labeling for fast food companies (Lotteria, Mc Donald's, Popeyes and KFC, and Burger King), pizza shops, coffee shops, and confectionery and bakery companies. In accordance with the Special Act on the Safety of Children's Eating Habits, it has been made mandatory for businesses (more than 100 stores) preparing and selling hamburgers, pizza, confectionery, bakery products, and ice cream to indicate the content of sugar, protein, saturated fat and sodium per serving since January 2010.

C) Voluntary Nutrition Labeling of Restaurants

MFDS organized a working group consisting of food service businesses of each industry (family restaurants, snack bars including tteokbokki stores, highway rest areas, children's playgrounds, snack corners in large movie theaters, food courts in department stores and large markets, and coffee shops) in order to expand the voluntary nutrition labeling system. As of August 2016, nutrition labeling is used in 11,625 food service companies.

D) National Nutrition Service

MFSD operates a national lab system for food nutrients, providing information on nutritional content in food. In addition, it prepared and released the 'Nutritional Content Book for Eat-out Foods' (paperback, e-book) on commonly consumed foods; the book covered 130 kinds of food in 2012, and expanded to add 108 kinds in 2013, 78 kinds in 2015, 72 kinds in 2016, and 250 kinds in 2017. In an effort to release information through the Government 3.0., the Food and Nutrient daTA System (FANTASY) has been opened to the public in phases since 2014, providing customized nutrition information. In 2017, MFDS added the latest information on the nutrition content of 3,000 food ingredients and established a sugar content database that will be made available to the public in 2018. The importance of these nutritional information has increased as they are now commercially used such as for development of a healthcare application, and also utilized as a basic DB for nutrition-related research projects, hospitals, and school meal services.

MFDS developed and provided 'Calorie Cody', a personal nutritional assessment management program, in 2010 to provide experience-based nutrition services to citizens. As the International Agency for Research on Cancer (IARC) under World Health Organization classified processed meat such as ham and sausages and red meat as carcinogens in Oct. 2015, national interest in the management of red meat and processed meat intake has grown. Accordingly, MFDS analyzed source food and intake of red meat and processed meat in 2016 and built a food database for calculating the intake to install a new program that automatically calculates the intake of red meat and processed meat for each meal through Calorie Cody. This service will be available in 2018.

In 2017, in an effort to provide consumers with information on a nutritious diet, MFDS produced and provided video clips and card news for single-person households including those who eat alone, and also developed and provided nutritious dietary card news for pregnant and lactating women who require special nutrition management. The card news dealt with practical tips for everyday life including information on nutrients; tips for selecting food rich in essential nutrients such as vitamins and minerals; safety rules for diets; tips to manage nutrition for underweight·overweight pregnant women; and nutrition management tips for pregnant women with diabetes or thyroid issues, etc. MFDS also developed and distributed guidelines on food intake that covered table manners for the elderly for whom it is difficult to swallow food and tips on how to control the viscosity of food.

3) Implementation Plan

In order to ensure a healthy diet for Korean people, it is essential to create an environment where users can count the calories they consume in each meal through nutrition labels on processed foods and eat-out foods.

Therefore, MFDS plans to strengthen education·promotion on nutrition labels for consumers so that nutrition labeling system can have a substantive impact on people's diets.

In addition, MFDS will do its best to encourage the use of voluntary nutrition labeling and nutritional content labeling so that more consumers can select healthy food through the labels. MFDS will continue its efforts to provide nutrition information by improving reasonableness of the system and reducing the burden of nutritional content labeling for businesses.

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2018 MFDS White Paper

Ministry of Food and Drug Safety

III

Medical Products

Section 1 Medicine

1. Introduction and Stabilization of GMP in Conformance with International Standards

A. Backgrounds

1) Introduction and Improvement of the of Good Manufacturing Practice

In 1969, at the 22nd World Health Assembly, World Health Organization (WHO) announced the Good Manufacturing Practices (GMP) and recommended that member states adopt the GMP. Accordingly, Korea implemented the GMP on 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 Korean pharmaceutical companies' competitiveness in the global pharmaceutical market. MFDS implemented measures such as securing overall quality of drug substance and finished products; introducing a system for inspecting manufacture and quality control of medicinal products by dosage form; requiring GMPs for Active Pharmaceutical Ingredients (API) and Medicinal Products; changing from evaluation by dosage form to evaluation by item; and introducing a '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 the quality of inspections and align Korea's GMPs with international standards, so that confusions that may arise during exports and imports due to differences in GMP regulations between nations can be minimized. The Pharmaceutical Inspection Convention (PIC), founded in 1970 by the 18 nations of the European Free Trade Association (EFTA), expanded and reformed to the Pharmaceutical Inspection Co-operation Scheme in 1995.

As the 2007 Presidential Advisory Medical Industry Advancement Committee decided on joining PIC/S and signing a Mutual Recognition Agreement with advanced countries, MFDS created a consultative body consisting of experts from home and abroad in 2011 and submitted the PIC/S application in April 2012. Since then, MFDS has continuously prepared for joining the PIC/S through system improvements to align Korean GMPs with international standards.

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) generally takes about 4 - 5 years. After an on-site audit conducted by an 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 held in the same year in Rome, Italy. It only took 2 years, the shortest period in history, for Korea to join the PIC/S. It is a meaningful result that is comparable to Korea's joining of OECD since it significantly improved global trust in Korea pharmaceutical industry. Also, it was significant that Korea joined PIC/S with its entire regulation as is, without having to change the system to conform to 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 enter into overseas markets. In January 2015, MFDS held a PIC/S-organized API workshop in Korea that had around 140 people including policy authorities and industry representatives from various parts of the world as participants. In April 2015 and October 2016, MFDS invited policy authorities from ASEAN nations and held the KOREA-ASEAN Pharmaceutical GMP Cooperation Conference to notify Korea's joining of the PIC/S and promote quality domestic pharmaceuticals to the world. In May 2015, MFDS launched a public-private council (GloPharmEx; "Medicine Overseas Regulation Issue Control Council") for managing overseas regulation issues related to the export of medicine.

2) Stabilization of Internationally Harmonized GMPs for Korea

To align Korean GMPs with PIC/S GMP, MFDS actively improved relevant regulations and standards.

On August 21, 2014, the 「Regulation on the Safety of Pharmaceuticals, etc.」 was revised and promulgated (effective on July 1, 2015). Its main contents were ▲Introduction of post-release stability tests on drug products and a validation system for herbal medication; ▲Development of separate standards for clinical trials and the APIs that were governed by the GMPs of medicinal products; and ▲Introduction of new GMPs for radioactive medicine and medical high-pressure gas. In addition, MFDS published a GMP guidance manual for radioactive medicine and medical high-pressure gas in December 2014 and another GMP guidance manual for APIs and medicinal products in the first half of 2015 in order to stabilize the new GMP by enhancing stakeholders' understanding of the revised regulations. The GMP guidance for APIs and medicinal products were revised in May 2017.

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 for the results of GMP evaluation for manufacturers so that evaluation can be carried out regularly for each pharmaceutical manufacturing site. Thus, 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)」was prepared and enacted in June 2015 through a notification of the 16 annexes of the GMP regulations pertaining to Pharmaceutical Inspection Cooperation Scheme (PIC/S). In addition, since July 2015, MFDS has held briefing sessions on the newly introduced GMP for radioactive medicine and medical high-pressure gas to ensure stable establishment. Also, in order to visit manufacturers' sites upon request to provide guidance and solve problems by listening to their difficulties, MFDS has been operating an on-site administrative support system at the headquarter and 6 regional FDAs since January 2015. In November 2016, MFDS added the PIC/S' GMP regulations for medicinal products to the 「Good Manufacturing Practice」 [Annex 17] for continuous international harmonization of the GMP amendment regulations; the new regulations have been effective since January 1, 2017.

On the other hand, management of manufacturing facilities for beta-lactam antibiotics, which requires attention due to possible hypersensitivity, is being strengthened in the US, Europe, and the advanced member states of the PIC/S. In order to create a safe environment for the use of medicine by reducing the possibility of crossover hypersensitivity at a level equivalent to the standard of manufacturing facilities of international beta-lactam antibiotics, MFDS revised the 「Enforcement Regulation of the Decree on Standards for Facilities of Medicinal Product

Manufacturers and Importers」 in October 2016 and ordered enforcement after two years considering the preparatory period pharmaceutical companies require for facility improvement, making it mandatory to separate workshops for carbapenem antibiotics and monobactam antibiotics.

In addition, after joining the PIC/S, MFDS has been striving to strengthen the competitiveness of domestic pharmaceutical companies in the global market by systematically classifying the supplementary items (by category, region, risk, etc.) and providing relevant information to companies when carrying out inspections on overseas manufacturing facilities. Further, to provide practical information that can be used as references when importing APIs, MFDS systematically extracted and classified supplementary items of overseas inspections by June 2016 and prepared and released a final report on the classification for domestic manufacturers.

C. Implementation Plan

1) Continuous International Harmonization of GMP standards

In order to enhance businesses' understanding of internationally aligned GMP standards, MFDS intends to prepare "ICH Q7 Q&A (guidelines for petitioners)", a guideline on GMP for APIs, validation of the computerized system used for manufacturing pharmaceuticals, and a guidance manual (supplement revision) that covers details on the storage, management, and change management of records in 2018.

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

In order to support the export of APIs to the European Union (EU), MFDS will continue its efforts to be registered in the White List. This will exempt Korea from EU written confirmation. MFDS filed an application in January 2015 for the purpose of registering Korea as a country exempted from written confirmation and responded to the European Commission (EC)' document reviews and on-site evaluation. In 2018, MFDS will strive to complete the registration by continuously carrying out the supplementary implementation plan that it submitted to EC, and utilizing various channels including EU delegation meetings, etc.

Also, based on the pilot projects for exemption from pharmaceutical GMP inspection with the Swiss Agency for Therapeutic Products (Swissmedic), MFDS will push forward to establish mutual trust with EFTA (European Free Trade Association) members including Switzerland regarding GMP in 2018.

Furthermore, MFDS will organize the 4th Korea-ASEAN GMP Cooperation Conference inviting regulatory authorities from 10 ASEAN countries to strengthen the ongoing cooperation system between Korea and ASEAN. MFDS plans to invite the ASEAN GMP Inspector for education and training on GMP-related domestic and overseas status and latest technologies, thereby promoting Korea's drug management system and excellence of domestic pharmaceuticals.

3) Introduction and Continuous Diffusion of Pharmaceutical Quality Improvement System

MFDS will continue to carry out the Quality by Design (QbD) application model and the basic technology development project which has been underway since 2015. In 2015 and 2016, MFDS developed a lab-level exemplary model for tablets and capsules. It also developed a lab-level exemplary model for Freeze-dried Injections in 2017 and will develop trial production of exemplary models for the already-developed 2 lab-level models (for conventional release dosage form and capsules) in 2018. In addition, MFDS is planning to hold workshops on QbD for pharmaceutical businesses and come up with and implement the phase-by-phase introduction plan for entering into the domestic market.

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

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2. International Harmonization and Advancement of Pharmaceutical Regulation

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

1) 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 the review process

for drug approval. To this end, MFDS 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, towards 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. MFDS has been continuously revising the guidelines so that the inspectors and applicants can utilize then for screening and applying for the license.

In 2017, MFDS established and revised a total of 29 guidelines and commentaries including 'Guideline for the Evaluation and Management of Pharmaceutical Metallic Impurities' by reflecting the International Council on Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH) guidelines. Further, a total of 45 medical examination manuals (27 examination criteria, 8 licensing tasks, 8 other types of duties, 1 disclosure of information) were enacted or revised in order to improve predictability and consistency of tasks.

MFDS will continue to enact and amend the Guidelines regarding the evaluation of drugs for conformance with international standards, by actively introducing ICH guidelines. In addition, MFDS plans to continuously establish and revise the Pharmaceutical Affairs Excellence Assessment Standards Operational Manual.

2) 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 capabilities of domestic pharmaceutical companies.

The results of the bioequivalence study of generic drugs are continuously disclosed, and the generic drug approval screening report published regularly. In addition, MFDS is expanding the disclosure items in 'Drug Approval Report' for submission of data on new drugs and has made the safety and efficacy screening review open for new drugs licensed since January 2017. MFDS will continue to disclose information on product licensing and screening results, thereby enhancing the consistency, transparency, and reliability of the licensing process.

3) Providing Medical Safety Information

Since 2010, MFDS has been continuously publishing manuals on various topics related to safe use of medicines through its website for the benefit of consumers.

In 2017, MFDS published a series of special articles in daily newspapers to provide information on safe use of over-the-counter drugs such as painkillers that are closely related to people's lives. In addition, it published a manual for the safe use of medicines such as thioctic acid injections, which led to a controversy over the possibility of misuse in order to help consumers use the medicines safely. Also, MFDS provided information of interest to consumers using the card news format in order to improve accessibility.

In 2018, MFDS plans to publish a manual on the safe use of medicines for chronic diseases such as osteoporosis, distribute card news on medicines intended for the elderly with dementia or stroke, and release educational materials on over-the-counter drugs for elderly people living alone.

4) Efforts for International Harmonization of Pharmaceutical Evaluation

A) Korea's Activities for the International Council for Harmonization (ICH) of Technical Requirements for Pharmaceuticals for Human Use

Korea has regularly participated in the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH) Assembly since 2006 and became a member country of ICH as a drug regulatory authority in November 2016. Since 2011, MFDS has been participating in the joint development of guidelines for 18 areas of the Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use. MFDS completed joint development of guidelines in 9 areas including "Genomic Sampling and Management of Genomic Data (E18)" which was finally approved in 2017.

Taking part in the joint development of the 'APEC Harmonization Center (AHC)-ICH Online Training Program' with ICH, MFDS has provided guidelines training program on ICH E2 (Safety Information Management) since August 2016 and guideline training on quality examination based on pharmaceutical designs (ICH Q8, Q9 and Q10) since August 2017 through E-learning Center of AHC. In 2017, MFDS chaired the International Pharmaceutical Regulators Forum (IPRF) to present the status of regulatory improvements in Korea and share the activities and action plans of the Biosimilars Working Group.

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 Japan in June and USA in November 2018.

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

The APEC Harmonization Center (AHC)[5], which was established in the MFDS (NIFDS) in June 2009, has held a total of 37 workshops until 2017 and co-organized training sessions on the pilot operation of CoE (Center of Excellence).

In 2017, AHC hosted 5 workshops and training sessions for CoE at home and abroad, enhancing the regulatory capabilities of developing countries in the APEC region and supporting the exports of domestic companies. By co-hosting workshops on Biotherapeutic Products and Pharmacovigilance and Medical Devices Vigilance, and training sessions for CoE in the fields of Global Medical Product Quality and Supply Chain Integrity and Advanced Therapies, AHC strengthened its position as an organization at the forefront of efforts to promote regulatory convergence.

In 2018, AHC will hold workshops for distribution system of medical products and international harmonization of medical devices and co-host CoE training sessions on Multi-Regional Clinical Trials (MRCT) and Good Clinical Practices (GCP), as well as on medical devices vigilance. In addition, AHC will develop and provide an online training program for regulatory harmonization and regulatory science through AHC e-Learning Centers.

C) International Cooperative Activities on Generic Drugs

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

The International Generic Drug Regulatory Programme (IGDRP)[6] had a total of 7 pilot meetings from 2011 to 2014. The official activities of IGDRP started from 2015. The 2nd IGDRP Assembly was held in Seoul in November 2015, and a total of 6 meetings have been held

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

6) The International Generic Drug Regulatory Programme (IGDRP) is a council formed in 2011 under the leadership of regulatory authorities of USA, Canada, Australia and various other nations to facilitate cooperation and harmonization of regulations on generic medicine. It consists of an 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.

so far including the 6th IGDRO Assembly held in November 2017. Since Jan. 1, 2018, IGDRP and IPRF will be integrated into IPRP (International Pharmaceutical Regulators' Programme).

WHO Pre-qualification (PQ) is a system to evaluate the quality, safety, and effectiveness of medical products that WHO supplies to underdeveloped countries. Since 2014, MFDS has participated in a total of 9 sessions (until 2017) of joint evaluation by dispatching Korean evaluators. Also, through a communication channel for supporting WHO PQ Certification (2014) and workshops and tailored technical consultations regarding WHO PQ (2015-2017), MFDS actively helped domestic companies to enter the market of WHO-supplied medicine.

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

D) 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 the development of standardized items for KP (Korean Pharmacopoeia) and USP (US Pharmacopoeia), interchange of personnel, and joint symposia.

The project to develop standardized items for pharmacopeias, in both Korea and the US, will strengthen the exports of Korean medical products to the US market as well as Pharmerging markets. This will also allow domestic pharmaceutical products to be listed in the highly regarded USP.

In addition, the symposia held by the two organizations every year are considered to have enhanced the global competitiveness of Korean pharmaceutical industry by providing opportunities to understand trends of standards in developed countries early on and thereby harmonize with international standards.

The major plans of MFDS for 2018 are to: participate in joint development of Gemifloxacin, a new drug approved by the US FDA, for the first time in Korea; take part in the joint research on standard products; support domestic companies to take part in the project to supply pharmaceuticals that cannot by supplied by the US anymore; support domestic companies to join WHO-PQ projects; help the Korean government's liaison officers to participate in the USPC (United States Pharmacopoeia Convention) Expert Committee; and hold joint symposia in order to promptly learn of the trends in standards of developed countries.

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B. Vitalization of Cooperative Projects with Foreign Regulatory Authorities

1) Invitation and Training by Pharmaceutical Official Development Assistance (ODA)

A) Background

Since becoming a member of the Development Assistance Committee (DAC) under the Organisation for Economic Cooperation and Development (OECD) in November 2009, Korea has continuously expanded the scale of its assistance to reach 2.25 billion dollars in 2016. So far, pharmaceutical Official Development Assistance (ODA) had been mainly focused on practical assistance such as the provision of emergency relief pharmaceuticals by the Ministry of Health and Welfare and the Korea Foundation for International Healthcare (KOFIH).However, in recognition of the growing necessity for assistance with the pharmaceutical related professional area along with the expansion of Korea's ODA, a pharmaceutical ODA project was developed as a part of "Health Technology (HT) Global Expansion Strategies" in May 2011.

B) Achievements

In May, 2012, in cooperation with the Ministry of Foreign Affairs and the Korea International Cooperation Agency, MFDS held a multi-country invitational training on 「Pharmaceutical Safety」 in order to reinforce the pharmaceutical safety management capacity of regulatory agencies in developing countries. The training was offered to pharmaceutical authority personnel from 8 countries (15 participants) including Laos, Myanmar, Bangladesh, Vietnam, Ethiopia, Indonesia, Pakistan, and Cambodia; participants were provided education· training programs on Korea's pharmaceutical safety management system. The scope of countries participating in the training was expanded from Asia to Africa, and pharmaceutical authority personnel from 7 countries (13 participants) including Ghana, Nigeria, Senegal, Algeria, Uganda, Egypt, and Kenya were invited in 2013; and 7 countries (12 participants) including Ghana, Angola, Bhutan, South Sudan, El Salvador, Haiti, and Egypt were added in 2014 respectively.

Furthermore, the training was conducted for 8 countries (16 participants) including Ghana, Mongolia, Burundi, Sri Lanka, Ethiopia, Uganda, and Egypt in 2015, and for 11 countries (16 participants) including Mongolia, Azerbaijan, Indonesia, Vietnam, Cambodia, Pakistan, Ghana, Uganda, Angola, Burundi, and Ecuador in 2016.

Moreover, based on the experience of the 「Pharmaceutical Safety」 training in 2012-2013, MFDS carried forward the 「Pharmaceutical Safety (Asia)」, a multiyear (2013-2015) invitational

training for government officials of pharmaceutical regulatory agencies in Southeast Asian countries (Vietnam, Indonesia, Philippines, and Cambodia) that are faced with the n urgent task of establishing a pharmaceutical safety management system for illegal· unwholesome medicines. This training focused on Southeast Asia was held aside from the existing training program. This training program was composed of an intensive course that focused on education· training on drug monitoring and pharmaceutical manufacturing· quality management, and reflected the pharmaceutical safety management training demands of the four countries. The training was conducted for 51 government officials from regulatory agencies in 4 countries for 3 years.

C) Implementation Plan

In the future, MFDS is scheduled to reshuffle the ODA projects from multilateral assistance to bilateral assistance, and carry out the capacity reinforcement projects for developing countries based on pharmaceutical safety, quality management system, and technological know-how, which are Korea's strengths.

2) International Coalition of Medicines Regulatory Agencies (ICMRA)

A) Background

The 8th Summit of Heads of Medicines Regulatory Agencies was held in Amsterdam, Netherlands, in November, 2013 by the World Health Organization (WHO) with the participation of heads of medicines regulatory agencies from the US, the EU, Japan, China, South Korea, Singapore, Australia, New Zealand, Canada, Mexico, Brazil, Argentina, Nigeria, South Africa, the UK, France, Belgium, Germany, Ireland, Italy, Netherlands, and Switzerland. In the summit, it was decided to establish the "International Coalition of Medicines Regulatory Agencies (ICMRA)" for task sharing and information exchange through cooperation among regulatory agencies. Accordingly, ICMRA was officially established in November 2015 after test operation.

B) Achievements

Following the 11th Summit of Heads of Medicines Regulatory Agencies in Switzerland in October 2016, a general meeting of the ICMRA was held. The main issues raised at the Summit were: regulatory activities appropriate for the 21C; roles of regulatory personnel as helpers;

roles of regulatory authorities as providers of information; introduction of project progress status for reinforcing transparency of regulatory agencies and raising efficiency of pharmaceutical information provision; exemplary rules for stakeholders; direction of the summit, etc. In addition, the main issues discussed at the ICMRA were about working group projects and strategic priorities including the supply chain integrity group of medicines; crisis management; pharmacovigilance; establishment of the ICMRA website; GMP inspections; and capacity building of regulatory agencies. Discussions about innovation were started in 2017.

C) Implementation Plan

Since 2016, MFDS has actively participated in pilot tasks of the ICMRA, such as a working group project related to crisis management of medicines. In addition, from 2017, MFDS plans to facilitate the advance of domestic medicines into the global market by aggressively participating in projects for developing/ promoting innovative medicines, product technologies related to development and approval of new technologies, regulation progress, and development of new technologies.

3) Expansion of Cooperation with Overseas Regulatory Agencies

A) Background

Thanks to the growing research & development (R&D) capacity of Korea's pharmaceutical companies, overseas expansion of domestically developed medicines with world-class competitiveness has been vitalized. In particular, international level products of Korea such as stem cell treatment drugs and biosimilars are advancing into the global biopharmaceutical market in earnest. For continued advance of these domestic medicines into overseas markets, cooperative relations such as information exchange with individual pharmaceutical licensing and approval authorities of other countries must be built as this will secure international credit rating of Korea's pharmaceutical safety management system.

B) Achievements

MFDS signed a Memorandum of Understanding (MOU) with Mexico (2016) for mutual cooperation in pharmaceutical manufacturing and quality (GMP) areas, following China (2009), Singapore (2010), Indonesia (2012), Poland (2013), Ecuador (2014), Brazil (2014), Vietnam (2015), and Japan (2015), as well as MOUs with Argentina (2016) and Peru (2016) for practical

cooperation in areas such as mutual information exchange, manpower interchange, and capacity building. As for China, the MOU signed in April 2009 was elevated to minister level agencies of both countries, and the "Cooperation Agreement on Food, Pharmaceuticals, Cosmetics, and Medical Devices between Korea's MFDS and China Food and Drug Administration (IATF)" was revised. In addition, follow-up measures for cooperation are in progress through a Korea-China Director General-level Meeting. In November 2016, a Korea-China Director General-level Meeting on Pharmaceutical Affairs was held to share pharmaceutical regulatory trends mutually and discuss Korean pharmaceutical companies' issues on exports to China. In the meantime, Seoul hosted a Korea-China-Japan Clinical Trial Area Cooperative Council that served as a venue for discussions on rapid approval and implementation of clinical trials conducted in the three countries. In addition, in order to establish a bridgehead for expansion of Korean pharmaceutical exports to Japan, it was decided to hold a "Korea-Japan Public and Private Joint Symposium" periodically, and the first symposium was held in Tokyo, Japan, in June 2016, in connection with the "Korea-Japan Director General-level Meeting on Pharmaceutical Affairs." Through this symposium, the two countries shared approval·review systems for active pharmaceutical ingredient (API) as well as the recent pharmaceutical regulatory trends in both countries, and discussed future direction thereof. Moreover, the "Korea-Japan Generic Pharmaceutical Forum" hosted by the Korean embassy to Japan served as a platform for exchange and communication to facilitate networking between Korea's API manufacturers and Japanese generic medicine manufacturers.

Besides, in order to relieve export barriers against countries in Central and South America, the cycle of Mexico's GMP regular inspection on Korean medicines was increased from 2 years to 5 years through an MOU in the GMP area with Mexico's Federal Commission for Protection against Sanitary Risk (COFEPRIS) in April, 2016. It is expected that this measure will reduce burdens of time and costs for domestic pharmaceutical companies. In December 2016, MFDS signed an MOU with Peru's Ministry of Health to register the Korean Pharmacopoeia (KP) as reference pharmacopoeia, laying the foundations by which KP can be officially recognized in Peru in the future like the United States Pharmacopeia or the European Pharmacopeia. In 2017, MFDS exchanged information on recent changes in clinical trials, etc. with Poland. In addition, through "The 2nd Korea-Japan Public and Private Joint Symposium" and "The 3rd Korea-Japan Director General-level Meeting," the two countries discussed international trends on biosimilars and a mutual information exchange system for the medicine and pharmacovigilance areas, supporting expansion of the domestic export to Japan.

C) Implementation Plan

Based on MOUs with overseas pharmaceutical regulatory authorities, MFDS plans to expand information and manpower exchange in areas such as pharmaceutical approval·review, inspection on pharmaceutical manufacturing, and quality management standards (GMP), and pursue and expand the scope of the Korean pharmaceutical industry's export strategies.

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

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

A) Background

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

B) Achievements

In August 2017, the approval history of pharmaceuticals for clinical trials used for the purpose of emergency or treatment was released to the public. This will enable patients or their caregivers to directly check codes of clinical trial pharmaceuticals approved for treatment of emergency patients, and hospitals using these pharmaceuticals. This measure has been aimed to expand treatment opportunities for emergency patients, etc.

In addition, the 「Regulation on the Safety of Pharmaceuticals, etc.」 was pre-announced (Sept. 2017) to prepare grounds to register clinical trial information and release the information for expanding treatment opportunities for patients and securing objectivity and transparency in the process of clinical trials; amendments are slated to be implemented.

C) Implementation Plan

In 2018, in order to build an environment where clinical trials can be quickly carried out, MFDS will review foreign cases including those in the US and increase the scope of matters to be exempted from approval process of a clinical trial plan to the extent that safety and effectiveness are secured.

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

A) Background

In order to safely and scientifically conduct clinical trials, guidelines of the "International Conference on Harmonization-Good Clinical Practice (ICH-GCP)" and internationally harmonized 「Good Clinical Practice (GCP)」must be complied with. In addition, it is prescribed in Article 34-2 of the Pharmaceutical Affairs Act that clinical trials shall be conducted by institutions designated by the Ministry of Food and Drug Safety.

[Table 3-1-1] Status of Designated Pharmaceutical Clinical Trial Testing Institutions

(As of Dec. 31, 2017; Unit: Number, Source: Clinical Trials Management Division)

Region	Seoul	Gyeonggi-do	Busan	Gyeongsang-do	Chungcheong-do	Jeolla-do	Daegu	Daejeon	Gangwon-do	Gwangju	Incheon	Ulsan	Jeju	Total
Sub-total	57	32	19	14	10	12	10	8	5	8	8	2	2	187

Since the introduction of the Clinical Trial Institution Designation System (1994), MFDS has designated and managed clinical trial testing institutions continuously through regular inspections, etc.

B) Achievements

MFDS has carried out both regular and random inspections for improving reliability and reinforcing overall competency of clinical trial testing institutions. In 2017, MFDS conducted regular inspections on 33 institutions and additionally carried out random inspections on inspected 27 institutions. In addition, MFDS conducted 54 regular and irregular inspections in 2016 and 84 in 2015 in an effort to continuously and systematically manage the clinical trial testing institutions.

C) Implementation Plan

According to changes in the domestic clinical trial environment, MFDS plans to expand inspections on clinical trial clients along with inspections on clinical trial testing institutions. This expansion of scope of inspection to clients aims to actively respond to situations where clients have additional roles such as protection of persons subject to clinical tests.

In addition, it is expected that inspections on clinical trial clients will increase the overall reliability of clinical trials since clinical trial clients play the role of selecting testing institutions, monitoring, compensation for persons subject to clinical tests, etc.

3) Reinforcement of Education for Personnel Involved in Clinical Trials (Clinical Trial, Bioequivalence Test)

A) Background

To safely and scientifically conduct clinical trials, it is essential that the personnel participating in the clinical trials have sufficient knowledge about trials and the relevant regulations and conduct trials in an ethical manner.

B) Achievements

Since 2016, pursuant to the Pharmaceutical Affairs Act, personnel intending to conduct clinical trials, etc. shall complete specified education courses for fixed hours in institutions designated to provide relevant education, in order to enhance professionalism and protect persons subject to clinical tests.

Considering the education courses and qualifications instructors require, MFDS designated 35 institutions for clinical trial education including Korea National Enterprise for Clinical Trials, for 7 education programs (for evaluators, examiners, clinical trial pharmacists, persons monitoring trials, coordinators, persons for quality assurance, and persons for tasks).

C) Implementation Plan

In 2018, MFDS plans to release the education schedules of all education institutions throughout the year in order to allow clinical trial personnel take the education courses smoothly. Further, MFDS will revise and publish “Clinical Trial Personnel Education Q&A” in order to provide necessary information for conducting clinical trials in a continuous manner.

4) Reinforcement of Safety Information Management of Clinical Trials

A) Background

There is an increasing need to reinforce management of drug safety information such as adverse drug reaction during clinical trials.

B) Achievements

With the establishment of an "Adverse Drug Reaction Electronic Report System" in Dec. 2016, safety information can now be systematically and efficiently managed through computer data (DB). In addition, MFDS prepared and distributed (Oct. 2017) an "Electronic Report User Manual for Clinical Trial Adverse Drug Reaction" and "Considerations for Pharmaceutical Clinical Trial Clients for Safety Information Evaluation and Reporting," and held briefing (Sept. 2017) in order to reinforce clinical trial clients' safety information reporting capabilities.

C) Implementation Plan

MFDS plans to make recording, storing, and continuous evaluation of adverse drug reaction compulsory, and institute penalties for false documentation or intentional delay in reporting of relevant records such as adverse reaction during clinical trials.

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3. Strengthening the Safety Management of Approved Pharmaceuticals

A. Cutting off Distribution of Illegal and Unwholesome Medicines and Activation of a Monitoring Network (Activating a Monitoring Network)

1) Background

The term 'illegal and unwholesome medicines' refers to ① medicines that have not been approved in accordance with the Pharmaceutical Affairs Act (=Unauthorized), ② medicines for which the Active Pharmaceutial Ingredients(APIs) are different from the AI for which the manufacturer secured approval or medicines that have significantly insufficient amounts of the

AIs (= Defective), and ③ counterfeit or fake medicines similar approved formulae (= Forgery & Counterfeiting) (Please refer to Article 3 of the Act on Special Measures for the Control of Public Health Crimes). In the past, MFDS focused on preventing the distribution of illegal and unwholesome medicines in the normal distribution channels by restricting any unauthorized or defective medicines at the manufacturing (import) stage of domestic pharmaceuticals. This approach was on the whole effective in achieving the desired results of cutting off distribution of illegal and unwholesome medicines. However, since 2000, the illegal distribution channels of noncompliant medicines have become vastly diverse due to improvements in people's standard of living, changes in the health care system such as the separation of prescribing and dispensing of pharmaceuticals, development of ICT represented by the Internet, and the development of (delivery) systems such as courier service and air mail. The blurring international borders have also contributed to an increasing trend of illegal distribution in terms of drugs with potential for misuse and abuse, referred to as "Happy Drugs." Further, illegal distribution of pharmaceuticals has been on the increase through SNS and mobile messaging services as well as Internet-based e-commerce websites.

2) Achievements

MFDS shared surveillance information about pharmaceutical manufacturers, importers, and sellers and jointly carried out monitoring in cooperation with local governments in order to prevent the distribution of illegal and unwholesome medicines such as unauthorized or defective medicines. In addition, it conducted a periodical GMP (Good Manufacturing Practice) evaluation on a total of 354 domestic pharmaceutical manufacturing sites for Active Pharmaceutical Ingredients (APIs) and medicinal products from 2015 through 2017. It also successfully introduced the "Certificate of GMP Compliance of a Manufacturer", a periodical GMP evaluation system based on a three-year cycle in 2015. MFDS carried out field surveys on 14 overseas manufacturing sites through a hazard information analysis in 2017. Following implementation of the 「Good Importing Practices, GIP」 in October 2016, MFDS published a Q&A Book (Apr. 2017) and manual (Dec. 2017) to support careful safety management of imported medicines. Prior to the full implementation of the medicines approval renewal system (2018), MFDS established a renewal-related handling system (Apr. 2017) and prepared guidelines for medicines approval renewal (Jul. 2017). Detailed guidelines (Dec. 2017) of the same were released in order to reinforce the post-management system after the approval or registration of medicinal products by enacting the Notification of Medicinal Product Renewal System in June 2016.

In addition, MFDS formed a consultative group with relevant government agencies to encourage pharmacies and wholesalers to install and use a "Hazardous Pharmaceuticals Sales Blocking System (developed in 2015)" that can quickly provide the hazard information on the collection of pharmaceuticals. We strove to resolve consumers' anxiety by encouraging pharmaceutical companies to fulfill their recall process in good faith by expanding the information (amount of manufacturing, sales, distributing, recall) available on the homepage of the MFDS.

[Table 3-1-2] Results of Regular Drugs Surveillance (2017)

('17.12.31. Standard, Unit : Sites, Source: Pharmaceutical Management Division)

Division	Target	Compliant	Non-compliant	Others*
Manufacturers	174	144	14	16
Importers	70	59	11	0
Total	244	203	25	16

※ Not possible to check, transfer, etc.

[Table 3-1-3] Results of Frequent Drugs Surveillance (2017)

('17.12.31. Standard, Unit : Sites, Source: Pharmaceutical Management Division)

Division	Target	Compliant	Non-compliant	Others*
Manufacturers	122	70	52	0
Importers	6	2	4	0
Sellers	12	5	7	0
Total	140	77	63	0

※ Not possible to check, transfer, etc.

[Table 3-1-4] Results of Inspection and Collection (2017)

('17.12.31. Standard, Unit : No. of items Source: Pharmaceutical Management Division)

Division	Manufacturing	Import	Total
Regional Offices	229	52	281
Local Governments	1177	75	1252
Total	1406	127	1533

In addition, in order to prevent illegal and unwholesome pharmaceuticals from being distributed at home and abroad taking advantage of changes in the new social environment

such as the era of e-commerce, MFDS carried out the internet monitoring of illegal pharmaceutical distribution through its own online monitoring personnel. It also encouraged "Pharmaceutical Safety Keepers" comprising ordinary people including university students and consumer groups to carry out Internet monitoring activities. Through this drive, MFDS was able to broaden the scope of the Internet monitoring activities and strengthen appropriate measures such as blocking access to or eliminating websites or postings for selling illegal medicines.

[Table 3-1-5] Number of cases handled such as blocking of Internet access

('17.12.31. Standard, Unit : Cases Source: Pharmaceutical Management Division)

Year	2015	2016	2017
No. of cases handled	17,858	18,949	10,454

Also, MFDS shared information and cooperated with judicial authorities such as the Central Investigation Group of Harmful and Illegal Acts within the MFDS and Korean National Police Agency. This way, it ensured an efficient system for monitoring the distribution of illegal and unwholesome medicines. It also collaborated with Korea Communications Commission and Korea Customs Service to prevent illegal and unwholesome pharmaceuticals from entering domestic and overseas sales websites and the Korean market as a whole.

MFDS also participates every year in the Interpol-led "Pangea Project" that regulates the distribution of illegal pharmaceuticals in cooperation with regulatory authorities, customs offices, and police agencies around the world to promote international cooperation by notifying Interpol of the illegal sales sites of foreign-based medicines.

[Table 3-1-6] Number of cases notified to Interpol

('17.12.31. Standard, Unit : Cases Source: Pharmaceutical Management Division)

Year	2015	2016	2017
No. of cases notified	837	971	954

Also, the MFDS concluded a business agreement with the Korea Internet Cooperation Association, portal companies, internet shopping malls, and overseas shipping companies to prevent the distribution of illegal pharmaceuticals thereby protecting consumers from the sale of illegal medicines and false/exaggerative advertisements. Especially, it helped online shopping

association sponsors to establish and promote "Voluntary Covenants for the Eradication of Illegal Medicine Sales."

Furthermore, MFDS has established a culture that encourages the safe use of pharmaceuticals through personal SNS promotion initiatives like "Pharmaceutical Safety Keepers," a national promotion campaign on the hazard of illegal medicines, Internet banner advertising, etc.

MFDS conducted international cooperation activities including identifying global trends, collecting the latest regulatory information, and introducing domestic activities to the international community by participating in the 6th WHO meeting on illegal and unwholesome medical products and working-level meetings.

3) Implementation Plan

A) Innovation in Pharmaceutical Manufacturing and Quality Management Systems

MFDS completed the GMP investigation and evaluation for all formulations of domestic manufacturing sites over three years (2015 ~ 2017) according to the international standards. Based on the evaluation results of the past three years, the risk of each manufacturing site was analyzed. A differentiated regular evaluation system will be applied to the regular evaluation for pharmaceutical manufacturing sites over the next three-years (2018 ~ 2020) by implementing repeated and intensive monitoring on the top 5% of high risk manufacturers. Simultaneously, MFDS will strengthen the foundations of pharmaceutical safety management through continued communication with the applicable manufacturers and strengthening of inspector's capabilities. In addition, by promoting the registration system for overseas manufacturing sites of imported pharmaceuticals and preparing the legal basis for on-site investigation of overseas manufacturing sites, MFDS will enhance full life-cycle quality management for imported pharmaceuticals from production to distribution. Along with this, for the rapid sales prohibition of hazardous drugs, MFDS plans to expand the scope of the existing 'Harmful Pharmaceuticals Sales Prohibition System' for pharmacies and wholesalers.

B) Support for the Culture of Safe Use for Consumers

MFDS plans to select, collect, and inspect items on a quarterly basis for quality inspection of drugs being distributed, by reflecting consumers' social concerns. In order to check whether appropriate information that influences the consumer's choice of medicines is provided and consumers' right to know is secured, MFDS will intensively investigate if the changes of usage,

dose, and directions for use are described on the contents and whether information is provided in a standard format that is easy for consumers to understand. Also, the MFDS will prepare and implement improvements for labeling items for enhancing the safe use of medicines. Furthermore, there is the frequent off-label use of medicines in the medical field, so the MFDS plans to provide objective and traditional management plans and more information.

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B. Adverse Drug Reaction Relief System [Damage Relief System for Adverse Drug Reactions]

1) Background

Every medicine has some side effects due to its diverse features, and unpleasant adverse reactions may also occur even with proper use depending on individual characteristics. MFDS has introduced a damage relief system for adverse drug reactions in which the government compensates the victims who die, get injured or hospitalized due to unexpected adverse events despite absence of negligence on their part. The relief system is operated through financial assistance from pharmaceutical companies without any legal proceedings.

2) Achievements

As the National Assembly proposed the Revision of Pharmaceutical Affairs Act in 2007, social debate on the damage relief system for adverse drug reactions began in earnest. However, the damage relief system could not be introduced at that point because the National Assembly did not pass the Revision.

In 2012, Korea Institute of Drug Safety Risk Management was established to collect, analyze, and evaluate information on the side effects of pharmaceuticals. The Council for Deliberation on Adverse Drug Reaction was also established for professional deliberations on the cause-and-effect relationship and causes of adverse drug reactions. In addition, the Korea Medical Dispute Mediation and Arbitration Agency that can arbitrate in a dispute on medical accidents was established, opening the doors to a damage relief system for medical accidents.

As part of these efforts, MFDS conducted a research and service project in 2012 for introducing a damage relief system. Based on the results of the project, it began reviewing the revision of the Pharmaceutical Affairs Act in 2013 to introduce the damage relief system. MFDS initiated discussions on the revision of the Pharmaceutical Affairs Act by forming an "Industry-Academy-Government Committee for Adverse Drug Reactions" comprising of pharmaceutical associations, consumer and civic groups, and experts from various fields. It collected a diversity of opinions on forming a damage relief system that fit Korea's circumstances, As a result of discussions with the National Assembly, finally, the Revision of Pharmaceutical Affairs Act was proclaimed on March 18, 2014, and enforced on December 19, 2014.

MFDS has currently assigned the project operation of the damage relief system for adverse drug reactions to Korea Institute of Drug Safety Risk Management. Project operating expenses including compensation for survey workers are covered by financial assistance from the government, and financial resources for payment of the damage relief are covered by financial contributions shared by pharmaceutical companies. To enable fair and objective deliberations on the damage relief payment, the Council for Deliberation on Adverse Drug Reaction within MFDS, composed of 15 members including doctors, pharmacists, representatives from non-profit NOGs, and legal experts, has been formed.

Under cooperation with the pharmaceutical industry, the cost of the damage relief has been charged to "those who received licenses for pharmaceutical manufacturing and received approval for medicinal products and imported pharmaceuticals" from 2015. Approximately funds of KRW 2.5 billion, KRW 4 billion, and of KRW 7.8 billion were secured in 2015, 2016, and 2017 respectively.

In accordance with supplementary provisions of the Pharmaceutical Affairs Act which is specified to have expanded coverage within five years gradually, MFDS expanded the coverage of the damage relief system for adverse drug reactions to deaths in 2015, and added disability and funeral expenses in 2016 and treatment costs in 2017, ensuring a fair social compensation system.

With regard to the current status of decisions on the payment of damage relief, 12 out of total 20 applications in 2015, 54 out of total 65 applications in 2016, and 62 out of total 126 applications in 2017, respectively received approval to be paid. In terms of the amount of compensation, it was equivalent to approximately KRW 560 million in 2015, KRW 1.43 billion in 2016, and KRW 1.43 billion in 2017.

3) Implementation Plan

The damage relief system for adverse drug reactions has become firmly established with expanding the coverage of compensation to treatment costs in 2017. In 2018, MFDS will invigorate the system so that more people will be benefitted. In this regard, MFDS plans to introduce various ways of promoting the system such as specifying guidance on damage relief in drug product instructions and providing education programs customized for medical professionals.

Also, in order to cope with the increase in the number of applications for damage relief and the growing number of complicated cases every year, MFDS plans to prepare a quick procedure by type of application received, and thereby shorten the period of submitting and handling applications and improve convenience for civil complainants.

MFDS will make efforts to ensure that the damage relief system serves as a firm and warm social safety net that protects those who are unjustly victimized by medicines.

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C. Collection, Evaluation, Production, and Supply of Safety Information on Released Drug Products

1) Backgrounds

After drug products are released in the market, an unspecified number of patients come to use them. Patients with different physical and health conditions and those with chronic illness may take the drug products for long-term, which may lead to side effects unobserved at the time of the drug approval stage.

In Korea, public interest in the management of safety information such as side effects of pharmaceuticals is gradually increasing. The MFDS is continuously collecting reports on adverse drug reactions in Korea from consumers, hospitals/clinics, pharmacies, pharmaceutical manufacturers (importers), and regional drug safety centers to manage pharmaceutical safety. Data thus gathered is ultimately developed into new safety information after they go through statistical analysis, literature review, examination of permits issued abroad, and consultation with experts. This leads to appropriate safety processes such as change of licenses, directions

for research investigation, suspension of sales, collection and disposal, and provision of related information to medical institutions, doctors/pharmacists, and consumers.

2) Achievements

A) Collection of Pharmaceutical Safety Information

Meanwhile, MFDS has revised safety management regulations for released drug products in terms such as mandatory designation of pharmaceutical safety management officers, mandatory education, and regular and prompt reporting of adverse effects of drug products. In addition, MFDS established the Korea Institute of Drug Safety Risk Management (January of 2012) dedicated to the collection, analysis, and management of safety information, including side effects of medicines, and also expanded the operation of Regional Pharmacovigilance Centers. As a result, the number of domestic reports on adverse side effects has more than doubled from 92,375 in 2012 to 252,611 in 2017, and the number of accrued reports has reached about 1.34 million in total.

Along with quantitative growth in the number of reports of adverse drug reactions, MFDS prepared related guidelines to enhance the quality of reports as well and developed education courses. Since April 2014, Korea Institute of Drug Safety Risk Management has established guidelines to evaluate the trustworthiness of data on abnormal cases of pharmaceuticals through trust scoring and ranking of the Regional Pharmacovigilance Center concerned. From 2015, the top 30 pharmaceutical companies of Korea have reported their trustworthiness evaluation results. In addition, Regional Pharmacovigilance Centers regularly conduct educational training related to the trustworthiness of adverse drug reaction reports for their adverse drug reaction monitoring officers and pharmaceutical safety management officers.

Starting with three locations in 2006, Regional Pharmacovigilance Center reached 27 sites in 2017. These centers collected about 180,000 adverse side effects reports, which accounts for more than 70% of all adverse side effects reports.

B) Safety Measures Carried out Based on Domestic Pharmaceutical Safety Information Reports

Based on the domestic adverse drug reactions reports, MFDS developed safety information through statistical analysis and consultation with Central Pharmaceutical Affairs Council after reviewing relevant literature and other data. As a result, safety measures such as approval changes of 24 ingredients were made. Safety measures were implemented for six cases in

2012, 25 cases in 2013, 14 cases in 2014, 17 cases in 2014, 21 cases in 2016, and 29 cases in 2017.

Since July of 2014, the newly developed safety information and related change of permits are publicized as "Clue Information Alert" through the homepage of Korea Institute of Drug Safety Risk Management to allow easier access and understanding of safety information.

C) Safety Measures Carried out Based on Information on Pharmaceutical Safety from Abroad

MFDS collects safety information from abroad through real-time monitoring of international organizations, foreign governments, and overseas media. It reviews permits, case reports, and stakeholder opinions from home and abroad, and then carries out safety measures such as reflection of permit articles for the improvement of public health through systematic pharmaceutical safety management. In 2017, MFDS issued a Letter of Safety regarding gadolinium contrast agents and implemented safety precautions to change the approval of about 2,400 items and a total of 102 ingredients, including changes to precautions for formulations containing S-omeprazole, which are drugs for peptic ulcer.

D) Provision of DUR(Drug Utilization Review)[7] Information

DUR information has been developed and provided since September of 2005, following transfer of the "Service for Development and Provision of Standards of Usage for Drug Products," which had been carried out by the Ministry of Health and Welfare (Health Insurance Review and Assessment Agency). In order to prevent misuse, abuse, and side effects that may occur during prescription and dispensing and help ensure safe and proper usage of pharmaceuticals, MFDS prepared "Guidelines for Supporting Proper Usages of Drug Products" (January 1st, 2006). As a result, all current DUR information is available to the general public as well as doctors/pharmacists through the MFDS homepage. Also, through the "Support System for Drug Products Prescription Dispensing" of the Health Insurance Review and Assessment Agency, some DUR information such as unsafe drugs for expectant mothers and age brackets are being delivered to doctors/pharmacists in real time.

In 2008, the DUR information provision service was established to extend the provision of DUR information on domestic licensed drug products; until then, DUR information was

7) DUR(Drug Utilization Review) : A system to ensure that prescriptions of medicines are appropriate, medically necessary, and do not produce improper medical results

only provided for drug products targeted for insurance benefits. In addition to expanding the scope of DUR drugs, MFDS has improved the effectiveness of DUR information and strengthened education and promotion by means of the Plan for DUR Information Provision Services, in addition to the establishment of Korea Institute of Drug Safety Risk Management (April of 2012).

In 2014, the Ministry of Health and Welfare enacted the "Regulation on the Prohibition of Combined Use of Drug Products" (Notification of MFDS) and notified the prohibition on the combined use of drug products and drug ingredients for certain age brackets. In 2016, the prohibition on drug ingredients for expectant mothers was added and the list revised accordingly.

In addition, DUR information became more important in 2015 based on the revision of the Pharmaceutical Affairs Act, requiring doctors/pharmacists to check drug product information at the prescription and dispensing stage (enforced Dec. 30th, 2016).

Thus, the scope of drug products with DUR information specified expanded gradually and at the same time DUR information developed to add to the list of at-risk users, cautions for elderly users, and blood donation warnings.

E) Providing Pharmaceutical Safety Information Customized to Consumers

As part of its efforts to provide drug safety information customized consumers' features and prevent consumer damage from drug adverse events, MFDS developed and distributed brochure and leaflets to public health centers, obstetricians, and gynecologists nationwide. Efforts were directed so as to inform women of the right way of using the necessary drugs during their life cycle ranging from adolescence to fertility, pregnancy, childbirth, and menopause to celebrate the Pregnant Women's Day (October 10). On this day, educational information was prepared and distributed to relevant academic communities, Regional Pharmacovigilance Centers, and pharmacies for the proper use of the major drugs pregnant women must be cautious of (hypertension and hyperlipemia drugs).

Also, in the case of patients with renal or hepatic diseases, special attention should be paid during the prescription and dispensing process of drug products in the medical setting. For this reason and in order to help professionals provide safer treatment, MFDS published and distributed a revised version of the appropriate information for patients with renal and hepatic diseases, which provides the latest drug information.

And also, MFDS distributed a leaflet containing safety guideline on the use of influenza virus treatment (oseltamivir) to public health centers and relevant academic societies throughout

the country, in order to guide safe use of oseltamivir-containing drugs that treat influenza virus.

Customized drug product safety information is also available through the online drug library website (http://drug.mfds.go.kr)

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

MFDS continuously presents analysis results of the correlation between drug product use and side effects using the claims data of the National Health Insurance Corporation and the Health Insurance Review and Assessment Service (HIRA). In 2016, MFDS conducted a risk analysis of severe skin adverse reaction by antiepileptic drugs (lamotrigine) and hypoglycemic agents (DPP-4 inhibitors). In 2017, a linkage analysis was conducted for the treatment of angina pectoris (nicorandil), broad-spectrum antibiotics (fluoroquinolone), and peptic ulcer treatment (Proton Pump Inhibitors).

3) Implementation Plan

Although public interest in drug safety has converged and safety management issues have been raised, it is necessary to investigate side effects in a reliable manner and clarify the causes. However, the analysis system is as yet inadequate compared with the growing number of reports on side effects.

In order to utilize and analyze insurance claim data held by the National Health Insurance Corporation and the HIRA, MFDS is establishing a cooperative system for linking the medical information held by individual institutions. Also, to overcome the limitations of insurance claim data such as non-covered drug charges and omission of test results, medical information on 2.5 million patients held by nine medical institutions nationwide was constructed as a common data model (CDM). By constructing a common data model for each hospital's electronic health record (EHR), integrated analysis between drug products and side effects can be conducted in a quick and accurate manner. If the linkage enables analysis of drug side effects and various medical information, it will be possible to provide various safety information based on reliable analysis results and promote proprietary safety measures for released drug products.

In addition, MFDS aims to continuously provide DUR information as necessary to protect public health by reducing the occurrence of predictable side effects and reduce the medical expenses created by side effects. DUR information, which was developed up to '17, already covers 68.8% of licensed drug products, and the untapped drug products are expected to be reviewed and completed soon. MFDS will continue to develop new fields of DUR information

besides already existing DUR information in order to meet requirements of the actual medical field and national demands.

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

A. Backgrounds

The patent-regulatory approval linkage system for drug products considers patent infringement on new drug products in the drug approval procedure. It is based on the permission data of original drug products during the process of original drug products' patent application. If latecomers apply for license on a generic drug, they should notify the patentee of the original drug and the patentee who has been notified of issues by a patent referee or a lawsuit. This will prevent the generic drug from being marketed for a certain period of time. This system was introduced in 2007 under the Korea-US Free Trade Agreement ("KORUS FTA"). Following the implementation of basic steps of filing for the patent of a drug product in March 2012 and notification of the application for permitted items, the system has been in full swing since March 2015, including prohibition of sales and permission for priority sales items.

Since the introduction of the Korea-US FTA, the patent-regulatory approval linkage system has been concerned about the negative impacts of the enactment of the system, including larger number of patent disputes and delayed entry of generic drugs into the market. In order to enable Korean pharmaceutical companies respond positively to patent-regulatory approval linkage systems and to strengthen their competitiveness, a strategic approach is required based on a clear understanding of the system.

The MFDS is carrying out various projects to minimize the adverse effects of the system and to support the pharmaceutical companies' response and utilization.

B. Achievements

1) Operation of the Patent-Regulatory Approval Linkage System

In order to minimize the side effects that may arise from the implementation of the new system and to ensure stable implementation of the system, the Pharmacist Affairs Act and its subordinate statue, which introduced the prohibition of sales and the approval of priority sales items, were revised (March 2015).

After the implementation of the Patent-regulatory Approval Linkage System in March 2015, as of the end of 2017, sale of 26 products (five ingredients) was prohibited, and 191 products (24 ingredients) were granted priority sales item approval. In particular, among the 61 pharmaceutical companies that obtained approval for priority sales items, 37 companies (60.6%) are small and medium-scale pharmaceutical companies (less than ₩100billion).

In addition, after the implementation of the system in March 2015, MFDS analyzed and evaluated the effects of the patent-regulatory approval linkage system on the domestic pharmaceutical industry and health policy, and reported the results to the National Assembly.

2) Expansion of Patent Information on Pharmaceuticals

Since the introduction of the Patent-regulatory Approval Linkage System that led to the emergence of patent issues in the development and launch of pharmaceuticals, domestic and foreign patent and license information related to pharmaceuticals are investigated and analyzed through the Patent Informatics portal (http://medipatent.mfds.go.kr) in order to support the development of pharmaceuticals (Feb.2009 ~).

By the end of 2017, MFDS established domestic patents and licensing information on 841 drug ingredients. In order to enter the overseas market, MFDS has developed and provided overseas patent information related to a total of 11 countries including China, Japan, four Latin American countries (Brazil, Mexico, Argentina, Colombia) and five ASEAN countries (Vietnam, Singapore, Indonesia, Thailand and the Philippines).

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

In order to support small and medium-sized pharmaceutical companies struggling to establish a patent strategy due to lack of patent personnel and relevant experience, the MFDS is conducting a “Consulting Support Patent Strategy Project for Pharmaceutical Companies.”

For 15 pharmaceutical companies with annual sales of less than ₩150 billion, MFDS provided 7 million won per company to support patent expert consulting expenses. The participating companies examined the present condition of the items to be developed, grasped the patent content information, held consultation on prescription design and proposal of medicines, and received consultation on pharmaceutical prescription design and proposals so as not to infringe on patent rights.

As a result of the project, substantial consulting required for drug development, such as formulation development through patent avoidance, patent application for a new formulation, and preparation of the patent appeal, was facilitated. It was found that the project helped to solve the uncertainties related to drug development and helped to set the direction for development. All participating companies were satisfied with the results of the consulting support.

Also, MFDS provided specialized education in order to support pharmaceutical companies to effectively cope with and utilize the system through understanding the Patent-regulatory Approval Linkage System, coping with patent disputes, and improving business ability. Five education sessions on the Patent-regulatory Approval Linkage System were provided for the benefit of 390 employees in the pharmaceutical industry. In particular, apart from lecturers with expert knowledge and experience from government, industry, academia and so on, a patent tribunal official participated to provide guidance and explanation on relevant policies and current systems.

In addition, MFDS made an in-depth analysis of 35 foreign patent cases from US, Japan, and Europe regarding the listed pharmaceuticals (30 ingredients) applicable to the Patent-regulatory Approval Linkage System, which gathered considerable interest and demand from pharmaceutical companies. This analysis supported the establishment of a patent dispute prevention and challenge strategy by raising the predictability of the domestic patent dispute settlement system for pharmaceutical companies.

4) Establishing a Customer-Oriented Administrative Service System

In order to make effective use of the patent-regulatory approval linkage system, MFDS provided consumer-centered administrative services such as establishing a management system for the list of drug patents and providing a question and answer book.

Electronic processing of complaints related to administration fees, such as inquiry for payment of applicable patent entry fee, mode of payment (credit card, bank transfer, etc.), payment

confirmation through the patent list management system of drug products, improved the convenience of the administrative process for complainants.

The 'Patent-Regulatory Approval Linkage System for Drug Products-Questions and Answers,' which contains frequently asked questions by domestic pharmaceutical companies, was published with information on the patent association system of drug licenses and patents. The Q & A book provides a clear description of the overall system, from the patent registration of drug products to notification on the application for the patent item, prohibition of sales, patent approval for items of priority sales, and agreement reports.

To propose and discuss developmental opinions of experts from industry-academia regarding current conditions related to the patent-regulatory approval linkage system, recent trends and issues, MFDS held two forums (May and June '17). Further, to share pharmaceutical companies' concerns and difficulties and to collect opinions for problem-solving, the ministry operated four private-public consultative groups composed of government-business experts.

C. Implementation Plan

MFDS plans to further strengthen support for the use of the system and help develop drug products, and advance into markets through the patent-regulatory approval linkage system of pharmaceutical companies.

In order to support the development of competitive drug products such as improved new medications and first generics and assist small and medium-scale pharmaceutical companies in their patent analysis and patent strategy efforts, the ministry plans to expand support for expert consulting expenses up to 10 million won.

MFDS will continue to expand the information needed for product development and export through patent informatics by establishment of patent information on newly listed drug products. MFDS will expand overseas patent information provision to 13 countries, including China, Japan, four Latin American countries, 11 ASEAN countries, Ecuador and India as well as investigate and analyze overseas case information.

MFDS plans to document the improvements and clarify detailed standards in the course of operation and settlement of the system and revise the commentary such that it reflects the various cases that have occurred over the past three years.

In addition, MFDS will use the Policy Forum for Capacity Enhancement in the Patent-Regulatory Approval Linkage System and the Patent Information Public Consultation Association

to share the latest issues and trends related to institutional response through discussions on cooperation measures. MFDS will continue to make sustained efforts to strengthen the competitiveness of the pharmaceutical industry by implementing education for persons in charge of the Patent-regulatory Approval Linkage system related to licensing of pharmaceutical companies.

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5. Establishment of a Management System for Preventing Abuse and Misuse of Narcotic Drugs [Innovative Changes in the Safety Management of Narcotic Drugs]

A. Improving the Narcotics Management System for Social Minorities

1) Permitted Usage of Hemp (ingredient) for Medical Purposes

A) Backgrounds

In the present situation where there is not enough analysis of the current status and the necessity of medical hemp, evaluation of medical effects, actual demand in the medical field, and opinions of stakeholders, etc., there is a constant flow of complaints about the petition for legalization of medical hemp (Court ruled suspended sentence for a patient family making overseas purchase of illegal Hemp oil) and the media posing issues. However, the current Act on the Control of Narcotics prohibits the use of hemp for medical purposes in principle, thus necessitating the revision of the relevant ordinance to allow the use of hemp for medical purposes.

B) Achievements

Through the collection and review of main applicants, academic data, clinical data, foreign regulatory status, and permission information, MFDS conducted field surveys in order to identify the medical effects of hemp and exchanged information to monitor the current status of domestic hemp cultivation.

C) Implementation Plan

In order to legalize medical hemp, MFDS plans to collect opinions from major stakeholders (civil applicants, the pharmaceutical industry, medical personnel and researchers, related organizations, etc.) through feedback and expert reviews. This information will be used to make amendments to the anti-narcotics drug law.

2) Expanded Usage of Medical Narcotic Drugs for Rare and Incurable Diseases

A) Background

Under the current law, medical narcotic drugs for self-treatment are not permitted to be imported into Korea except when they are carried directly by the applicant. Since there are no domestic licensed items and/or the demand is low, imports are not made through the pharmaceutical companies. Hence, there is a need to improve the system to expand treatment opportunities for patients with rare and incurable diseases.

B) Implementation Plans

In order to identify the diseases, items, and needs that require importation for self-treatment and to collect stakeholders' opinions to review the possible side effects, MFDS has revised the law to allow domestic carry in and imports of self-treatment narcotic drugs.

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6. Establishment of a Pre-emptive Narcotic Drugs Prevention Management System for Reassuring the People

A. Provision of Foundation for Introduction of a Handling Reporting System for Medical Narcotic Drugs

1) Provision of Implementation Plan for Handling Reporting System and Establishment of an Integrated Management System for Narcotic Drugs

A) Background

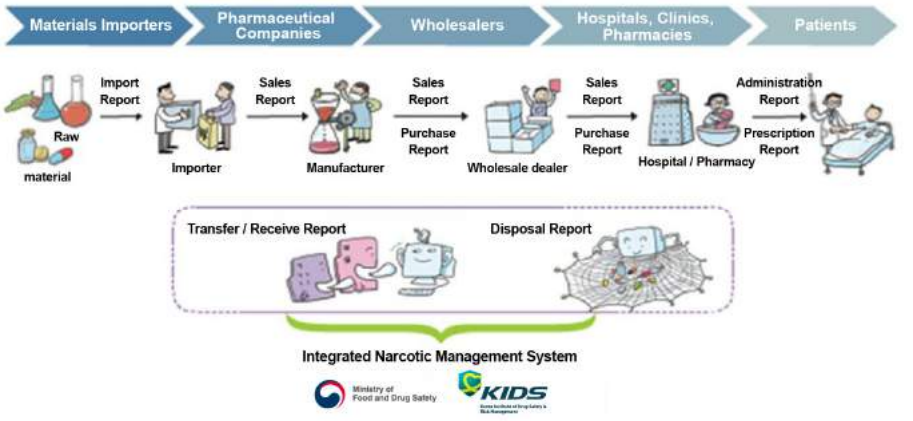
With the whole country buzzing in 2017 with the so-called 'molar daddy' murder case using

Zolpidem, or the 'Geoje case of propofol death disguised as suicide by abandonment of the body,' news about narcotic drug cases, accidents, and abuse has come receive widespread publicity, and public awareness of social problems has led to social consensus on the need for systematic management of medical narcotic drugs.

In accordance with the amendment of the 「Act on the Management of Narcotic Drugs」, the obligation to record and keep the previous handlings was changed (May '15) to a computerized reporting system (Integrated Narcotic Drug Management System). After two years of preparatory work, a three-step phased implementation was ready to be carried out from June 2017 to May 2018.

However, there was growing opposition to the introduction of the system from medical institutions such as hospitals, clinics, and pharmacies. It was necessary to review the plan from the starting point and prepare a full-scale countermeasure due to constant appeals made regarding the difficulties such as work burdens that arose from the implementation of the system.

(Source: Narcotic Management Division)



[Image 3-1-1] Overview of the Handling Reporting System through the Integrated Narcotic Drugs Management System

B) Achievements

(1) Enhancement of System Acceptance through Rational Modification of the Narcotics Handling Reporting System

As a result of conducting a two-year (2015~2016) pilot project for handlers of narcotics and psychotropic drugs to electronically report to the Integrated Narcotic Drugs Management

System, improvement needs have been confirmed in areas such as poor system processing speed, reader recognition errors, burden of serial number reporting, and linkage report for the internal management program of pharmacies.

From early 2017 onwards, MFDS has been holding meetings with the Korean Pharmaceutical Association and other professional organizations about details of the implementation plan to explain the system and collect opinions. Accordingly, in April 2017, the 「Enforcement Regulations of the Anti-Narcotics Control Act」 was pre-announced for re-legislation with differentiated management of central and general subjects, reporting method, and implementation date (enforced in May 2018).

(2) Preparation of an Integrated Narcotics Management System (hereinafter referred to as "system") for Smooth Handling History Report

As indicated by two pilot projects, there were difficulties due to some system failures in reporting narcotics handling since June 2017, and major changes in April's re-legislation notice had to be reflected in the system.

In addition, hospitals, clinics, and pharmacies, which account for 95% of the 57,000 handlers, manage handling information such as administration and prescriptions separately. Therefore, when the system is reported directly to the integrated narcotic drugs management system, difficulties arose in terms of increased human effort and duplication of work such as entering the same information twice.

As a result, the handling and reporting functions on 17 kinds of narcotics were classified into the central and general management according to the Re-Legislation Notice, and the development of 44 kinds of standard information such as operator code and integration test according to the work flow such as import/export, and prescription/administration was implemented for final checking of the reporting unit function. On the other hand, to simplify handler reporting and for reporting convenience, MFDS conducted a pilot verification test of reporting functions with three IT companies that have a high share of administration/prescription, as well as hospitals, clinics, and pharmacies.

(3) Enhancement of the Acceptance of the System through Active Communication and Customized Education and Promotion

As of June 2017, on the very first day after the establishment of the obligatory reporting clause of the narcotics handling history in May 2015, the anti-system public opinion was expressed vehemently through pharmaceutical professional organization such as the Korean Pharmaceutical Association.

Therefore, MFDS held roundtable meetings (9 times) for system users such as doctors' associations and pharmacists' associations and received comments on the implementation of the system, and visited the sites of general hospitals and pharmaceutical companies (9 times) to resolve their difficulties. In addition, policy briefing sessions (29 times) were held to take into account the national medical situation and the local government officials' educational conditions. Promotion and educational video were produced and posted on the websites of pharmaceutical professional organizations, and technical journals and professional media (Drug Information) were used to promote the system to the pharmaceutical companies. In addition, MFDS created and distributed posters, promotional leaflets, and system user manual for handlers. MFDS also organized a group of consultative bodies (7groups) in June 2017, considering the different work characteristics of each hander and held a total of 17 meetings until September. As a result, it was able to prepare Operator's Handbooks (6 kinds) for each handler.

C) Implementation Plan

(1) Operation during Guidance Period after Implementation of Narcotics Handling Reporting System

On May 18th, 2018, due to a major change to the narcotics handling reporting system, the need for institutional devices to address the concerns related to mass production from an inadequate adaptation of the computerized environment has arisen. Therefore, MFDS will operate a guidance period to adapt to the system.

(2) Operation of the System to Support Early Securing of the System

MFDS provides various support measures for the smooth implementation of the 'Narcotics Handling Reporting System' such as establishment of the automatic linkage reporting function in connection to the Narcotics Integrated Management System and the prescription and administration software of the hospital, clinic, and pharmacy; implementation of focused education and promotion; as well as operation of exclusive counseling centers.

(3) Establishment of a National Scientific Safety Management Base Using Handling Information

MFDS will develop a 'detection statistics algorithm' to track illegal distribution and abuse of medical narcotics. Also, it will verify the possibility of establishing a nationwide-information

based screening system and develop and simulate intelligent surveillance algorithm in order to monitor regional and on-site activity. MFDS will also enable nationwide and selective surveillance systems by utilizing narcotics big data and statistics algorithm.

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Section 2

Biopharmaceuticals and Cosmetics

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

A. Improvement of Safety Management and Quality Management for Biopharmaceuticals

1) Background

Biopharmaceuticals include traditional biopharmaceuticals such as vaccines and blood products, as well as products using state-of-the-art technologies such as genetically modified drugs, cell therapy products, and gene therapy drugs. Unlike synthetic (chemical) drugs, the field of biopharmaceuticals has developed at a rapid pace continuously releasing new products. However, as the ingredients or materials of these bio-drugs come from organisms, it is difficult to maintain their quality and the processing is complicated. Since ultimate sterilization is not possible, it is important to ensure thorough sterility during the manufacturing process. MFDS strives to provide quality and safe biopharmaceuticals to the public through Good Manufacturing Practice (GMP)[8] and Good Pharmacovigilance Practice (GVP)[9].

2) Achievements

In order to strengthen the safety management of imported biopharmaceuticals (the latest five-year statistics), which account for about 45% of the domestic biopharmaceutical market, MFDS inspected 63 overseas manufacturing facilities by 2017.

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8) Good Manufacturing Practice alludes to best practices involved in manufacturing of pharmaceuticals and quality management standards which need to be complied by all pharmaceuticals manufacturers and importers in order to enable quality-assured good medicines. Only GMP compliant pharmaceuticals can be manufactured and sold.

9) It is a safety management standards to be used after a pharmaceutical product is released in the market. It includes pharmaceutical safety information for all stages from medicine approval to use including pharmacovigilance plan, strategies for reduction of medicines risk, monitoring of post-marketing side effects, periodic reports on side effects, analysis of safety signals. (post-marketing safety management standards for pharmaceuticals, etc. It was established in [Appendix 4-3] of 「Enforcement Rule of Medicinal Product Safety」 in October 2016)

In order to introduce Quality by Design (QbD), a new quality assurance system, MFDS developed the QbD model using genetically modified drugs from 2015 to 2017 (2015: cultivation and fermentation; 2016: collection and purification; 2017: medicinal products) and published a guidebook for industry application of QbD.

For the safety management of blood products according to its characteristics, on Jan.4, 2017 MFDS enacted the "Standards for the Manufacturing and Quality Control of Blood Products" of [Appendix 3-4] in the 「Enforcement Rule of Medicinal Product Safety」 which will take effect (on Jan.1, 2019). In 2017, MFDS also prepared "Guidelines on GMP for Blood Products" and "Evaluation Guide on GMP for Blood Products" and carried out a pilot evaluation and on-site training for blood banks.

In addition, MFDS supported Pre-Qualification (PQ) of World Health Organization (WHO), which can be a stepping stone for domestic vaccines to advance to the global market. As a result of MFDS' support drive, 22 products from four companies have obtained PQ (Dec. 2017). For prompt information sharing and consistent response to serious problems after vaccination, a cooperation system between related departments was established (in 2013). The system analyzes and evaluates information on vaccine-related cases collected from each department on a quarterly basis. In 2017, MFDS released a guideline on the safety management of shingles vaccines and rotavirus vaccines, and prepared a "Plan for Sharing Information on Vaccine Cases and Establishing a Connected Management System" in order to build a basis for life-cycle safety management of vaccines.

For stem cell therapy and gene therapy, 'long-term follow-up study' became mandatory (implemented in Jan. 2017) to identify any possible long-term serious adverse impact.

3) Implementation Plan

The Ministry of Food and Drug Safety plans to inspect 11 domestic and 12 overseas factories in 2018 in order to ensure that safe and high-quality biopharmaceuticals are provided to the public. To introduce QbD in Korea, MFDS will develop a QbD model for vaccine medicinal products and publish guidelines in 2018.

In order to improve credit rating based on the actual condition survey for GMP of Biopharmaceutical manufacturers, MFDS will provide many educational programs including intermediate education for GMP inspectors (3 days, 2 times), intensive education for GMP inspectors (3 days, one-time), overseas GMP training institution education (2-3 days, 2-3 times), on-site and practical education for international GMP manufacturers (3 days, 2 times), and

international GMP seminars with visiting experts (1 day, one-time). Also, as a GLO Learning Center designated by WHO, MFDS will continue to train GMP inspectors from foreign regulatory agencies.

As for blood products, MFDS plans to develop a "Blood Product GMP Standard Document Model" and provide it to blood product manufacturers, and continue its on-site training and pilot evaluation as it did in 2017.

MFDS will extend its support for WHO Pre-Qualification (PQ) in the field of biosimilars to provide customized services through on-site technical advice, and invite experts from home and abroad through seminars for sharing information and case studies.

In an effort to create an environment where biopharmaceuticals are safely used, the vaccine cases that are being reported to two different channels, MFDS (Korea Institute of Drug Safety & Risk Management) and Korea Centers for Diseases Control (KCDC), will be effectively managed by sharing information on problems (reaction) after vaccination and establishing a system for connected management.

MFDS also plans to revise the relevant regulation in order to manage the long-term follow-up study on the safety of stem cell therapy and gene therapy as a state-led advanced biopharmaceutical tracking system. The advanced biopharmaceutical tracking system aims to manage the history and long-term safety of donors as well as recipients.

B. Safety Management and Advanced Quality Management 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 tools in the medical field. With an aging society and development of medical technology, the demand for human tissues has been growing every year. However, the total demand cannot be met by domestic donors, and accordingly, about 80% of the total demand is met by imported human tissue.

In order to secure the safety of tissues donated in Korea and imported from foreign countries, after the enactment of 「Safety, Management, Etc. of Human Tissue Act」 in 2005, MFDS made it mandatory to check the donor's medical and medication history and strengthened the management of donor's transplant compatibility, preventing donation of tissues of which

distribution or transplantation is banned. In addition, MFDS made it compulsory to attach standard codes and bar codes to the label of all human tissues and register those tissues in the Human Tissue Safety Management System, enabling management of tracking.

In order to establish a basis to provide quality and safe human tissues under stringent management standards for each stage such as collection·processing·storage·distribution, MFDS prepared the Good Tissue Practices (GTP)[10] and implemented phased application. MFDS also prepared and distributed (in 2007) a "Good Tissues Practices (GTP) Manual" followed by guidance on 'Standard Operating Procedures (SOP)'[11].

2) Achievements

In November 2015, MFDS established the Human Tissue Safety Management System (HUTIS) to ensure rapid and efficient traceability of human tissues through the entire process comprised of donation, collection to transplantation. Each tissue bank can use HUTIS for registering fundamental approval information and history of each process including warehousing and distribution of foreign manufacturers that import tissues, and for overall safety management in terms such as reporting side effects and registering recall and disposal reports.

In order to strengthen the capability of the tissue bank employees, MFDS has been providing training sessions from 2014. Also, to reinforce the expertise of the human body monitoring officers, it has prepared an education course on relevant laws and GTP, etc.

In order to enhance the safety management of imported human tissues, MFDS has conducted surveys on overseas manufacturers since 2011 and also introduced an "Import Approval System" (in 2015) for the type of tissues that are imported for the first time, so that only safety-assured human tissues can be imported through the pre-examination of the appropriateness of the import. Since 2016, MFDS has conducted special inspections on overseas manufacturing companies with high risk.

3) Implementation Plan

MFDS established and operated the Human Tissue Safety Management System (HUTIS) for the safety management and real-time tracking of every process from screening of donors to

10) Good Tissue Practice: a quality management standard that all tissue banks must comply with for donation, collection, storage, processing, keeping, distribution of good and safe human tissues

11) Standard Operating Procedure (SOP): a document that describes special instructions, operating procedures, and performance methods in detail for the purpose of consistently implementing tasks following a standardized procedure.

processing, distribution, and transplantation. This has enabled prompt blocking of risky tissues from being distributed and transplanted. However, HUTIS is not as yet extensively used by tissue banks, and MFDS plans to improve the system for better user convenience and increase the relevant education and promotions.

Also, in order to secure and enhance the safety management for imported human tissues, a "Pre-registration System for Foreign Manufacturers" will be introduced.

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2. Providing Medicinal Herbs and Safety Management of Natural Medicine

A. Background

As the population ages and chronic diseases become rampant, the public's interest in and demand for herbal medicine are increasing, and accordingly, there are increasing social demands for quality control of herbal medicine. MFDS has made significant efforts to improve the quality of herbal medicines and secure the safety of oriental medicines.

To establish a systematic herbal medicine manufacturing environment for the overall system from medicinal herbs to final herbal medicine products, MFDS introduced the "Good Manufacturing Practice (GMP) for Medicinal Herbs" on June 15, 2012, and made it mandatory on Jan. 1, 2015 requiring all oriental herbal medicine manufacturers to follow the policy. MFDS carries out customs inspection on medicinal herbs being imported as the ingredients of herbal medicines and from 2008, it started carrying out GMP inspection on overseas manufacturers when approving products, for consistent management of imported pharmaceuticals.

B. Achievements

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

First, to stabilize the mandatory "GMP for Medicinal Herbs," MFDS held policy seminars

with the relevant organizations and companies to provide education sessions on manufacturing and quality management and promote and share information on GMP policies. Also, to reduce the burden of quality test cost on small manufacturing companies, MFDS continues to run an open laboratory at Seoul Oriental Medicine Market. This laboratory supported pilot tests for 915 products (7,141 items) in 2017. As a result of implementing policies for stabilizing "GMP for Medicinal Herbs," the number of GMP-verified manufacturing companies has greatly increased from 12 in 2012 to 151 in 2017.

Moreover, MFDS strengthened customs inspection of imported medicinal herbs through random sample monitoring, cross-checking, and sensory tests carried out by testing and inspection organizations. MFDS also carried out inspections on overseas manufacturers in order to secure the safety of imported pharmaceuticals.

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 natural medicine industry development committees.

C. Implementation Plan

In keeping with the ultimate goal of safe management of oriental medicines, in 2018 MFDS will continue to push forward and strengthen the projects that have been carried out since 2015. MFDS will fortify monitoring and cross-checking of imported medicinal herbs at customs clearance inspection and continue to carry out periodic inspections of overseas manufacturers.

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

Moreover, by means of 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」 to establish reasonable standards and specifications for oriental medicine (herbal medicine).

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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 Using Safe and Proper Cosmetic Products

A) Establishment of Regulations for Safety Standards on Cosmetics, Etc.

Since the 「Cosmetics Act」 was fully revised (on February 12, 2005), MFDS has strengthened corporate responsibility for securing 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 boost the cosmetics industry and meet domestic regulations at the international level, the cosmetic ingredient management system has been modified to the "Negative List Method", which notifies raw materials that cannot be used in cosmetics and allows other raw materials to be used.

MFDS is constantly revising the criteria for raw materials that cannot be used and those that need to be used by reflecting the controversial cases of domestic and foreign cosmetic raw materials and the results of the risk assessment. The safety management standards for cosmetics on the market will also be revised to meet international standards.

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

MFDS encourages cosmetics manufacturers to comply with the standards for excellent cosmetics manufacturing management and also notifies Cosmetic Good Manufacturing Practice (CGMP), the management standard for excellent cosmetics. Since March 2011, MFDS has evaluated and approved cosmetic manufacturers upon their application for cosmetics GMP evaluation, and a total of 132 companies (as of the end of December 2017) have been approved for excellent cosmetics manufacturing and quality control standards. Those approved companies have contributed to the improvement of domestic cosmetics and increased the international competitiveness of exported cosmetics.

In addition, in order to disseminate GMP for cosmetics, manufacturers of some processes have been allowed to evaluate their implementation status, and the method of evaluation changed from evaluation by product group to evaluation by manufacturer. In order to alleviate the burden on applicants for Cosmetics GMP evaluation, the evaluation 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 reinforce CGMP in Korea. For this purpose, MFDS plans to provide customized consulting services for companies to get CGMP certification. This will help to improve quality control standards of small businesses. In addition, designated evaluation of cosmetics GMP is planned to be transferred to each regional FDAs to ensure the consistency of GMP designated evaluation and follow-up management of cosmetics.

2) Strengthening of Industrial Competitiveness through Production Safety Management

A) Strengthening the Control of Harmful Substances in Cosmetics

MFDS designates raw materials that cannot be used for cosmetics manufacturing including lead, arsenic, and mercury as prohibited raw materials. In the case of controversial raw materials at home and abroad that are suspected to be harmful to public health and to contain harmful substances, the risk factors will be quickly assessed to determine whether they contain harmful substances or not.

MFDS has established an unintentional detection tolerance test for raw materials that are not added by artificial means but migrated unintentionally from the packaging materials at manufacturing or storage stages where removal of the harmful content is not technically possible.

MFDS will reflect domestic and international harmful cases and the results of risk assessment to increase the detection tolerance of unintentional prohibited raw materials. MFDS will also improve the related regulations so that, when a prohibited raw material to which the detection tolerance is not set is unintentionally detected, MFDS can evaluate its risk and take measures according to the results.

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

According to Provision 2, Article 5 of the 「Cosmetics Act」 and Provision 2, Article 12 of its enforcement rule, MFDS notifies the 「Cosmetics Good Manufacturing Practices (CGMP)」 and encourages cosmetics manufacturers to comply with it. The CGMP delineates the manufacturing and quality management standards required for producing and providing quality-assured excellent cosmetics. It sets forth the handling and implementation methods

regarding employees, facilities, equipment and raw materials, semi-finished products and finished products. By implementing CGMP. cosmetic manufacturing companies can significantly reduce possible risks and potential problems in various processes, and thereby expect better quality and improved productivity.

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. MFDS also revised the Guidelines in December 2015 (1st revision) and December 2017 (2nd revision) to promote the cosmetic GMP.

When new technologies or knowledge related to manufacturing and quality management of cosmetics are released at home or abroad, or when the 「Guidelines for the Cosmetics Good Manufacturing Practices (CGMP)」 are revised, MFDS will reflect them in the guidelines for the improvement of quality control of cosmetics.

3) Strengthening Safety Management of Cosmetics Being Distributed

A) Monitoring Cosmetics

To establish an environment that allows safe manufacturing and distribution of cosmetics, MFDS sets up the direction of inspection every year to carry out a "Master Plan for the Management of Cosmetics Manufacturing and Distribution" and conveys the plan to each regional FDA and local government for follow-up management of cosmetics. Inspections on cosmetics can be classified as 'ordinary inspection' that includes allegation, petition, reporting, and monitoring; 'periodic inspection' that is carried out following the plan of each local government; and 'planned joint inspection' that is implemented on vulnerable or problematic areas by MFDS, regional FDAs, and local governments together.

In 2017, MFDS carried out a planned joint inspection on whether cosmetics sellers who directly sell to consumers comply with the standards for labeling and raw materials and the safety management standards for products with social issues such as products that are applied on women's sensitive areas.

To establish a safety management system for cosmetic products that consumers can trust, in 2018, MFDS will promote voluntary inspection of cosmetics manufacturers and sellers. This will include a planned joint inspection of the cosmetic products for vulnerable consumers such as children and the products that possibly contain prohibited ingredient mixtures by analyzing and focusing on areas that are potentially hazardous or closely related to the public.

B) Inspection of Ads and Labeling

Cosmetics are everyday items that are most frequently and widely used. Recently, cosmetics are attracting a larger number of consumers, cosmetic products have diversified, and it is possible to manufacture and sell cosmetics without taking any special measures. Although emotional marketing takes a large share in cosmetics advertisement and labeling, an effective response system had been lacking due to lack of dedicated personnel to monitor and inspect ads and labeling of cosmetics. However, in 2016, to strengthen the inspection on various cosmetics advertisements on online shopping sites, social network services (SNS), and company websites, MFDS set up a monitoring system with a greater number (from 3 to 4) of personnel dedicated to monitoring cosmetics ads and labeling. In 2017, MFDS carried out intensive monitoring on cosmetics advertisements that can misguide people to mistake the product as pharmaceuticals or promote their products as natural cosmetics. Based on the results of monitoring, relevant measures such as the shutdown of those companies' websites were taken by public health care centers in each province and city and the Fair Trade Commission.

In 2018, MFDS will improve the clarity of violation criteria by revising guidelines on cosmetics ads and labeling management and strengthen regular monitoring by inspecting the violation of guidelines in cosmetics ads and labeling through a substantiation system. It is expected that these measures will enable MFDS to manage false or exaggerated ads that can lead people to misapprehend cosmetic products as pharmaceuticals.

C) Collection and Testing of Cosmetics

To secure the safety and quality of cosmetics on the market, MFDS has been collecting 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.'

Along with the need for prior management for cosmetics on the market, the need for rapid collection and inspection of cosmetic products has also increased. In order to meet these requirements, MFDS increased the budget and secured KRW 5.41 million for cosmetics collection and inspection in 2018. By the present capabilities, over 1,500 items in total can be collected and inspected each year. In addition, for regular quality check, MFDS sets the number of products and test items by product for each local government, collecting and inspecting 800 or more products on a regular basis.

In order to promptly withdraw and dispose of non-conforming products after collection and inspection, MFDS prepared detailed procedures for recall and disposal in the 「Cosmetics Act」 and introduced voluntary recall systems for manufacturers and sellers.

In 2018, MFDS plans to carry out intensive collection and inspection on products of which quality is not appropriately managed. This includes products like feminine care products such as feminine cleansers. In addition, it has collected domestic and overseas information on hazards in real time to preemptively prevent unsafe cosmetic products from being distributed in the domestic market. MFDS will continue to inspect and manage the ingredients that have safety issues by conducting risk assessments.

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B. Safety Management of Quasi-Drugs

1) Reinforcement of Safety Management of Quasi-Drugs

A) Background

Quasi-drugs are everyday items such as a sanitary pads, toothpaste, mosquito repellent, etc. that are most frequently and widely used and deeply linked to people's lives. Hence, consumers are very sensitive about the safety of quasi-drugs, and false and exaggerated advertisements for quasi-drugs and the distribution of fraudulent and defective quasi-drugs can negatively influence consumers to a great extent. In the regard, MFDS is making efforts to supply safe quasi-drugs and lay the foundations for the safe use of drugs so that the public can feel relieved. The efforts are focused on strengthening management such as safety verification and reasonable system improvement of quasi-drugs.

B) Achievements

(1) Relief of Public Anxiety Related to Controversy over Detection of Volatile Organic Compounds (VOCs)

As soon as consumer anxiety and social controversy arose due to detection of volatile organic compounds (VOCs) on sanitary pads, MFDS immediately launched (Aug. 2017) analysis·hazard evaluation of 84 VOCs for all sanitary pads (666 products) prior to distribution. Analysis·hazard

evaluation is a testing method that secures reliability through verification processes of the "Sanitary Pad Safety Verification Committee" composed of medical· analysis· hazard evaluation· communication experts related to sanitary pads and the "Central Pharmaceutical Affairs Council," the official advisory committee of MFDS. Through the evaluation, the whole body exposure dose on account of the VOCs in the sanitary pads being absorbed to the body is compared with a toxicity reference value, evaluating whether a safe level is secured. The first complete enumeration was carried out for 10 VOCs among 84 VOCs, and the results were announced in Sept. 2017; additional enumeration for the remaining 74 VOCs was carried out and announced in Dec. 2017 in order to provide the public with rapid information. MFDS confirmed that hazard concerns were not identified from any product in terms of safety and, this way relieved national distrust of sanitary pads.

In addition, MFDS held a consultative body composed of sanitary pad manufacturers for the autonomous safety of sanitary pads (3 meetings), in order to make and recommend (Oct. 2017) a VOC reduction plan through self-monitoring and process improvement, laying the foundations for continuous distribution of safe sanitary pads.

(2) Removal of Blind Spots in Quasi-Drug Safety Management

Due to changes in life environment, various products that come in contact with the human body are released to the market without any safety standard. In this context, in order to preemptively secure safety of consumers who use those products, "a product to regulate color of teeth temporarily by being coated on the surface of teeth (manicure/polish for teeth)" and "a portable product (portable air·oxygen product) for temporarily supplying air or oxygen through inhaling of air or oxygen directly or indirectly" were newly approved (May 2017) and will be managed as quasi-drugs from Nov. 2018.

(3) Efficiency Increase and Rational Improvement of the Safety Management System for Quasi-Drugs

MFDS revised the 「Standard Manufacturing Criteria for Quasi-Drugs」 to increase the efficiency of approval· notification· evaluation of quasi-drug products and clearly specified the scope of using additives that are allowed to be used in dermatologic ointments in according to standard manufacturing criteria. In addition, standard manufacturing criteria for hair dye, baths, and depilatory agents that are changed from quasi-drugs to cosmetics were removed (March 2017), and 「Standards and Testing Method of Quasi-Drugs」 were revised through continuous improvement on criteria specifications for quasi-drugs and used ingredients. The

revisions were carried out in order to improve suitability determination standards for a fluorescent whitening agent test of unwoven fabric, etc. used for paper quasi-drugs (March 2017). In addition, for the rational operation of regulations, safety test materials according to 「Safety Test Standards for Medical Devices」 were recognized as products with similar features as medical devices, such as a menstrual cup, etc. For the same product (e.g. healthcare masks) that comes in different sizes, the total inward leakage (TIL) of only one product is required to be submitted at the first approval. Furthermore, MFDS revised (Dec. 2017) the 「Regulations on Approval·Notification·Evaluation of Quasi-Drug Products」 for regulatory improvement including specifications for describing instructions on name, specifications, etc. of mixed substances in an additive. On the other hand, as social interest in contamination of the environment including the marine ecosystem and human health risk concerns due to "microplastic" has increased, and international regulations on the use of microplastic have been strengthened, the 「Regulations on Approval·Notification·Evaluation of Quasi-Drug Products」 were revised (May 2017) in order to prohibit the use of products for the purpose of washing such as toothpaste, breath refreshers, and tooth whiteners.

(4) Establishment of a Detailed Labeling Plan According to the Quasi-Drug Ingredient Labeling System

For reinforcing consumers' right to know and right to select products, the Quasi-Drug Ingredient Labeling System for toothpaste, etc. was introduced through revision (Dec. 2016) of the 「Pharmaceutical Affairs Law」 and enforced in December 2017. Thus, a detailed guideline was prepared (May 2017) for labeling the entire substances, centered on substances of consumers' interest.

(5) Public Campaign for Safe Use of Quasi-Drugs

MFDS indirectly promoted and guided quasi-drug safety management policies (May-June, 2017, 5 times) by developing guidelines on how to rightly select and use healthcare masks, toothpaste, and smoking cessation supplements through morning information programs of terrestrial TV networks. In addition, MFDS provided customized safety information on quasi-drugs that are normally used in people's daily lives, such as healthcare masks (March and November), toothpaste and menstrual products (May, Family Month), smoking cessation supplements (May 31, Smoking Cessation Day), mosquito repellents (summer), and tick repellents [Chuseok (Korean Thanksgiving Day)].

(6) Introducing a System for Blocking Sales of Hazardous Quasi-Drugs

Throughout 2017, MFDS continuously expanded the number of distribution companies (as of Dec. 2017, 24,171 stores of 37 distributors) participating in the "Sales Blocking System of Hazardous Quasi-Drugs" (introduced in June, 2016) and led drug stores and wholesalers to newly introduce the system (as of Dec. 2017, 17,251 drug stores and 1,737 wholesalers). This system rapidly provides quasi-drug sellers with information on hazardous products to block sales of the products at the site in real time. Accordingly, MFDS has promoted distribution informatization, and modernization of information on quasi-drugs has minimized the possibility of users purchasing and using quasi-drugs subject to recall or sales suspension and, in turn, actively secured national safety and improved consumer confidence in currently distributed quasi-drugs.

(7) Monitoring and Quality Control of Quasi-Drugs

In 2017, with the goal of securing pre-emptive safety management of quasi-drugs from ingredients to complete products, MFDS intensively inspected the suitability of manufacturing (importing) companies' ingredient management and monitored compliance to allowable standards for preservatives such as CMIT/MIT used in quasi-drugs.

In addition, as for labeling and advertising, MFDS planned intensive inspection on advertising (selling) for seasonal high-consumption quasi-drug products following the year before last, and intensively inspected products with misleading labels or advertising, such as a face mask for industrial use presented as a quasi-drug (a healthcare mask) in March and a normal bracelet for industrial use presented as a quasi-drug (a mosquito-repellent) in June, and advertisement (sales) of an unlicensed humidifier disinfectant in September.

Meanwhile, MFDS collected a total of 513 items for quality monitoring of currently distributed quasi-drugs and took measures of administrative disposition, collection, and disposal on 12 items that were judged to have inadequate quality.

C) Implementation Plan

Because controversies over the safety of daily essential quasi-drugs such as toothpaste and sanitary pad arise every year, MFDS attempts to establish a mid- and long-term quasi-drug safety management system by considering pre-preventive verification. For this purpose, MFDS plans to collect clues to information and pursue customized safety verification by means of a circulating safety verification system for 32 quasi-drug products with a cycle of 3-4 years.

To prevent consumer anxiety, MFDS has been reinforcing quality and management of hazardous substances for masks, re-evaluating smoking cessation supplements, and continuing research and study on hazardous substances in inhaled smoke.

As part of the "Women's Health Relief Project", MFDS will participate in a government-wide (MFDS, Ministry of Environment, and Korea Centers for Disease Control and Prevention) joint epidemiological survey (health impact survey) on damage appeals by sanitary pad users, and prepare guidelines on reduction of VOCs in sanitary pads, in order to continuously manage hazardous substances. Furthermore, MFDS will develop and distribute leaflets on safety information related to menstrual products including VOCs survey results on sanitary pads, and usage patterns and product status of menstrual cups.

Sales of toothpaste, breath refreshers, and tooth whiteners using microplastic, an additive for which manufacturing and import have been prohibited since May 2017, have been prohibited from May 2018. In addition, the scope of the quasi-drugs subject to the Quasi-Drug Ingredient Labeling System will be expanded from the existing toothpaste, pesticide, etc. to paper items such as sanitary pads and masks from October 2018 by reflecting consumers' demands.

In order to secure quality of products in the manufacturing and importing stages, MFDS plans to collect opinions of relevant industries and proceed with present condition investigation for recommending and introducing the Good Manufacturing Practice (GMP) for paper items (sanitary pads, masks, etc.) and contact lens care items, besides the existing products subject to GMP.

Furthermore, MFDS will rapidly control illegal online sales and false·exaggerated advertisements through integrated and reinforced cyber monitoring, and significantly reinforce safety management for quasi-drugs including expansion of collection· test of products distributed online.

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4. Support for biopharmaceuticals penetrating the global market and global cooperation

A. Support for Korean biopharmaceuticals penetrating the global market

1) Background

Diverse biopharmaceuticals such as recombinant DNA products including vaccines, and plasma derivatives, cell culture-derived products, and gene and cell therapy products have received intensive attention in the customized therapeutic fields. In addition, in line with the increasing development of new biomedicines, their market share has been on the rise.

In this context, the global growth possibility of Korean biopharmaceuticals has been increasing, and the import and export rates have been rising by 29.8 percentage point every year.

Market share of the first antibody biosimilar 'Remsima Inj. 100mg' has been increasing in the American market as of 2017, since its launch in September 2013 in EMA (Europe), in December 2014 in Japan, and in April 2016 in FDA (the U.S.) respectively.

As of December 2017, the number of domestic biopharmaceuticals' clinical trials stands at 23 for vaccines, 34 for biosimilars, 10 for antibody products, 60 for gene therapy products, 145 for cell therapy products and 87 for stem cell therapy products. Furthermore, more diverse Korean products are expected to enter the market soon since there are many pipeline products in vaccines, biosimilars and stem cell therapy products, which have a global competitiveness edge.

2) Achievements

The Ministry of Food and Drug Safety (MFDS) has established safety control systems for advanced biopharmaceuticals, strengthened tailored support for the global competitiveness of domestic vaccines, and provided diverse information on global and domestic regulations and WHO Pre-qualifications as well as professional advice. Moreover, the ministry has been developing a close partnership with global regulatory agencies encompassing WHO and APEC in order to help domestic biopharmaceuticals to take the lead in the global market.

MFDS also established the QbD system roadmap in 2013, and delineated the process for development to apply the QbD model in 2014 to advance the quality management system for the biopharmaceuticals. Further, from 2015 to 2017, the development to apply QbD model

and application guideline for QbD for recombinant DNA product was published.

In addition, to ensure the safety of medicines for the public, the Regulation on Approval and Review of Biological Products was revised twice in June and August 2017. For example, medical experts including doctors and pharmacists can now receive further information needed for diagnosis or prescription such as clinical trials or pharmacology.

The MFDS also has annually held the Global Bio Conference including IPRF (International Pharmaceutical Regulations Forum) and AHC (APEC Harmonization Center) to promote the global growth of the biopharmaceutical industry, the future growth engine by providing the opportunity to share recent global information.

With the plan to support global vaccines, MFDS has reinforced the support for cell bank distribution, customized technologies, and systems, and WHO PQ to promote export and also strengthened global cooperation.

In order to increase the vaccine production capabilities in Korea that mostly relies on imported essential vaccines, MFDS operates a committee of industry, academia, and government so that the public can be immediately provided with the vaccines in an urgent situation.

MFDS also established review and approval criteria relatively earlier than other countries to expedite approval following Europe, and has been cooperating with global regulatory agencies such as WHO to lead the global market.

Furthermore, since 2014, MFDS has been promoting the bio-IT platform business to provide information on countries in which the biopharmaceutical industry is expected to enter overseas. It is a tailored program to support export; MFDS has provided international regulations and guideline information to domestic companies and will provide the 'Smart Information Guidance System' at a glance to users so that they can use complicated regulatory information effectively.

3) Plans

The MFDS is planning to increase the number of biosimilars, stem-cell therapy products, gene therapy products, and domestic vaccines to 7, 5, 2, and 20 respectively by 2020 through its global biopharmaceutical support initiative.

By this initiative, MFDS will strengthen its expertise in giving professional advice to companies that aspire to penetrate the global market, and publish its domestic and global biopharmaceuticals review and approval systems, regulations, and industrial information, titled 'The Data Package for Entry Strategy for the Global Market'. The publication will be provided to relevant agencies to help the companies export their products.

Following the development of the QbD model for recombinant DNA products, in 2018, MFDS is planning to make guidelines and develop the QbD regarding development and quality management for the manufacturing process of vaccine bulk. It will also hold workshops for biopharmaceutical manufacturers and importers. Further, by 2020, MFDS will develop a QbD model for cell therapy products.

MFDS also plans to streamline the regulations to expedite production by starting a committee comprising public and private sector members to support each product, and establish relevant guidelines immediately.

From the development of the product, this MFDS committee will continuously give advice and review and also provide specific guidelines to commercialize state of the art biopharmaceuticals so that companies can facilitate rapid commercialization. The MFDS is also pushing to streamline the current regulations.

In response to evolving biotechnologies, the ministry will forge a management system for better control of advanced biopharmaceuticals including tissue engineering products, cell therapy products and gene therapy products and also will lay the foundations ranging from research and development to commercialization of the products.

In particular, in anticipation of diverse recombination products including tissue engineered products made from bio material; combined advanced therapy medicinal products made from the combination of cells, scaffold, and growth factor; and 3D printing products using cells, to avoid delays in review of a new technology product, MFDS will contribute to the development of combination products and boarding line products by establishing specific classification standards and processes.

By establishing and distributing cell lines for the production of vaccines and expanding vaccine self-supporting items through measures such as operating a support team for global vaccine production product, MFDS was able to supply 9(32%) vaccines as of 2014 and 11 (39%) in 2015, and will be capable supply 20 (71%) vaccines by 2020 to expand vaccine self-sufficiency.

The MFDS will provide standards and processes to provide vaccines and other medicines even before its approval in emergency situations such as bioterrorism or epidemics, and also establish comprehensive strategies to provide national medicines by making 'T/F for a stable supply of national medicines.'

MFDS has been operating a support team for global vaccine production to provide support for technologies and regulations for commercialization of vaccines by securing cell line and

offering them to the companies.

MFDS will lay the groundwork for allowing importers to outsource their manufacturing to domestic CMOs and building standards to review orphan drugs again by revising the 'Regulation on Approval and Review of Biological Products'.

The ministry has been making necessary policies to provide safe and quality products to the public and establishing and implementing comprehensive and customized support strategies by forging close cooperation between industry, academia, and the government.

MFDS will also ceaselessly exert its utmost efforts to facilitate Korean biopharmaceuticals spearhead the Fourth Industrial Revolution by ensuring global competitiveness.

B. Securing of Global Competitiveness of Biopharmaceuticals through International Cooperation

1) Background

The global biopharmaceutical market is growing at a high growth rate annually. This is attributed to rapid growth of the market for gene therapy, stem cell therapy, and biosimilars. In order to push Korea as one of the top 7 biopharmaceutical powerhouses, the Korean government drafted a "Global Biopharmaceuticals Support Plan" in August 2013, and has been providing administrative, technical, infrastructure, and international cooperation supports, and implemented measures to assist businesses in their efforts to advance to the global market.

2) Achievements

A) Maximizing of International Cooperation through Information Sharing with Major Countries' Regulatory Agencies and International Organizations

(1) World Health Organization (WHO)

In January 2011, MFDS participated in a joint study as one of the World Health Organization Collaborating Centres for Standardization and Evaluation of Biologicals. In 2017, an international joint study for establishing an international reference standard was carried out in relation to the evaluation of candidate substances for meningococcus serogroup W and Y polysaccharide international reference standards. In 2007, MFDS was designated as an education center for the WHO Global Learning Opportunity (GLO) and, accordingly, it has been providing education sessions on manufacturing and quality management standards for vaccines. Furthermore, since

2012, MFDS has been carrying out National Shipment Approval Skills Education for Vaccines, and 48 trainees from 17 countries have completed the training held over 6 education sessions until 2017.

(2) International Pharmaceutical Regulators Forum (IPRF)

MFDS was elected as the chair country of the "Biosimilar Regulation Harmonization Working Group" at the International Pharmaceutical Regulators Forum (IPRF), which was held in conjunction with the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) Assembly simultaneously in Osaka, Japan, in November 2013. Since then, MFDS took part in a variety of activities including establishment of biosimilar approval· review criteria, identification of regulation status and differences by region and country, prevention of overlapping biosimilar-related activities among international organizations such as WHO, and harmonization of regulations on drug monitoring. Recognizing the necessity for scientific evaluation of safety and efficacy of cutting-edge pharmaceuticals and regulatory harmonization, Korea also participated in IPRF as a member country in the cell therapy (Mar. 2011) and gene therapy (Oct. 2012) working groups. In 2017, Korea prepared "Scientific Guidelines on Biosilimar Indication Extrapolation" for making unified review criteria for biosimilar indication extrapolation that had until then been operated by each country's regulatory agency, and put the guidelines on the IPRF website and MFDS's English version website. (Nov. 2017)

(3) Asia-Pacific Economic Cooperation (APEC)

At the Asia-Pacific Economic Cooperation (APEC) Senior Officials' Meeting (SOM) held in September 2011, MFDS was elected as a champion country for Biotherapeutic Products Roadmap. Accordingly, MFDS has hosted workshops organized by the APEC Harmonization Center (AHC) since 2009. In February 2016, MFDS was approved by the APEC Regulatory Harmonization Operation Committee for running a Center of Excellence (CoE) as a pilot project for providing pilot programs for representatives from regulatory authorities in the APEC region. MFDS also held a workshop based on the concept of pre-CoE in an attempt to attract a professional education and training institution in Latin America that has a high demand for regulation harmonization education and training.

(4) Reinforcement of International Cooperation among Advanced Regulatory Agencies

In October 2013, MFDS established cooperative relations with Paul-Ehrlich-Institut (PEI) in Germany and built collaborative relations with the US Food and Drug Administration (FDA) by signing Confidentiality Commitments. In addition, MFDS established cooperative relations with many regulatory authorities: it signed a cooperation agreement with the Japanese Ministry of Health, Labour and Welfare; a regulatory cooperation agreement in the Biopharmaceutical field with Health Canada; and an MOU for cooperation with the Vietnamese Ministry of Health, in 2015.

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

In March 2017, MFDS launched "the 3rd MFDS Special Advisory Board for Advancement of Biopharmaceuticals" with 23 eminent scholars and experts around the world as members. The MFDS Special Advisory Board offers advice on biopharmaceutical policies and regulations, responses to major issues by stages, and the latest technology and science trends. The Board continues its efforts to hold international forums and workshops in an effort to reinforce professional capabilities in the field of advanced biopharmaceuticals. In every June since 2015, MFDS has integrally held 「Global Bio Conference」, which has grown into an event where approximately 2,000 experts from government organizations, industries, academia, and press are gathered together.

3) Implementation Plan

To become a global top 7 country in the biopharmaceutical field by 2020, MFDS is planning to continue its efforts to help increase exports of biopharmaceuticals and engage in various international cooperation activities by establishing bilateral and multilateral cooperative relations.

A) Proceeding of the Hub of Multilateral Cooperation

(1) World Health Organization (WHO)

MFDS, which was designated as WHO Collaborating Centre in January 2011, was redesignated by WHO after evaluating its work performance for the last 4 years. Accordingly, MFDS will run the WHO Collaborating Centre until January 2019, and the scope of its work has also been expanded. In addition, MFDS has continued the ODA project called, "Technical Support

for Biopharmaceutical Evaluation and Approval System for Developing Countries in the West Pacific Region." Furthermore, MFDS has been conducting a joint research project with WHO to develop reference standards and various guidelines.

(2) International Pharmaceutical Regulators Forum (IPRF)

As chair country of the 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 regulation harmonization in the APEC region, MFDS designated and operated CoEs for biopharmaceuticals based on analysis on regulatory differences found during the workshops.

B) Expansion of Bilateral Cooperation

In 2017, MFDS will discuss on-site training and cooperation plans with Paul Ehrlich Institut (PEI) in Germany for reinforcing evaluators' capabilities by pharmaceutical or by field. In addition, MFDS signed a working agreement with Health Canada and will continue to cooperate with WHO, National Institute for Biological Standards and Control (NIBSC), and US Pharmacopoeia (USP).

C) Reinforcement of Expertise through Regulation Harmonization

To support domestic biopharmaceutical companies to make forays into the global market, MFDS will hold the "2018 Global Bio Conference" from June 27-29, 2018, with experts invited from home and abroad. The latest international trends and prospects in the biopharmaceutical field and recent regulatory issues will be discussed at this conference. The conference will also serve as an opportunity for Korea to become a global biopharmaceutical powerhouse by maximizing synergy effects through sharing of knowledge and experience among the participating experts.

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5. Advancement of Approval & Evaluation System for Biopharmaceuticals

A. Advancement of Approval & Evaluation System for Biopharmaceuticals and Initiation of International Standards

The biopharmaceutical industry has become a core field that countries around the world are now focusing on to nurture as a new growth engine for the future. Korea also has been actively supporting this industry through the "Biohealth Future New Industry Nurturing Strategy," "Global High-Tech Biopharmaceutical Technology Development Project," etc. In accordance with trends in biopharmaceutical development such as increasing importance of biopharmaceuticals, market expansion, and global market advancement of Korea's pharmaceuticals including biosimilars[12], it is necessary to sharpen competitive edge in order to preoccupy the global market and lead the international standards.

As a biopharmaceutical approval· evaluation control tower, MFDS newly established the Biopharmaceuticals Review Management Division that will generally coordinate civil complaints and play the role of a unified civil application window, to introduce new systems and procedures in the biopharmaceutical field including introduction of a preliminary evaluation system; expansion of the scope of official public seminars; a civil complaint data processing history system throughout the whole cycle; and establishment of a biosimilar information room. The Division will also make efforts to secure transparency, consistency, and predictability of approval evaluation including development of excellent evaluation standards and guidelines. In addition, MFDS enhanced expertise and capabilities of evaluators through evaluator education programs by field, and invited biopharmaceutical experts from major foreign regulatory agencies and academic fields to share information on the latest development trends, safety management, regulatory trends of each country, and the criteria and direction of biopharmaceutical evaluation.

Through continuous progress such as expanding the scope of biopharmaceuticals subject to pump-priming projects, starting in 2014, MFDS approved products including Korea's first gene therapy and the shingles vaccine. MFDS has since been supporting the development of domestic biopharmaceuticals through product classification for bio-based high-tech convergence products.

12) BIosimilar is a generic concept equating chemical medicines to biopharmaceuticals. Latecomer companies manufacture biopharmaceuticals (original pharmaceuticals) approved as a product according to their manufacturing processes in order to prove that the quality, safety, and effectiveness of their generic pharmaceuticals are equivalent to those of original pharmaceuticals.

In order to operate the biopharmaceutical approval· evaluation system in a predictable and reliable manner now and in the future, MFDS will continue to provide education for strengthening evaluation capabilities, identify and monitor difficulties of the industry, and establish and revise evaluation guidelines for each product. The ministry will enable reasonable evaluation criteria and preemptive preparation for evaluation criteria for new and cutting-edge biopharmaceutical products.

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B. Advancement of Approval & Evaluation of Herbal Medicinal Products

With growing demands for reinforcement of management in areas such as quality, regulations on Herbal Medicinal Products (HMP) have been strengthened including expansion of substances subject to active pharmaceutical ingredient (API) registration (drug master file, DMF) (2015) and mandatory submission of review of safety evaluation of benzo[a]pyrene on HMP and API (Oct. 2016). In addition, growing interest in the medicine development process of the Traditional Korean Medicinal Practitioners has led to an increasing number of applications for formulation change of Oriental Medicines for Health Insurance (OMHI) and applications for clinical trials in oriental medicine hospitals. In view of these circumstances, MFDS has been considering changes in regulations and future evaluation direction through public seminars.

In the future, MFDS plans to revise standards and specifications of the official compendium in order to strengthen quality management of HMP, and hold public seminars and discussions by sub-groups in order to maintain consistent review levels for product approval (notification), application (industry), and evaluation (MFDS). Furthermore, MFDS will continue to support the herbal medicinal industry through establishment and revision of guidelines.

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C. Efficient Improvement of Evaluation System for Quasi-Drugs and Cosmetics

1) Reinforcement of a Basis for Evaluation of Quasi-Drugs for Public Relief

Recognizing the need for a reasonable and systematic evaluation system that can address a variety of new quasi-drug items, MFDS has been developing guidelines and amendments of the relevant regulations. In order to support the industry's product development, MFDS prepared guidelines for an 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 consistency and objectivity of evaluation. In addition, MFDS will continue to strengthen the quasi-drug review system, develop efficacy evaluation and standard specification guidelines, and revise the standards and test methods for quasi-drugs to help product development in the industry. Moreover, to improve consistency and efficiency of the approval and review system, MFDS will continue to communicate with the industry by holding regular meetings among quasi-drug evaluators, and organize public seminars on the approval and review system.

2) Reinforcement of the Competitiveness of Cosmetics through Improvement of Relevant Systems

As the scope of functional cosmetics has been expanded, in order to secure safety, help the development of high-quality functional cosmetic products, and enhance consistency and efficiency of evaluation, amendments of cosmetic-related regulations were prepared, the handbook on the evaluation of functional cosmetic products was revised, and guidelines for evaluating efficacy were established. In addition, to protect customers from false·exaggerated cosmetics advertisements, vitalize the cosmetics industry, and support the development of new products, MFDS came up with a testing method for reviewing substantiation. In order to raise consistency and efficiency of valuation on newly added functional cosmetics and support development of safe and quality functional cosmetics, MFDS plans to advance the evaluation system according to the changing environment by developing standards and testing method for new functional cosmetic substances, improving the testing method, and continuously revising regulations on evaluation of functional cosmetics. Furthermore, MFDS will hold public seminars in order to raise understanding on the evolving system and support the development of new products, and continue to carry out public campaigns on the safe use of cosmetics.

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Section 3 Medical Devices

1. Strengthening Life-Cycle Support System and Safety Management of Medical Devices

A. Background

The 4th Industrial Revolution has led to the emergence of new medical devices that utilize cutting-edge science and technology. As the medical device market has broken the boundaries of the existing medical device industry, many companies have entered the healthcare field. It has been more important to establish a customized support system and safety management system for activities ranging from development to export to keep up with the pace of development of medical device technologies.

B. Achievements

The "Integrated Information Bank of Medical Devices" provides information on the life-cycle of medical devices ranging from development to export. The Integrated Information Bank added information on market trends of emerging exporting countries such as Vietnam, Mexico, and Canada to pioneer this export market. It also publishes a newsletter that analyzes the domestic and global medical device market and regulatory and development trends for 3D printing and artificial intelligence (AI) healthcare products. Also, MFDS provides "one-to-one customized service for providing information on the entire cycle of medical devices" to ensure that companies can easily inquire about overseas licensing and export-related information. MFDS expanded and operated the "100 Next Generation Medical Devices Project" supporting the entire cycle of medical devices in a systematic and technical manner by selecting promising medical devices (20 medical devices every year, a total of 100 medical devices over five years). MFDS held a seminar on customized mentoring support for mutual information exchange, including sharing of mentoring support outcomes and regulations on medical devices made in Europe, thereby minimizing trials and errors of related companies and shortening the period of product development.

In addition, for the clinical application of the NGS (Next Generation Sequencing) technology, MFDS introduced the NGS Clinical Laboratory Certification System. Once an NGS device passes the evaluation and certification for quality control system, skillfulness, test performance, etc. in a clinical laboratory, it is available to be used in the relevant clinical laboratory. It also prepared detailed guidelines that provide considerations or recommendations to evaluate and maintain a quality control system, skillfulness, and test performance in case of certifying each area of the NGS test in a different clinical laboratory.

To strengthen the follow-up management of medical devices, MFDS revised the Medical Devices Act in December 2016 and attached internationally standardized codes to all domestically manufactured and imported medical devices to register their integrated information. Also, MFDS built and operated the UDI (Unique Device Identification) system that can track and manage all processes ranging from licensing to distribution and use. The ministry is now working on preparing detailed measures to collect and use the integrated information on the entire cycle of medical devices such as distribution information through reporting of medical device supply.

C. Implementation Plan

In 2018, MFDS plans to provide new information including inputs about emerging and promising exporting countries, test requirements, and considerations for the preparation of technical development documents so as to enter overseas markets. MFDS also plans to expand the scope of customized support for the entire product development of promising medical device developers that have technological capabilities but lack development experiences and relevant information.

In addition, MFDS plans to prepare additional guidelines by inspection field to standardize genetic information analysis methods that are presently self-operated by each genetic testing organization in order to enhance reliability and secure safety of NGS test results.

Finally, MFDS plans to operate the UDI system gradually starting from 2019. It also plans to gradually apply the system to medical devices from grade 4 as mandatory by considering international trends and acceptability within the medical industry. This measure is expected to provide consumers with safer use and a better distribution environment of medical devices.

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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 due to the again population and changes in the chronic disease-centered healthcare structure. Accordingly, the provision of accurate information on medical devices and safety and quality management of these medical devices are becoming more crucial than ever. Therefore, MGDS is working on safety and management policies for medical devices through monitoring, quality inspection, advertising management, etc.

B. Achievements

MFDS reorganized its monitoring system into a "Target" based one focusing on risk factors, and conducted risk-based monitoring to concentrate on selected targets so as to strengthen preventive monitoring practices. To this end, it set targets such as products vulnerable to quality control, products with high social impacts, and those with severe physical hazards. Accordingly, MFDS inspected 198 places and identified 40 that needed improvements.

In addition, MFDS conducted quality inspections on 631 medical devices that received the most complaints from consumers and medical personnel, and took measures for 46 non-conforming products that failed to meet relevant quality standards, such as suspension of sale, and product recall order, administrative penalties, thereby contributing to a safe and effective distribution environment for medical devices. Especially, the rate of non-conforming products was down to single figures (7.3%).

Furthermore, MFDS cooperated with local governments to reinforce the management of medical devices by supervising and cracking down on 1,290 medical sellers twice in the first and second half of 2017 respectively. The crackdowns focused on sellers that target the vulnerable groups including elderly with false and exaggerated advertising in the form of free trial room, resulting in the exposure of total 67 illegal sites.

Finally, MFDS prepared a civilian handbook to prepare for the application of the latest GMP International Standard (ISO13485:2016). It also joined the International Medical Device Regulators Forum (IMDRF) to build the foundations for participating in the GMP Medical Device Single Audit Program (MDSAP) between countries. Based on these activities, MFDS has

strengthened the qualifications and capabilities of professional and systematic GMP auditors and promoted the international harmony of GMP system for medical devices to lay the groundwork for mutual recognition among countries.

C. Implementation Plan

In 2018, MFDS will continue to operate a "Target" monitoring system by selecting products based on risk factors and social issues. It will carry out quality verification inspections on defective products reported through medical device monitoring centers, products commonly consumed by the gaining population and those with a high interest in health, and products that consumers complain about and are socially controversial. It is expected that this will improve the user environment to ensure that consumers may better trust the distributed medical devices. In addition, MFDS will check and disclose the price of medical devices handled in free trial rooms to prevent the elderly from suffering damage by purchasing expensive medical devices. Finally, it will introduce the GMP Unannounced Audit System for medical devices to conduct a random check on medical device manufacturing facilities that caused foreign objects or side effects frequently without any notifications, thereby quickly taking corrective measures and strengthening precautions.

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3. Establishment of a Safety Evaluation System for Medical Devices

A. Background

The use of domestic medical devices is steadily growing with the rising social demand for health care including increased demand for treatment of chronic diseases. These demands are spurred by the aging population and needs for disease prevention arising from enhanced income level. Accordingly, MFDS places greater importance on the safety and management of medical devices distributed in the market and pursues measures such as collection and analysis of

unusual cases of medical devices, tracking control of medical devices for human transplant, and re-evaluation of medical devices.

B. Achievements

In order to promote reports on side effects of medical devices and establish an advanced management system, MFDS has been running a "Medical Device Safety Information Monitoring Center" since 2011. In 2017, it designated 19 general hospitals as monitoring centers. After analyzing and evaluating the collected information on side effects of medical devices, MFDS provided information on safe use to those who use medical devices and strengthened directions for the use of medical devices. It has also made efforts to ensure that medical device manufacturers take corrective and preventive measures, thereby helping consumers use safe medical devices.

MFDS has designated human transplant medical devices that may cause fatal injuries to the human body due to side effects or defects in use as the object of tracking management, ensuring that it can track the entire distribution of medical devices, ranging from manufacturing to use. In 2017, MFDS improved the records of medical devices used by medical institutions and made it mandatory for devices to be submitted and managed through a computer system. It also established the foundations for distribution tracking and quick response through information sharing with relevant organizations including the Health Insurance Review & Assessment Service and Korea Medical Devices Industry Association.

In addition, MFDS has carried out re-evaluations on the safety and efficacy of approved (licensed) or registered medical devices. Between 2013 and 2014, it re-evaluated safety information on 9,360 medical devices with grade 2 and 4, and applied the information to matters to be permitted (directions for the use of medical devices, method of use, etc.). It also re-evaluated 903 medical devices with grade 3 and 4 from 2015 to 2017. In addition, MFDS re-assessed silicon-filled breast implants for which many side effects were reported, to unify the purpose of use and to take measures to strengthen the precautions for use.

C. Implementation Plan

In December 2017, Korea became a formal member of the 「International Medical Device Regulators Forum (IMDRF)」, which is an international consultative body for the medical device

regulatory field. In 2018, MFDS plans to hold an international workshop on harmonizing the monitoring of adverse effects of medical devices in cooperation with the International Medical Device Regulators Forum (IMDRF) and Asia Pacific Economic Cooperation (APEC). It also plans to concentrate its efforts on strengthening the capability of academic, industrial, and institutional personnel and reinforce the safety information management of medical devices through running professional educational institutions.

Furthermore, MFDS will continue to promote safety management of distributed medical devices by developing a distribution system of medical devices targeted for tracking control and by re-evaluating products with social concerns such as the occurrence of side effects of medical devices.

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4. Advancement of the Medical Device Approval Review Process

A. Securing International Confidence in Domestically Licensed Medical Products

1) International Harmonization of Medical Devices through Participation in the International Medical Device Regulators Forum (IMDRF) and the Asian Harmonization Working Party (AHWP)

It is essential to acquire membership of the IMDRF to enhance the regulatory status of medical devices in Korea and to support the export industry. Korea applied for the membership of the 11th and 12th General Assembly of the IMDRF. On December 1 of 2017, Korea was formally recognized as a member country by a unanimous vote of all member countries of the IMDRF, winning recognition around the world for the excellence of the country's medical device regulation system. In addition, at the general assembly of the AHWP in 2017, three representatives from the Medical Device Evaluation Department were elected as vice chairman of the technical committee, and chairmen of the working-level groups for the "Preliminary Approval-General Medical Devices" and for "Prior Approval- Software" respectively. MFDS plans to complete relevant activities by 2021. Accordingly, Korea will support the country's export of medical devices.

2) Training Professional Personnel for Supporting the Commercialization of Medical Devices

Given that the medical device industry has a high added value and growth potential, MFDS has prepared and operated training programs for research developers and licensors in order to enhance the efficiency of professional training. In 2018, MFDS plans to expand the scope of training programs for supporting the commercialization of medical devices and carry out education on the medical devices related to the 4th Industrial Revolution.

3) Supporting Raid Commercialization of In Vitro Diagnostic (IVD) Medical Devices through Contracting-out

With the recent development of new diagnostic techniques, an efficient management system is required more than ever before. MFDS entrusted in-vitro diagnostic medical devices with Grade 2 to a private examination agency and is currently conducting an examination on the devices with Grade 2 at seven private consignment agencies (as of February 2018). In order to keep pace with the era of the 4th Industrial Revolution, MFDS plans to introduce a negative regulatory approach to meet the standards of judgment on major approval changes and to make reasonable improvements to the subject of the clinical trial plan approval for the development of the in vitro diagnostic industry.

B. Establishment of Preliminary Approval Screening Basis against Future Technology and Environmental Changes

1) Establishing Preemptive Safety Standards for Medical Devices Operated by Artificial Intelligence (AI)

To support the rapid commercialization of medical devices applied with artificial intelligence[13] (AI), MFDS developed guidelines for evaluating the clinical effectiveness of medical devices based on AI. It introduced a retrospective clinical trial to verify the effectiveness of AI in operating medical devices, and suggested measures to manage the approval of any changes in clinical trials efficiently.

13) A technology developed to substitute human intelligence (learning ability, reasoning ability, perception ability, comprehension ability, etc.) in diagnosing or predicting diseases

2) Establishment of Preemptive Safety Standards for Medical Devices such as Rehabilitation Robots

Korea is currently preparing comprehensive measures for supporting the development of rehabilitation robots. To ensure the safety of rehabilitation robots that have various product characteristics (product type, product performance) and clinical application areas (causes of disease, severity, application site, etc.) and to support rapid development, MFDS published the "Screening Guidelines for Licensed Rehabilitation Robots (Handbook for Civil Petitioners)" in October 2017. In the future, the Ministry will present its opinions when participating in the International Standards Meeting (IEC 80621-2-78) related to rehabilitation robots and use it as basic data for the establishment of 「Medical Device Standards」

3) Supporting the Establishment of 3D Printing Medical Devices

As a variety of products using 3D printers are currently being developed, MFDS conducted comprehensive training for personnel who license and evaluate patient-customized medical devices manufactured by 3D printers in 2017. In 2018, it plans to continue to develop a guideline for each item that reflects the characteristics of each product, and deliver the contents necessary for the production of 3D printing medical devices, such as medical device licensing examination, materials, software, etc.

4) Support and Approval of Development Technology of IVD Products Leading the Precision Medicine Industry

With the rapid development and convergence of proteomics, genomics and bioinformatics technologies, MFDS recently supported rapid authorization for new IVD products to be developed. Through this, the ministry licensed a lung cancer diagnostic device for the first time in Korea by using a specific biomarker and NGS-based breast cancer diagnostic products, ensuring that consumers can use new medical products. In 2018, MFDS plans to prepare a way to evaluate the performance of IVD medical devices used for predicting the prognosis of diseases through big data. It also intends to develop evaluation methods by considering international harmonization and domestic environment through gathering opinions from experts from industry, academia, and the government.

C. Expanding Communication and Cooperation for Reassuring the People

1) Strengthening On-site Promotion of the Safe Use of Life-Friendly Medical Devices Targeting Information Vulnerable Groups

MFDS carried out on-site promotion of the safe use of medical devices related to mobile medical examination, targeting vulnerable groups (children and the elderly). In addition to the publicity leaflet, it promoted the safe use of medical devices through live telephone interviews with the public and provided information such as the precautions for the purchase of medical devices via broadcasting programs.

2) Holding a Communication Forum for Medical Devices

The medical device industry is one of the major industry fields for realizing the creative economy. It requires preliminary preparation through identifying future issues and listening to the on-site voice. It is also necessary to strengthen public-private communication to cope with the changing medical environment by discussing the latest technology trends related to medical devices and related difficulties. To ensure that Korea grows into a medical device power, cooperation with international organizations and strengthening of networks with foreign regulatory authorities are needed. Therefore, MFDS held communication forums for medical devices two times in 2017.

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2018 MFDS White Paper

Ministry of Food and Drug Safety

Ⅳ

Risk Prevention

Section 1

Establishment of Foundations for Preemptive Risk Prevention and Crisis Response System Focused on Customers

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

A. Preventive Risk Management

The MFDS has been carrying out preliminary surveys on food and pharmaceuticals since 2006, based on hazards-related information collected from domestic and overseas government agencies, international organizations, and public media, with a view to preventing food safety issues such as prohibition of import, sale, or distribution. In order to eliminate blind spots in safety management, MFDS has since 2015 also conducted preliminary surveys focusing on items for which standards have not been set. MFDS has set standards and specifications, and implements safety and management measures such as suspension of manufacturing and sale of items for which risks are identified through assessment. In 2017, MFDS conducted preliminary surveys on a total of 600 cases involving 17 items: 181 cases related to 2 items of health functional food containing EPA/DHA (acid value and peroxide value); 15 cases related to 1 item of hijikia pills (heavy metals such as inorganic arsenic); 20 cases related to 2 items of processed food with embryo bud of rice and rice bran (inorganic arsenic); 150 cases related to 8 items of health functional food (benzophyrene); 134 cases related to 1 item of paper product targeting hamburger brands, etc. (material inspection), and 100 cases related to 3 items including cotton swabs, disposable dish cloths, and towels (fluorescent whitening agents, number of general bacteria, etc.).

Out of these total 600 cases, MFDS is in the process of setting standards and specifications of acid value and peroxide value, inorganic arsenic, etc. regarding 13 items including health functional foods, hijikia pills, and processed foods containing rice. In particular, in the 11 cases where dangerous levels of inorganic arsenic was detected in hijikia pills, MFDS took safety measures such as recommendation to suspend manufacturing and sale. For four cases where excessive quantity of general bacteria was detected in cotton swabs, it notified the preliminary survey results to Korea Agency for Technology and Standards so that the results would be applied to the safety investigation works carried out by the concerned ministry and office.

In 2018, MFDS has developed plans to do its best for preventive risk management. The agency will conduct about 500 preliminary risk surveys for managing blind spots through actively collecting and analyzing domestic and overseas risk information and identifying safety issues of special interest to customers.

B. Establishment of Basis for Tobacco Hazard/Risk Management

Tobacco smoke contains thousands of harmful substances such as carcinogens. These substances affect human body through direct and indirect smoking; however, information on harmful substances contained in manufacturing ingredients and smoke is insufficient.

In May 2003, the World Health Organization (WHO) adopted the International Convention on Tobacco Control (「the Framework Convention on Tobacco Control」[14]) and adopted regulations on demand and supply, including measurement, control, and disclosure of tobacco ingredients. However, Korea started discussions on introducing regulatory policies such as measurement, control, and disclosure of tobacco ingredients only in recent times.

MFDS has been investigating and reviewing methods of analyzing tobacco ingredients, toxicology studies, and overseas regulatory cases since 2013 as a base study to measure and disclose the harmful components of tobacco. In 2017, the content of harmful components of cigarettes and electronic cigarettes was announced. In addition, MFDS has begun to analyze the harmful components of t electronic cigarettes in view of the controversy about its harmfulness since the surge of usage after its release in 2017.

In addition, the tasks related to hazard management such as measurement, control and disclosure of tobacco components are managed by the MFDS, which has expertise in toxicity assessment and analysis of harmful components where amendments to related laws are being pursued.

MFDS will continue to conduct basic studies on hazard management, including establishing systematic methods for measuring tobacco components and toxicity assessment. The results of the analysis of harmful components in cigarette-like electronic cigarettes will be announced in 2018. In particular, submission of data on tobacco ingredients will be made mandatory for tobacco manufacturing/import/sales agents. Further, MFDS plans to consult closely with related ministries to revise relevant laws and casing material regulations, to enforce disclosure of information to the public.

14) It is the first international treaty unanimously adopted by the WHO in May 2003. As of July 2017, 181 countries have ratified the Convention. It contained price/non-price policies and institutional devices to reduce the supply and demand of tobacco.

2. Establishment of Crisis Response Base for the Prevention of Safety Accidents

In order to respond promptly and preemptively in case of a crisis that poses risk to people's health or a food and drug accident that raises anxiety, it is necessary to maintain a regular emergency response manual and strengthen the capacity of practitioners through systematic and repetitive education and training.

MFDS has prepared and operates crisis response manuals that specify the measures to be taken in the event of a crisis in the field of food, pharmaceuticals, and other sectors, as follows: food (2009), pharmaceuticals (2009), medical devices (2011), and cosmetics (2012). MFDS has also prepared a 'Practical Manual for Radioactive Leakage Countermeasures for Neighboring Countries' (2012) and 'Crisis Response Practice Manual for Nuclear Safety Sector (Radiation Leakage Countermeasures)' (2015).

In March 2013, following the government reorganization, the Ministry of Agriculture, Fisheries, and Marine Products Safety was transferred to the jurisdiction of to the Ministry of Food and Drugs Safety. Further, initial prompt response before a crisis, crisis type reclassification through the analysis of food accidents and case analysis, crisis level criterion, etc. were specifically supplemented. Also, MFDS has established a crisis response system that constitutes and operates the "Central Headquarters for Food Safety Accidents" in order to strengthen government-wide countermeasure capacity.

In 2017, to ensure consistency in incident response to accidents involving food, pharmaceuticals, cosmetics, and medical devices, MFDS revised the four sector-wise crisis response manuals and also revised the Practice Manual for Infectious Disease Crisis Response. The Manual for Crisis Response divides a crisis into four phases: Attention (Blue), Caution (Yellow), Alert (Orange), and Serious (Red). It describes how to respond quickly to each situation and incorporated improvements in manual application capacity and checklist for early response, and proposed ways to simplify decision-making procedures.

In addition, in order to enable field personnel respond quickly to on-site industry-specific safety accidents, countermeasures manual operation system for MFDS and city/provincial officials, practical training on countermeasures, and training for simulated crisis situations were enforced. MFDS continuously strives to strengthen its ability to respond to crises, by means such as creating an environment where cyber education courses can be used at any time by public officials who have difficulty in attending on-site training.

In 2017, the Emergency Response Headquarter (situation management team, media response team, general response team) was organized and operated to cope with the pesticide egg crisis. We carried out collection/ inspection, tracking of nonconforming products, decommissioning, and communication with the public regarding the domestic production/ distribution of eggs where pesticide ingredients were detected in order to prevent the spread of consumer damage.

In 2018, in order to prepare for crises caused by food and drug related accidents, MFDS will continuously improve the crisis response manual. This will strengthen concerned personnel's capabilities to quickly utilize the manual and respond appropriately in case of an actual crisis. As an emergency crisis management organization, MFDS will continue to focus on enhancing the crisis response system and strengthening the capacity of practitioners through simulation exercises centered on practice and discussions. The MFDS will hold "The 5th Symposium on Food and Drug Crisis Response" where a virtual training system will be used for the purpose of securing a realistic training environment, and will continue to strengthen the rapid response system to address new types of crises.

3. Strengthening the Cooperative System on Food and Drug Safety Issues between MFDS and Korea Consumer Agency

As consumers' interest in health-related food·pharmaceuticals·cosmetics·medical devices has increased rapidly, various organizations including Korea Consumer Agency (KCA) and consumer groups are strengthening efforts to carry out promotional campaigns on consumer safety and provide damage relief services.

In particular, Korea Consumer Agency directly collects and analyzes consumer complaints and risk-related data, and announces information on the safety of a product to the public after conducting research·study, as needed.

In this regard, there is a need for a close cooperative relationship between KCA and MFDS, which executes policies on the safety of food and pharmaceuticals with its expertise to provide accurate information on relevant product and carry out joint research and study when necessary.

MFDS signed an MOU with Korea Consumer Agency in 2009 and continues cooperative relations by sharing consumer injury information and conducting joint research·investigation on the safety of food and drugs. In particular, the MOU was renewed in 2015 and it was

mutually agreed to hold a consultation meeting prior to any public announcements related to food and drug safety to prevent confusion caused by inaccurate information. Also, through mutual consultation, the two organizations provided information on 27 cases including the results of a survey on food and pharmaceuticals in the market and pushed ahead with improvements to the system.

The two organizations also announced plans for joint investigation on agendas that can attract consumers' interest, established a communication channel for mutual cooperation, and built a constructive cooperative relationship through regular meetings and joint workshops.

In 2018, MFDS will continue its close, cooperative system with KCA through having prior consultations before public announcements, carrying out joint researches·studies, and holding working-level meetings and joint workshops.

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

The 「Act on the Promotion of Technology for Ensuring the Safety of Food, Drugs, Etc.」 was passed by the National Assembly on May 18, 2015 and entered into force on November 19, 2015. The Act comes with a total of 18 articles, including the mandatory establishment of master plans to promote safety technology and the basis for granting research fund contributions (Act No.13333, 18. May 2015).

The Enforcement Ordinance (Presidential Decree No. 26657, November 18, 2015) and the Enforcement Rules (Prime Ministerial Decree No. 1206, Enacted on November 19, 2015) of the Act were enacted and enforced in order. MFDS also enacted and implemented its own regulation on the operation of R&D projects on technologies related to food·drugs safety (MFDS Directive No.84, Jan. 18, 2016), marking a big turning point for MFDS, since the agency became fully equipped with the legal and institutional framework for research and development through this directive.

In addition, as the Act was enacted and enforced, MFDS' 「The First Master Plan for the Promotion of Safety Technologies for Food, Drugs, etc. (2016~2020)」 was established and implemented from April 2016. Based on this Master Plan, MFDS establishes an implementation plan every year, as part of its efforts towards ensuring public health and food safety.

Further, the stability of major policies will be ensured by establishing a provision regarding initiation and deliberations on Research and Development of Safety Technologies for Food,

Drugs, etc. according to the 「Act on the Promotion of Technology for Ensuring the Safety of Food, Drugs, Etc.」. This way, the Review Board prescribed in the 「Regulations for the Operation of Research and Development of Safety Technologies for Food, Drugs, etc. (Instruction)」 will be facilitated and allowed to deliberate on important matters regarding the development and promotion of technologies for safety of food and drugs, etc. There are also plans to establish a provision to restrict the participation of offenders related to R&D projects, thereby raising the legal predictability of the restrictions and carrying out the projects efficiently.

5. Establishment of a Safety Management System for Sanitary Goods

The 「Public Health Act」 was terminated in 1999 and the 「Public Health Control Act」 was enacted in its place. In accordance with Article 3 of the addendum of the 「Public Health Control Act」, sanitary goods such as detergents, wet wipes for restaurants, etc., which are closely related to the daily lives of the public, were to be governed by the (former) 「Public Health Act」 until the enactment or amendment of the law. This means that those goods have been under the influence of the abolished act so far.

Therefore, MFDS made efforts to enact a separate legislation for sanitary goods in order to improve their management system and raise hygiene level, promoting public health. As the 「Cleansing & Hygiene Products Control Act」 was enacted and promulgated on April 18, 2017, the legislation of 「Enforcement Ordinance of Cleansing & Hygiene Products Control Act」 and the 「Enforcement Rules of Cleansing & Hygiene Products Control Act」 were pre-announced. Also, MFDS made pre-announcement of administrative rules including 「Standards and Specification for Sanitary Goods」, 「Regulation on the Inspection of Imported Sanitary Goods」, 「Labeling for Sanitary Goods」, 「Regulation on the Operation of Consumer Hygiene Watchdog System for Sanitary Goods」, 「Regulation on the Designation and Operation of Hygiene Education Institutions for Sanitary Goods」.

According to the 「Cleansing & Hygiene Products Control Act」, the category of hygiene products was expanded, it was made compulsory for items (5 types of products) that might be exposed to chemicals to submit an Item Manufacturing Report and Ingredient Labeling, and the import business was reorganized for the safe management of imported hygiene products.

In addition, under the Administrative Rules, the contents and structure of 「Standards and Specification」 and 「Labeling Standards」, which had been subject to several laws, were organized for sanitary goods. As the import business was newly established, 「Regulation on the Inspection of Imported Sanitary Goods」 was also established in order to facilitate the safety management of sanitary goods. Further, detailed standards were prepared for designating and evaluating institutions that provided education related to sanitary goods and for appointing Consumer Hygiene Watchdog for Sanitary Goods. It is expected that these measures will secure transparency in safety management.

Following the implementation of 「Cleansing & Hygiene Products Control Act」 (Apr. 19, 2018), MFDS will enact relevant ordinances and administrative rules in order to enhance the safety management of sanitary goods and reorganize unreasonable systems, thereby promoting public health and healthy development of the sanitary goods industry. Moreover, MFDS will include daily supplies that need to be managed under the category of sanitary goods after reviewing relevant matters and continue to reduce the number of products placed in blind spots of safety management.

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Section 2

Building Consumer Trust through Reinforced Communication on Food and Drugs with the Public

1. Enhancing Two-way Communication by Identifying Consumer Needs

In order to reduce the gap in understanding between the government and the public on the safety of food and drugs, and to ensure that the public has confidence in policies on food and drugs safety, it is important to have regular communication with the public in a trustworthy and reliable manner. In this regard, the Ministry of Food and Drug Safety has strived to identify, correct, and improve the blind spots in food and drug policies by establishing a two-way communication channel.

MFDS established "National Communication Council" consisting of 1,000 people aged 19 or above to identify consumer complaints and concerns on the safety of food and drugs (55 cases) and to provide necessary information, thereby improving the relevant systems. Through a chat room (Consumer Talk Talk) with working-level staff of consumer groups, MFDS provides prompt feedback on questions regarding the safety of food and pharmaceuticals and offers information on current food and pharmaceutical issues at all times.

MFDS will enhance a two-way communication channel through which it receives and provides inputs from/to the public, in order to reassure the public about the safe management of foods and pharmaceuticals and proactively identify and respond to any concerns through a preventive communication system.

2. Disseminating a Food·Drugs Safety Culture in Korea

It is necessary to build consensus on food·drugs safety policies and establish the right food safety culture through diverse participatory programs in which people of various classes from youth to seniors take part.

In 2017, MFDS visited welfare centers, senior-citizen centers, public health centers, etc. in seven areas and carried out food·drugs safety educational sessions for a total of 7,914 people including the elderly with poor access to information. This program achieved a high level

of satisfaction among target groups (90 points).

In addition, the regional FDAs and six affiliated public organizations collaborated to offer a variety of theoretical and practical learning opportunities according to characteristics of organizations. The offerings included the experiential 'Food·drugs Junior' program (48 times, 1,120 participants) and 'Food·drugs Young Leader', a food·drugs-related promotional program (55 teams consisting of 211 middle and high school students). Each team produced promotional contents such as characters, video-clips, and pickets covering 6 topics including "Know your sugar to eat healthily".

Further, MFDS used crowd-sourcing, the latest publicity trend, and selected 200 general citizens including college students who are interested in food·drugs safety and have wide experiences in SNS activities to promote open, people-centered communication.

MFDS will continue to expand the scope of the "Outreach Consumer Food·Drugs Safety Class" to help vulnerable groups such as elderly people receive more food·drugs safety education. Also, MFDS will continue to operate various youth experiential programs to nurture future smart consumers.

3. Promotion of Policies that the Public can Relate to

Despite continued publicity on food·drugs-related policies, apparently the impact of those policies has not been perceived and felt in people's daily lives. Hence, it is necessary to establish a strategic and integrated publicity system to effectively promote food·drugs policies.

In 2017, MFDS became the first government department to produce a VR web drama titled "The Birth of Pro" (7 episodes). In that drama, the spectators feel like the main character in the virtual reality that rotates 360°, and get to vividly experience vividly the sites where foods are safely managed.

In addition, in order to educate the public on how to prevent food poisoning, MFDS also developed 'Food poisoning job GO', an educational game content using AR technology. It has been made in a game format so that people can actively participate and enjoy the contents while learning how to prevent food poisoning. Interestingly, 95% of the users said that it improved their awareness on how to prevent food poisoning.

Furthermore, MFDS also carried out a campaign to develop food safety culture nationally through a drug prevention song titled 'Don't Start'; a children's song about healthy diet titled 'Check HACCP Song'; and an idea contest.

In 2018, MFDS plans to come up with policies that the public can see, hear, and feel with their five senses, provide experiential contents regarding the food·drugs safety, and promote MFDS' image as a safe and reliable partner so that the public can trust the safety of the food and drugs they consume throughout the full life cycle.

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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

With the expanded free trade agreements and increased volume of trade with major countries, stricter management of foods and drugs safety has become indispensable. MFDS has established a rigorous system for prevention of safety hazards through prompt and accurate collection·analysis·evaluation of information on safety of domestic and foreign foods and pharmaceuticals. MFDS has monitored and collected information on hazards in food sector from 189 websites of 29 countries and in pharmaceuticals sector from 156 websites of 20 countries, and has, with the help of Overseas Information Reporters consisting of overseas Koreans and overseas students, gathered food and drugs safety information of foreign countries. MFDS collected 35,758 pieces of information regarding hazardous foods and drugs in 2017 alone and took preemptive safety management actions in 342 cases with measures such as stricter inspection and temporary suspension of distribution and sales. Among the 1,146 pieces of overseas information gathered through Overseas Information Reporters, 462 pieces of information were used as references for departments in charge of information analysis and business operation. To preempt the direct overseas purchase of adulterated foods and medical products through the internet, MFDS also provided 371 pieces of relevant information to online shopping sites including Auction and Gmarket and blocked access to 63 websites.

Along with these measures, MFDS has organized an "Industry·Academy·Government Cooperative Support Team" that collects and exchanges information, facilitating the exchange of food safety-related information. Further, the private-led "K-Food Safety Information Forum"was launched by integrating the existing "Food Safety Information Exchange Council" and "Industry·Academy·Government Cooperative Support Team" reflecting advantages and characteristics of the two organizations. The forum has made significant contributions to the prevention of food safety-related incidents.

MFDS will continue its effort to develop the "Asia International Food Safety Authority Network" which was established to expand the system for information collection among nations and thereby enhance cooperation for the prevention of food safety-related incidents at home

and abroad. MFDS will continue efforts to strengthen information exchange through hot-lines with Asian countries that have a high trade volume with Korea.

2. Pan-Governmental Linkage of Food Safety Information and Advancement of Food Safety Administration

A. Background

Until the Integrated Food Safety Information was established, food administration had been implemented through department-level tasks and region-oriented administration system of local governments. Government departmental·nationwide unified management and real-time response were not possible by this approach. When a food-related accident occurred, it was difficult to share and check the relevant information which in turn left gaps between departments in responding to the accidents. It was also difficult to realize prompt cooperation and response, causing anxiety about food safety among the people.

In order to solve these problems regarding food administration and to secure public trust in food safety, the Ministry of Food and Drug Safety (MFDS) established the Integrated Food Safety Information (June 2015) by integrating food safety information of 12 government ministries, provinces, and municipal districts.

B. Achievements

1) Integrating, Sharing and Utilizing Food Safety Information of All Government Departments

First of all, in order to ensure continuity and traceability between food safety information generated and managed by each department and local government, MFDS prepared and has continuously managed a standard food safety system. With this system, it became possible to extract more reliable statistics related to food safety and rapidly share information on prohibited ingredients, untrustworthy businesses, and unwholesome foods among the related institutions. Also, the officials in charge of foods are now able to prevent food accidents in advance and respond promptly by eliminating blind spots as they can access and utilize information from not only their departments, but nationwide information from government

departments linked·shared in the Integrated Food Safety Information database.

In addition, MFDS conducts continuous quality control by monitoring error information, comparing with the original data for verification, and organizing basic data in order to ensure the reliability of information. It has also expanded the scope of information sharing to 19 institutions and continuously increased the variety of information to be shared and integrated from 159 to 184 types, enhancing the availability of food safety information.

2) Supporting Scientific Food Safety Administration by Analyzing and Utilizing Big Data

Since the establishment of Integrated Food Safety Information (June 2015), national department-wide food administration became possible, and a vast amount of big data (about 170 million cases, as of June 2017) has been accumulated. This enables the analysis and processing of information to have meaningful statistics that in turn has strengthened the food safety administration system. First, by analyzing data of the Integrated Food Safety Information, it became possible to track and manage offenders who intentionally·frequently violated regulations, so that MFDS could remove them from the market even after those problematic businesses changed their name or the type of business. In addition, MFDS established a system that can automatically sort out companies that required crackdowns, such as food manufacturing·processing businesses, general restaurants, and group meal service facilities that are closely related to the daily lives of the public. Along with this, MFDS could reduce overlapped crackdowns and enhance efficiency by concentrating its HR and resources on necessary crackdowns.

In addition, MFDS developed a statistical algorithm that calculates the "probability of non-compliant food" (a score that shows the need for collection and inspection) after identifying variables that are highly related to non-compliance through the analysis of manufactured product lists, collection history and actual output reports. This has made it possible for MFDS to avoid unnecessary inspections and concentrate its efforts on unwholesome food management.

The automatic text messaging service, which automatically notifies businesses that do not post the guidelines in the Food Safety Korea portal, was developed for business managers to identify and comply with relevant matters such as self-quality controls, which should be checked on a regular basis through prior notification. Furthermore, a remote management system was established so that businesses that do not publish inspection results can get on-site inspections.

3) Opening and Providing More Public Information Reflecting People's Needs

The Food Safety Korea portal (formerly 'Food Safety Information Portal') provides various food-related services to the public by collecting food safety information distributed to several departments including MFDS; Ministry of Agriculture, Food, and Rural Affairs; Ministry of Oceans and Fisheries; and Ministry of Education. The portal publishes various food safety information on: Non-compliant foods that are subject to recall and disposal, hygiene information about restaurants in individual neighborhoods, information about school meals in specific schools of interest to the user, food-related issues and news, and knowledge regarding safe diet. Through the "My Company Self-Checking Service," food companies are provided with information on licensing and administrative dispositions. Further, 91 kinds of civil complaints regarding items' manufacturing report, etc. can be filed and settled online through the integrated civil service of the Food Safety Korea portal. In addition, MFDS has released a mobile app so that people could easily search and browse for information anytime, anywhere.

A total of 129 types of information from 12 government departments, including food nutrition ingredient DB and restaurant status are being provided in various forms such as Open-API. By developing smart refrigerators through agreements with the big three home appliances manufacturers (Samsung, LG, and Daewoo), MFDS also supports private businesses with a variety of services such as customized one-to-one consultations to address their difficulties. In addition, in order to secure the hygiene level of food delivery and provide real-time food safety information including administrative dispositions, MFDS has concluded a business agreement with delivery app vendors such as Baedal Minjok, Baedaltong, and Yogiyo.

MFDS also provides services to support and enhance the autonomous food safety management capacity of businesses including food manufacturers, restaurants, and mobile application developers. To encourage food manufacturers to voluntarily examine the safety of their products, MFDS provides the "Self-inspection of My Company" service so that manufacturers can check basic matters such as medical checkups, hygiene education, water analysis, insect/pest control, self-quality control, labeling, standards for preservation and distribution, etc. and report the results online to the competent authority. Besides, MFDS provides information that businesses are interested in, such as Korean Food Standards Codex, thereby enhancing the utilization of information.

C. Implementation Plan

1) Providing Useful Integrated Information Services for Citizens and Industries

Using big data of the Integrated Food Safety Information portal, MFDS will continue to help the public check food safety information through the Internet and smart devices. MFDS will also prepare a basis to establish a future-oriented food safety information system, with which people can check information on manufacturers and items, product ingredients, whether it is recalled or not, non-compliance history, illegal advertisements attached to barcodes printed on products via mobile devices, smart refrigerators, etc.

In addition, MFDS will provide differentiated information by processing data in the Integrated Food Safety Information portal or by combining different kinds of information that meet the demands of the age of data journalism. Also, customized food safety information by age group, region, season, and issue will be provided and posted on the websites (such as Naver, and delivery service apps, etc.) to provide exposure to more people.

2) Advancement for Enhancement of Data Utilization and Expansion of Data Linkage

MFDS will continue to provide scientific food administration by analyzing and utilizing big data collected through the Integrated Food Safety Information system. First of all, MFDS plans to analyze data in the integrated network to quantify the risk of each element and establish related systems phase by phase. In addition, a scientific monitoring system will be established using data in networks such as “Standard Classification System for Restaurants” and “System for Selecting Products to be Collected.”

Moreover, for prevention of food-related accidents and respond promptly to them, MFDS will expand the linkage of information such as safety at the production stage between institutions and reorganize the Integrated Food Safety Information system to enable real-time information sharing. For the management of livestock safety, information on livestock burial sites, licensing and approval will be newly linked, and information on licensing and approval of livestock industry and the occurrence of food poisoning will also be included. MFDS intends to continuously identify the additional demand for information linkage between government departments and the private sector.

MFDS will establish a real-time sharing system for expanding the scope of information sharing to other areas such as livestock burial sites*, feed items, and ingredients for prompt tracking and investigation when food safety-related accidents occur. With this, the foundations for the next-generation integrated food safety information network will be established.

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Section 4

Enhancing International Competitiveness through the Advancement of Testing and Inspection Agencies

1. Advancement of Testing and Inspection Agencies in the Food and Drug Industry

MFDS enacted 「Act on Testing and Inspection in the Food and Drug Industry」 in 2013 and the enforcement ordinance and enforcement rule of the same act, and 「Regulation on the Evaluation of Testing and Inspection Agencies in the Food and Drug Industry」 (Jul. 31, 2014) in 2014 to efficiently manage testing and inspection agencies and improve the convenience of filing civil complaints.

In the area of testing·inspection activity, there are statutory inspection agencies that are designated according to the ordinance of the Prime Minister, private inspection agencies that are designated by the Minister of the Food and Drug Safety, and overseas testing·inspection agencies located in foreign countries. Inspection agencies can also be classified by category: food, livestock, pharmaceuticals, cosmetics, and medical devices.

Any entity that wants to be designated as a testing·inspection agency shall meet the requirements regarding inspection facilities and human resources specified in the 「Act on Testing and Inspection in the Food and Drug Industry」 and relevant regulations and apply for the designation. The applicant shall be evaluated through the documents submitted and on-site inspection and designated as a testing·inspection agency if the specified requirements are met.

The table below shows the current status of testing·inspection agencies designated by MFDS as of the end of December 2017.

[Table 4-1-1] Testing·Inspection Agencies by Category

(As of Dec. 31, 2017, Unit: agency, Ref.: Laboratory Audit and Policy Division)

Category	Total	Domestic Institutions		Overseas Institutions
		Statutory Agency	Private Agency	
Food	156	25	72(P 12, C 60)	58
Livestock	64	26	38(Import 2, C 36)	0
Pharmaceuticals	36	23	13(pharmaceuticals 8, medicinal herbs 5)	0
Cosmetics	38	23	15	0
Medical Devices	16	1	15	0

※ P: Professional Food Testing and Inspection Agency
C: Commissioned Self-Quality Testing and Inspection Agency

MFDS has been strengthening efforts to raise the level of tests and inspections and help testing·inspection agencies to implement accurate tests and inspections by improving the relevant system, managing the testing·inspection capabilities, and carrying out regular check·inspections every year, so that the public is provided with safe food and pharmaceuticals.

In addition, MFDS maintains close cooperation with the Public Health and Environment Research Institutes in cities and provinces and the Animal Hygiene Laboratories of local governments in order to promptly respond to food·pharmaceutical-related accidents.

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2018 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. Carrying Out Research and Development on Technologies Related to Food, Drugs etc.

In response to the rising public interest in securing safety of food and drugs, and in view of the need to strengthen the government's role in managing national health and safety, since 2016, MFDS has been carrying out the 「General Plan on Safety Technologies for Food and Pharmaceuticals」 (2016-2020) phase by phase following its annual implementation plan.

In order to protect the public safety and health through scientific safety technologies for foods and pharmaceuticals, MFDS carries out R&D through six specific projects including safety management of food, etc.; safety management of drugs, etc.; safety management of medical devices, etc.; R&D for safety evaluation technology; advancement of safety technology; and safety management for livestock and fisheries. The budget for these R&D projects has increased steadily (annual average growth rate of 2.3%), reaching 83.1 billion won in 2018; details are shown in [Table 5-1-1].

[Table 5-1-1] Financial Operation of Major R&D Projects for the Last 4 Years

(As of Dec. 31, 2017 Unit: 100 million won, %, Rec.: Research Planning and Management Division)

Classification	Budget for 2015	Budget for 2016	Budget for 2017	Budget for 2018	Average Growth Rate
Total	776.1	792.7	818.6	830.7	2.3%
Safety management of food, etc.	292.3	269.8	280.8	298.0	0.6%
Safety management of drugs, etc.	200.0	224.0	240.9	233.1	5.2%
Safety management of medical devices, etc.	79.4	73.0	85.2	76.6	-1.2%
R&D for safety evaluation technology	134.0	145.5	125.3	133.4	-0.1%
Advancement of safety technology	38.4	38.4	34.4	32.4	-5.5%
Safety management for livestock and fisheries	32.0	42.0	52.0	57.2	21.4%

In 2017, for the safety management of food, etc., MFDS invested KRW 28.08 billion and implemented 106 R&D tasks that were carried out to prepare a preventive food safety management system. R&D in this area focused on foundational preventive measures such as establishment of the basis for enactment and revision of food standards and specifications, eradication of adulterated food, technologies for reduction of harmful substances, and prevention and eradication of the causes of food poisoning. For the safety management of drugs, etc. Further, MFDS invested KRW 24.09 billion won and carried out 119 tasks to improve the pharmaceutical safety system by preparing a scientific basis for safety management policies for pharmaceuticals, etc., and developing technologies for screening and evaluation to help rapid commercialization of pharmaceuticals. For safety management of medical devices, etc., MFDS invested KRW 8.52 billion and carried out 47 tasks that focused on preemptive policies for safety management of medical devices; establishment of an internationally harmonized system; development of evaluation technologies to prepare a scientific basis for standards and approval; and development of a rapid approval system for medical devices that are newly developed related to the 4th Industrial Revolution. In the area of R&D for safety evaluation technologies, MFDS invested KRW 12.53 billion and carried out 51 tasks. The tasks were directed towards the establishment of evaluation-based technologies and safety prediction for toxicity, pharmacology, clinical and advanced analysis, laboratory animals, and alternative tests in order to establish a scientific foundation for safety management of food, drugs, etc. For the advancement of safety technology, MFDS invested KRW 3.24 billion and carried out 9 tasks to strengthen the competitiveness of food·drugs safety technologies. The tasks focused on developing and propagating food·drugs safety management technologies that can be utilized in the private sector, and developing safety evaluation-related technologies for advanced convergence medical products and supporting businesses. For safety management of livestock and fisheries, MFDS invested KRW 5.72 billion and carried out 19 tasks to develop and prepare scientific inspection technologies and evaluation methods for hazardous elements and to ensure food safety and a healthy dietary life for the public through a preventive safety management system.

MFDS plans to reinforce investment on fields closely linked preferentially to daily lives of people, and prepare a scientific regulatory foundation to cope with the low birth rate, aging society, and new·environmental hazardous elements. MFDS also will develop new prediction·prevention technologies against substances with probability of being hazardous to humans, promote approval· review policies to reinforce international competitiveness of industries such

as pharmaceuticals and cosmetics, and promote technologies for leading the 4th Industrial Revolution. MFDS will strengthen its R&D efforts with a view to preoccupying markets and expanding investment on safety technologies in industries with future prospects.

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2. Impartial Research Management and Provision of Services for Researchers

To establish transparency and impartiality in research projects, MFDS carries out 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 (Q&A) in order to help researchers with administrative work related to the projects and provide a proper understanding of MFDS' research funds, which are general accounts such as research fund, outsourced R&D fund and contributions according to the Act on the Promotion of Technology for Ensuring the Safety of Food, Drugs, etc.

In 2017, a total of 232 new R&D projects were selected through 11 sessions of selection evaluation. These included 78 self-R&D projects, 152 outsourced R&D projects, and 2 funded R&D projects. In case of outsourced R&D projects, a price evaluation system based on the bidding price in a price proposal was introduced (March 2016) according to the contract regulation for 「Contract Agreement Standards by Negotiation」, a contract regulation of the Ministry of Strategy and Finance. A difference of 600 million won was generated in 2017. In order to manage R&D performance, final evaluations or annual evaluations were carried out for 380 projects over a total of 15 sessions.

In addition, 7 projects were selected in 2016 with the budget allocated from the contribution fund pursuant to the Act on Promotion of Technology for Ensuring the Safety of Food, Drugs, etc., and 2 projects were additionally selected in 2017, carrying out 9 projects in total.

MFDS introduced a research fund and card system in 2003 in order to manage its R&D funds systematically and transparently, and has been outsourcing the R&D fund management system (July 2017). To prepare a pan-government integrated R&D cost management system, it plans to shuffle MFDS' R&D fund management system and link to Ezbaro, an integrated management system.

MFDS held a briefing session (May 2017) on R&D cost settlement for research directors and related researchers who were carrying out MFDS' R&D projects, and "Q&A on R&D Costs for Outsourced R&D Projects" (August 2017) by organizing frequently asked questions and answers about outsourced R&D costs.

MFDS will continue its efforts to promote fair and transparent evaluation. For vitalizing creation of outcomes, MFDS plans to revise the R&D project evaluation guidelines by reflecting the guidelines for evaluation standards. In addition, it will update "Q&A on R&D Costs for Outsourced R&D Projects" continuously, and organize and share frequently asked questions and answers about self-R&D·outsourced R&D·project unit R&D·funded R&D·projects. Furthermore, MFDS is slated to hold "Visiting Briefing Sessions for the Use of R&D Costs by MFDS" for research directors and research institutions, and carry out on-site inspections for commissioned settlement of R&D expenditures and management. These measures will serve as part of efforts to encourage researchers to appropriately execute the research funds, and thus create a transparent and reliable environment for management of research funds.

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3. Outcome Management for Research and Development Projects

The research and development initiatives of MFDS aim to realize scientific safety management for securing safety of food and pharmaceuticals and reinforcing international competitiveness and are thus focused on policy utilization rather than the academic aspect or economic outcome. The final goal is to contribute to people's quality of life in terms such as improved health. To this end, the most crucial R&D performance indicator set by MFDS for performance management is the connection rate between food· drug safety and policies. On the other hand, the R&D performance indicators for unit projects such as food and pharmaceuticals are deduction of food and pharmaceutical safety standards (number of developed test methods, number of suggested guidelines, and number of manufactured reference standards) and thesis index. The results of each of the indicators exceeded the 2017 targets by more than 100%.

In 2017, MFDS conducted a mid-term (self-assessment) evaluation on two projects, "Safety Management of Pharmaceuticals" and "Safety Management of Livestock and Fisheries." Following receipt of "Normal" rating from the Ministry of Science, ICT and Future Planning,

the evaluation was reflected in the budget and business plan for the following year.

Follow-up evaluation of utilization·dissemination of R&D projects' performance is carried out every year in the case of projects for which the completion data has passed 1 year by considering time required for performance utilization. Projects with evaluation results of "Poor" or lower are subject to follow-up evaluation again in the following year for addressing/remediating for poor performance. Follow-up evaluation in 2017 was carried out in the case of 250 projects for which the evaluation results were "Normal" or above.

In order to enhance the qualitative performance of MFDS' R&D projects, the current quantitative "R&D Normalized Performance Items and Indicators" was improved into a qualitative performance indicator. Among the overall performance indicators, the rate of qualitative performance indicators was raised up to 50% or more. For example, the simple thesis indicator focusing on numbers was redesigned to apply the Modified Rank Normalized Impact Factor (mrnIF). In the future, MFDS will also revise relevant regulations and guidelines, and improve the performance management system.

In 2018, the detailed projects, "Safety Management for Food" and "Safety Management for Medical Devices" are subject to performance evaluation, and R&D self-evaluation on the performance of these projects over the last 3 years is being carried out presently. Comprehensive analysis of detailed projects for the following year will be carried out to improve and set performance targets and indicators based on the characteristics of the project and guidelines for evaluation. Furthermore, the "MFDS Self-Evaluation Committee" will be established to carry out professional and comprehensive performance analysis and thereby enhance reliability of self-evaluation of the "Performance Indicators and Indicators (draft)."

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Section 2

Expanding Risk Assessment for Scientific Food Safety Management

1. Improvement of the Risk Assessment System with Expanded National and International Cooperation

From the humidifier disinfectant accident and pesticide egg accident, to harmful sanitary pads, continued controversy over safety of chemical substances has made it vital to establish a system for integrated risk assessment on chemical substances, which comprehensively considers impacts on human life through exposed media such as household items, various foods, cosmetics, and environment and through paths such as mouth·skin·breathing.

In the next five years from 2018, integrated risk assessment on substances exposed to human body through various products and paths will be carried out as a major government project. The project will also address management blind spots in the domain. MFDS has pursued continuous (re)evaluation on human exposure safety standards, realized advancements including calculation of the amount of food intake and standardization of exposure evaluation models, and developed phased uncertainty reduction technologies for increasing reliability of risk assessment. In addition, MFDS has laid the foundations for integrated risk assessment including development of Physiology Based Pharmacokinetic Core Model (PBPK Core Model) for calculating the amount of external exposure from human bio-monitoring results on harmful substances. In the future, MFDS plans to establish a close collaboration system with relevant ministries and departments including the Ministry of Environment and the Ministry of Trade, Industry and Energy, in order to comprehensively evaluate risks related to various products that come in close contact with human body, from a people-centered perspective. Furthermore, to realize practical risk assessment cooperation with the European Food Safety Authority (EFSA), MFDS will conclude a business agreement in 2018. This is expected to largely contribute to elevation of Korea's expertise in risk assessment and international reliability.

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2. Advancement of the Risk Assessment System for Residual Substances in Agricultural, Livestock and Marine Products

A. Establishment of International Level Residual Substance Testing Method

To expand the scope of imported products and introduce the Positive List System (PLS)[15] that MFDS is currently working on, it is necessary to prepare testing methods that can accurately and promptly check the residue of pesticides and animal drugs that are not approved for use in Korea.

Therefore, according to the verification process suggested by the CODEX Alimentarius Commission (CAC), MFDS has been developing testing methods to detect and measure 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. Residual Substance Risk Assessment and International Level Harmonization

In order to mitigate consumers' anxiety about animal drugs as well as residual agricultural pesticides in food, scientific risk assessment has been conducted through evaluation on the amount of intake and typical rate of exposure for Korean people. Based on this, MFDS will establish maximum residue limits considering a safe level. In addition, to activate export and import of agricultural·marine·livestock products internationally, MFDS plans to propose reasonable standards and specifications in a continuous manner.

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15) 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 of Scientific Basis for Reducing Hazardous Contaminants in Food

The likelihood of human exposure to harmful contaminants (heavy metals, dioxins, mycotoxins, etc.) has gradually increased due to environmental pollution and changes to eating habits. Consumers' anxiety about harmful contaminants in food has also increased as a result of accidents·incidents and hazard information published at home and abroad. In this regard, to properly manage the amount of human exposure to harmful contaminants through food, MFDS is carrying out surveys and risk assessment on the state of exposure to harmful contaminants. MFDS will accordingly establish a reduction plan for substances that need to be reduced on a priority basis.

In 2017, MFDS calculated the total amount of exposure to human body and conducted risk assessment in about 2,743 cases including 273 dioxin items, 283 PCBs items, and 2,882 cases of pollution level. Among the results, concern over intake of food containing dioxin and PCBs was assessed at a low level. Further, in the risk assessment survey on harmful contaminants such as heavy metals and mycotoxins, the concern over intake of the relevant food was also assessed at a low level.

In 2008, expose dose calculation and risk assessment will be conducted through the "Survey on Aflatoxin in Korean Homemade Soybean Paste" as basic materials for setting the foundations of reduction. Transfer rates of heavy metal by processing method will be researched, and effects of processing conditions in reducing heavy metals in food will also be analyzed. Through establishment of reduction plans and cooperation among government organizations over the entire food chain (environment-producer-distribution-cooking), a pan-governmental cooperation system will continue to be built for reduction of exposure to harmful contaminants.

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4. Research and Development of Expeditious and Precise Microbial Testing Methods

A. Microbial Risk Assessment based on Scientific Methods

Microbial risk assessment is required as a scientific basis for establishing standards and plans for national food safety management. Hence, MFDS carried out risk assessment on low-risk food poisoning bacteria including staphylococcus aureus for bread, etc. in order to establish a scientific basis for setting reasonable specifications, and also revised a total of 3 quantitative specifications from 「Standards and Specifications for Food」. Furthermore, the risk assessment results were released to the public as a report with an abstract in English through the National Institute of Food and Drug Safety Evaluation's website, and also published as booklets in order to reinforce the people's right to know. The scope of microbial risk assessment, which has so far been focused on distribution and consumption stages, will be expanded to the whole stages from production to distribution· consumption of Salmonella in the livestock products from 2018, and risk assessment on resurgent harmful microorganisms such as vibrio cholera and vibrio vulnificus septicemia will also be carried out.

B. Research and Development on Expeditious and Precise Microbial Testing Methods

In order to secure accuracy and increase reliability of inspection, continued research is required including comparison·review of the national system with the testing methods used by advanced countries, and verification of testing methods. Further, development of reduction technologies and reinforcement of prevention are also necessary in order to detect food poisoning in the early stages, fundamentally control the occurrence of food poisoning, and prevent further spread. A plan for improvement of the approved microorganism testing method was prepared after carrying out systematic verification procedures as well as comparison· analysis with internationally used microorganism testing methods, and revision plans for a total of 8 testing methods were proposed. In 2018, MFDS plans to develop revision plans for methods of testing for food poisoning bacteria such as Campylobacter by continuous research on approved microorganism testing methods and verification of testing methods and laboratories. In addition, MFDS developed 7 and 6 simultaneous detection kits for food poisoning viruses

and protozoans respectively in order to quickly identify causes of food poisoning. Starting from 2018, these kits will be used for rapid inspection in mobile inspection vehicles and for food monitoring projects. Furthermore, to facilitate rapid response to food poisoning accidents, MFDS will analyze information on various features of food poisoning bacteria and establish a DB in the integrated information network for food poisoning bacteria in a continuous manner.

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5. Strengthening the Safety Management of Food Additives, Utensils, Containers, Packaging, and Hygiene Products

Due to the recent westernization of diet style and the development of food processing technology, consumption of processed foods containing food additives, packaged foods, and cooking utensils has significantly increased. In addition, as public concern on transferable substances derived from food additives, food utensils, containers, and packaging has increased, there have been calls for a continuous evaluation to secure public health.

In this regard, in 2018, the MFDS is carrying out risk assessment on food additives (23 items including color fixing agents) contained in foods, publishing and distributing related reports, and releasing them at the National Institute of Food and Drug Safety Evaluation website. It is also carrying out safety assessment on transferable substances (7 items including 1-hexene polylactide) present in food utensils, containers, and packaging material (Polyethylene, Polypropylene, and Polyactide).

Improper uses of food additives, in which area standards and specifications have been set, continue to occur to the present day. Food additives for which standards and specifications are not established also continue to be detected in foods. In addition, with regards to food utensils, containers and packaging, there is growing demand for management of raw materials for which standards and specification are established in several countries but not in Korea.

In this regard, to strengthen the management of standards and specifications, MFSD will carry out researches on analysis methods for 5 coating agents in foods, improvement of testing methods through cross-validation between laboratories mentioned in 「Food Codes」 and 「Analysis Methods for Food Additives in Foodstuffs」, improvement of testing method for

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 domestic-unestablished sweeteners (5 additives including Citrus Red 2) for preventive safety management, and developing testing methods and monitoring for transferable substances in food utensils, containers, and packaging (bisphenol and mineral oil).

MFDS is establishing a scientific licensing and assessment system and developing risk assessment technologies to ensure the safety of hygiene products. In the case of hygiene products, it is preparing a method of evaluating exposure to human body by selecting the harmful substances according to the priority of food ingredients and then analyzing the content of hazardous substances remaining or transferred to foods after their use. It is also planning methods to improve the review of ingredients in detergents and rinse aids, standards and specifications, and relevant testing methods.

Lastly, MFDS plans to investigate the content of naturally derived food additives in potatoes, beans, and other vegetables and to carry out a technical review to check whether to recognize naturally derived food additives and whether to use raw materials of cleaning products, thereby preparing scientific evidence.

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6. Establishing a Basis for Safety Management of Food Nutrition, Dietary Life, and Functional Health Foods

In recent years, the public's interest in nutrition, diet safety, and functional health foods has grown in response to issues related to aging and changes in dietary patterns. Therefore, in carrying out policies for nutrition and diet safety management at the national level, studies for establishing the scientific basis are continuously required. MFDS continues to work on the following activities: analysis on nutritional intakes with possible health hazards; analysis on the correlation with chronic diseases; a study on the reduction of nutritional contents in children's favorite foods with possible health hazards; and a study on the establishment of a National Food and Nutrition Database. Based on these activities, MFDS has laid the scientific foundation for establishing nutrition management and safety policies by demographic groups.

It has also continued to enhance the efficiency and reliability of the testing methods for nutrients and functional (index) ingredients contained in foods.

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7. Strengthening the Scientific Surveillance System for Adulterated Foods

A. Strengthening the Scientific Surveillance System to Eradicate Defective and Adulterated Foods

In recent years, people's interest in health and safe food has increased following improvement of living standards; however, it is still common practice to use raw materials with low quality and price (Economically Motivated Adulterated food, EMA food). Cases involving manufacture and distribution of adulterated food have been decreasing thanks to the unwholesome food eradication policy. However, as a result of tricky techniques and new types of adulterated food, economic losses are still created. Therefore, in order to minimize economic and industrial losses through effective countermeasures for protection of the domestic food industry and international trade, it is necessary to develop a method for scientifically discriminating adulterated foods. In this regard, the MFDS has developed a 3D scanner system and discrimination algorithm for identifying frozen octopus with water added artificially. Also, a melamine detection kit has been developed in order to quickly make determinations in food collection scenes by using the Lateral Flow Assay (LFA) sensor strip method.

In addition, MFDS has been able to develop techniques to identify: the mix-in of prohibited raw materials such as groundsel/Caltha palustris; determine the authenticity of blueberry and pomegranate juice; and differentiate the origin of sun-dried salt and sesame/perilla seeds[16]. Recently, there were concerns about consumer damage from prohibited raw materials acquired through direct overseas purchase and food containing drug ingredients. Therefore, MFDS completed a survey on the status of illegal substances, focusing on foods directly purchased overseas, foods for self-consumption (sexual function improvement, diet efficacy/effect, claims

16) Number of development cases (accumulated) : ('14) 3 cases → ('15) 8 cases → ('16) 13 cases → ('17) 24 cases

of 300 cases) and requested to block internet sales (95 cases) where illegal substances were detected. In addition, two illegally added pharmaceutical ingredients (dithiopropylcarbodenafil, chlorocipentramine) were identified in a world-first and notified in 〈The Food Standards and Specifications〉. In the future, MFDS will complement the artificially weighted frozen octopus' determination method using a 3D scanner detection system (by shortening the detection time through application of the light source rotation method or the specimen rotation method of the 3D detection system). MFDS will also conduct verification of field applicability and hold demonstrations, and plans to develop a histamine detection sensor with a lateral flow sensor strip for high sensitivity field diagnosis. In addition, MFDS will examine and verify the field applicability of method for determination of sun salts' origin and plans to identify the origin (domestic or Chinese) of red pepper powder distributed nationwide based on multi-spectral analysis. Finally, more than 400 food and health functional products are analyzed annually to investigate the status of illegal substances in food and to search for new illegal substances. MFDS plans to enhance food safety management by preparing a testing method for illegal substances and sharing the relevant information with related organizations, so that illegal substances cannot be mixed into foods.

B. Research and Development of Adulterated Food Identification Methods Using the Latest Gene Technology

Recently, there have been cases of deceiving and taking unfair advantage of consumers by manufacturing and distributing adulterated foods such as red pepper powder mixed with seasoned red pepper sauce, Chinese drum fish sold as croakers, and sauced intestine using Iridescent shark intestine. In addition, fake raw materials are being mixed in health functional and it is necessary to develop a method for determining the authenticity of the raw materials used in foods. MFDS has developed genome-specific primer development and genetic analysis methods for eight kinds of animal raw materials such as toothfish and croaker and 13 kinds of plant species such as cherry and mulberry, and selected and verified five kinds of raw material such as mistletoe. MFDS developed an on-site rapid detection kit for eight species such as tile fish that require raw material management, and secured a basis for establishing a database of morphological characteristics and gene barcode information to identify similar fish species of marine products. MFDS has also developed a method for determining health functional food ingredients (6 cases including Dansam and Goji berry) that pose concerns of

forgery and alteration. In the future, we will investigate the naming methods and morphological characteristics of raw materials used in health functional foods (big blue lilyturf, peony, conidium, etc.), domestic raw food materials (bream type, croaker type, eel type), and expand the development of genetic analysis methods to determine their authenticity. In addition, we have developed a rapid detection method and a detection kit to quickly determine the authenticity of food raw materials on the scene so that the test and analysis can be more objective so as to eradicate the distribution of adulterated foods.

C. Preparation of a Management Plan for Food Hazard Control Technology

Although the number of reported foreign substance cases has decreased by about 45% since the enforcement of the Foreign Substance Reporting Mandatory System (2010), consumer complaints continue to develop due to the lack of improvement in the identification of contamination cause[17]. Therefore, it is necessary to establish a scientific analysis system such as a method to reduce the inclusion of foreign substances in food and a quick and accurate determination method to improve the identification rate of contamination from foreign substances. In this regard, MFDS has gathered opinions of personnel responsible for testing and analysis of foreign substances to improve the method of testing metallic biomass in food. In order to increase the detection rate of foreign substances in food and prevent obliteration of foreign substances, a manual called 'How to Preserve Foreign Substances for Reporting (draft)' was prepared. In order to construct a foreign substance library, MFDS completed revision and supplementation of the raw materials database (Raw Data) after analyzing foreign substances that are mixed into food or are possibly contaminating food.

In addition, after developing a packaging tape and adhesive that can prevent insect infestation during food distribution and storage, we tested the insect repellent effect by using environment-friendly insect repellent material. In the future, MFDS will make improvements (draft) of the foreign substance test method considering the characteristics and properties of the food type. After expanding the database on the result on analysis of foreign substances with reported cases of food contamination, MFDS plans to develop a library search program based on image and spectral band using results of morphological and instrumental analysis of foreign substances. In addition, a large-scale on-site application test, using box packing

17) Result of Investigating the Cause (2016)
Manufacturing stage 8.9%, consumption and distribution stage 19.3%, misidentification 10.1%, no judgement 30.7%, no investigation 31.1%

tapes and adhesives to reduce insect infestation, will be extended to examine the possibility of commercialization. Further, MFDS will provide and verify insect control technology based on the analysis of the food manufacturing environment and comprehensive pest management concept.

D. Preparation of a Plan to Reduce Hazardous Substances from Manufacturing, Processing, and Cooking

It is necessary to implement safety management according to the total exposure amount of unintentional hazardous chemical substances generated during food manufacturing, cooking, and processing. Further, it is necessary to enhance technology by improving the manufacturing process, quality control, test methods, etc. so as to reduce exposure. In view of this requirement, MFDS published a risk assessment report for 50 kinds of harmful substances such as benzo-pyrene and acrylamide through total dietary survey (TDS) by considering the actual dietary intake. In addition, MFDS conducted a survey on the re-evaluation of standards and specifications such as 3-MCPD that can be generated during manufacturing, processing and cooking. For the safety management of Glycidyl ester and 3-MCPD ester, which are fatty acid-derived products found in food, MFDS surveyed domestic and foreign technical data and prepared a testing method applicable to domestic processed foods. In the future, MFDS plans to continuously reduce exposure to harmful substances, which is the top priority in management to reduce presence of hazardous substances in food manufacturing, processing, and cooking. MFDS will continue to provide basic data on food safety management through analyzing hazardous substances in raw materials and final food products, which will serve as an effective reduction measure in the stages of food manufacturing, processing and cooking, and improvement of testing methods.

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Section 3

Supporting Research and Commercialization for Medical Products Safety Management

1. Advancement of the Basis of Quality Management of Medical Products

An official compendium in the field of medical products provides a minimum quality standard for distributed medicines, quasi-drugs, etc. It includes Korean Pharmacopoeia, one of the representative official compendiums, Korean Quasi-drug Codex, Korean Functional Cosmetics Codex, and The Korean Herbal Pharmacopoeia, etc.

The standards and specifications presented in the official compendium should be continuously improved and reasonable standards should be developed considering the introduction of new technology, the rapid reflection of international harmonization, and the evolving conditions of the pharmaceutical industry. For this, MFDS presents a revision based on its research projects and has developed a pharmacopoeia of international level by gathering internal and external opinions through publications such as “Korean Pharmacopoeial Forum.”

A reference standard, which is a reference material used for the testing and inspection of pharmaceuticals, is directly linked to the quality of medical products and public health. MFDS has steadily secured and distributed the reference standard for medical products starting with reference standards for chemical pharmaceuticals since 1991. MFDS now provides a total of 454 reference standards including 176 items of chemical pharmaceuticals, 28 items of bio-pharmaceuticals, 218 items of herbal medicines, 31 items of IVD medical devices, and 1 item of quasi-drugs.

In addition, to secure the reliability of quality, MFDS periodically conducts stability test on the reference standards it stores. It published and distributed the “2017 MFDS Comprehensive Guide for Reference Standards.” MFDS will continue to expand and provide reference standards for medical products in the future by reflecting demand surveys in the field.

Also, to secure the quality of the distributed pharmaceuticals, MFDS conducted testing and inspection of 25 items of chemical pharmaceuticals, 29 items of bio-pharmaceuticals, 491 items of Chinese(herbal) medicines, and 18 items of cosmetics and quasi-drugs. In particular, it conducted rapid testing, inspection and risk assessment of 84 items of volatile organic

compounds (VOCs) among distributed sanitary pads (666 items) in view of the recent controversy. Since obtaining ISO 17025 from an internationally-accredited testing organization in 2004, MFDS expanded its accreditation field and acquired accreditation for 13 test items in 2 areas in order to ensure the objectivity and reliability of the testing and inspection results. The ministry will also 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, Drug Research Division
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2. Research on Pharmaceutical Safety Management

MFDS prepared 213 cases to be included in the revised version of the Korean Pharmacopoeia for establishing the foundations of quality management of pharmaceuticals. Further, MFDS enhanced scientific validity and reliability of the revised pharmacopoeia through three meetings led by the Central Pharmaceutical Affairs Council. It actively reflects external opinions about the revision from industrial settings and gathers internal and external opinions through the publication of "Korean Pharmacopoeial Forum" twice a year.

Also, MFDS held a briefing session for working-level people in the industry to share the direction of improving testing methods and to listen to complaints and opinions about quality management within the industry. In order to supply reference standards that is another important factor in quality management of pharmaceuticals, MFDS gathered views about desirable reference standards. Under the supervision of an internationally-accredited testing organization, it produced and established 50 new reference standards. MFDS also safely managed the quality of the reference standards by carrying out stability tests for 89 items among the reference standards already established. The agency continuously cooperated with the WHO, USPC (United States Pharmacopeial Convention) and EDQM (European Directorate for the Quality of Medicines & Healthcare) for quality control of the reference standards at the international level.

MFDS also tested 21 pharmaceuticals that raised concerns over illegal online distribution and four pharmaceuticals required to be introduced urgently or needed to check the quality of products to protect public health through safe medicine distribution.

Since 2010, MFDS has published braille books, sign language videos, and information booklets translated into multiple languages on the safe use of pharmaceuticals for the visually/hearing impaired and multi-cultural families who are unable to access pharmaceutical usage information easily. In 2017, the ministry developed the basics for the safe use of medicines and information on otitis media for hearing impaired people in the form of sign language video. The ministry distributed the information to related organizations such as the National Association of the Deaf and the Deaf Community Welfare Centers, etc. in the form of portable storage media (USB), significantly enhancing information accessibility for vulnerable information groups.

In addition, MFDS developed the drafts of Korean LCD (Linguistic Convention Document) and training materials to support to implement the ICH Medical Dictionary for Regulatory Activities (MedDRA). It conducted several studies on the guidelines (proposal) for supporting multi-regional clinical trial designs and plans, educational materials (proposal) for preventing drug usage errors, and guidelines (proposal) for equivalency evaluation of injectable liposome formulation. These studies would be used for policy-making. MFDS will continue its research efforts on safety management focusing on unmet demands such as medicines for chronic diseases and orphan drugs; preemptive development and research on screening and evaluation techniques supporting development of new technology and product commercialization; and research on consistency and scientific evidence for approval and evaluation of pharmaceuticals.

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3. Research on Prevention and Safety Control of Infectious Diseases

In response to national health crises such as the spread of new infectious diseases, in 2015 MFDS prepared a technology roadmap and implementation plan for review and evaluation of vaccines against new infectious diseases and established a rapid licensing strategy in order to support vaccine self-sufficiency more systematically. Based on this, MFDS conducted researches on the development of methods for testing the quality of vaccines against new infectious diseases; the researches also included the development of reference standards for clinical evaluation and testing methods. In 2017, MFDS developed testing methods for vaccines against MERS, ZIKA, and CHIKUN GUNYA and also a method to test the immuno-adjuvant

to be used for MERS vaccine. It conducted research and development of testing methods for quality evaluation of vaccines against diphtheria, tetanus toxoid titer to ensure self-sufficiency in major domestic vaccines. It also performed research and development of immunogenicity testing methods and standard serum for vaccines against HPV (Human Papilloma Virus), B-type streptococci, meningococcus, herpes zoster, and pertussis to develop immunogenicity assays and standard serum panels for each vaccine. It also developed and proposed "Guidelines (proposal) for the Approval of Vaccines through Benefit-risk Evaluation" to advance the vaccine licensing policy.

In 2018, MFDS plans to develop standard antigens and antibodies for vaccines against infectious diseases such as dengue that occur domestically, and carry out research on the development of testing methods for antibody titer. For supporting self-sufficiency in major domestic vaccines, MFDS plans to develop testing methods and relevant standard materials for BCG (Bacille de Calmette-Guerin), aquarium, rota, and protein tyrosine tympanic vaccine antibody titers. Further, MFDS is currently engaged in a project called "Research Study on the Surrogate Markers for Vaccine Efficacy Evaluation" to support a licensing policy for vaccines.

MFDS will carry out research to develop technologies for evaluating allergic reactions to vaccines. Another MFDS project titled "Trans-government R&D of Infectious Disease Related to the Prevention of Epidemics", a joint project led by multi-government departments, is focused on quality evaluation on vaccines used for prevention of epidemics in the field. It will also continue to interact with overseas organizations such as WHO, NIID (National Institute of Infectious Disease), etc. and perform joint research on vaccines against new infectious diseases.

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4. Research on Management of Biopharmaceutical Safety

MFDS developed 25 quality and safety evaluation technologies for innovative antibody medicines, immune cell therapies for gene transfer, and stem cell therapies; these technologies will be utilized towards building a preemptive regulatory basis for the safe supply of new bio-pharmaceuticals applying innovative technologies. Furthermore, the agency strengthened the reliability of the advanced biopharmaceutical testing and inspection capabilities it owns

by obtaining the ISO 17025 accreditation for testing items in the advanced biopharmaceutical field. Based on the mid and long-term roadmap for advancing biopharmaceuticals in the Korean Pharmacopoeia, MFDS prepared two proposals for the registration of the Korean Pharmacopoeia including flow cytometry method, etc. to advance the standards and specifications for biopharmaceuticals. In addition, MFDS ensured the quality of domestically distributed biopharmaceuticals through quick and accurate collection and inspection of 18 genetically modified medicines including antibody medicines, etc.

As part of efforts to enhance the quality analysis capabilities of the domestic biopharmaceutical industry and to support its commercialization, MFDS shared the latest internal and external regulatory information and research results related to advanced biopharmaceuticals such that the information may be used as basic data for product development and quality control. Typical examples include 「Collections of Quality Test for Antibody Drugs」, 「The 2016 Report on the Development of Stem Cell Therapy and Regulatory Trends」, and 「The 2016 Report on the Development of CRISPER and Regulatory Trends」. In addition, MFDS held a "Workshop on the Development of Advanced Biopharmaceuticals and Its Analysis Techniques" for domestic biopharmaceutical developers to provide the latest analysis techniques and trends as well as relevant practical training. MFDS also built networks of experts from industry-academia-institutes and discussed the direction for mid and long-term implementation of regulatory science research through the "Science Forum for Biopharmaceutical Regulatory."

Ahn Chi-Young, Advanced Therapy Products Research Division
☎ 043.719.4751

5. Research on Safety Management of Chinese Medicine

To strengthen the full cycle of quality and safety management ranging from raw materials to finished products of Chinese (herbal) medicines, MFDS carried out various activities including developing a technology for distinguishing counterfeit Chinese(herbal) medicines. Initiatives were also taken towards developing international standards and standardized quality of Chinese(herbal) medicines, responding to the Nagoya Protocol, managing herbal medicine resources, and establishing a customized Chinese(herbal) medicine policy.

To improve the quality of Chinese herbal medicines and ensure pre- and post- safety management, MFDS conducted cross-validation of imported Chinese herbal medicines at the

stage of customs, checked the quality of distributed Chinese herbal medicines, and carried out benzopyran test and risk assessment of raw materials of natural medicines and medicinal products. For preemptive safety management, it also developed advanced analysis methods such as DNA barcodes and chemical profiles for a total of 39 cases(until 2017) including Chinese herbal medicines that cannot be verified with sensory test(Cynanchum Wilfordii and Cynachum Auriculatum) or come with similar names leading to confusion (Zizyphus Spinosi and Ziziphus Mauritian). It made posters of "Tips for Distinguishing Confusing Chinese Herbal Medicines" that can be used on the file when conducting a sensory test of imported and distributed herbal medicines, and distributed these posters to related associations, inspection agencies, etc. Based on accumulated know-how in the quality control of Chinese (herbal) medicines, MFDS also signed an ODA agreement with WHO WPRO and offered three- month training programs for civil servants from Mongol. Moreover, MFDS held two international meetings to establish a database for quick sharing of information on counterfeit pharmaceuticals at the Forum for the Harmonization of Herbal Medicine (FHH). It also continues to participate in the general meeting of ISO/TC249 (Hong Kong, June) and the Committee of Chinese Herbal Medicine Experts in order to lead the international initiative for standardization of Chinese herbal medicines (ISO/TC249). Further, MFDS established a comprehensive response system for identifying projects led by Korea and preparing a roadmap for project development.

MFDS held a multi-ministerial workshop (Jeju in June of 2017) and consultative meetings for experts (four times in 2017), and established measures such as response to the Nagoya Protocol through the cooperation of each ministry and long-term projects in order to preserve and utilize national herbal medicine resources. It opened the "Okcheon National Herbal Medicine Resource Management Center" to actively proceed with the preservation, management, and researches of temperate herbal medicines. MFDS also conducted a feasibility study and secured economic validity, basic plan, and implementation budget for establishing the "Jeju National Herbal Medicine Resource Center," thereby establishing the basis for the conservation, management, and research of (sub) tropical herbal medicines.

In order to improve users' accessibility and the utilization of information and policy provided for the management of Chinese(herbal) medicines' safety, MFDS newly established a database for Chinese(herbal) medicines titled the Comprehensive Herbal Medicine Information System within the MFDS website. It also included Chinese-based terminology along with the Korean version as well as information such as the efficacy and effect in the database, ensuring that people can easily understand the terminology.

In 2018, MFDS will continue to prepare a classification method that synthesizes and applies research techniques such as morphology, chemical profiles, DNA barcodes, etc. for Chinese herbal medicines in order to prevent forgery and falsification. It also plans to develop and share contents for each class to provide relevant information for the safe use of Chinese herbal medicines. It will launch a new project to lead the international standardization of Korean oriental medicines (ISO/TC249) and has already established the foundation for expanding the National Herbal Medicine Resource Management Center, thereby leading the efforts to develop international quality and safety standards for Chinese (herbal) medicines.

Lee Hyo-Min, Herbal Medicine Research
☎ 043.719.4801

6. Research on Safety Management of Cosmetics and Quasi-Drugs

Cosmetics and quasi-drugs are frequently used in everyday life. As Korean people are taking greater interests in products that do not contain hazardous substances, it has become more important than ever to reinforce product safety management. In general, cosmetics and quasi-drugs are distributed after obtaining permission for safety and efficacy before the sale. MFDS also introduced a human health risk assessment to evaluate the level of human health risk concerns and to suggest the safety level regarding raw materials that come with restrictions for use in cosmetics and quasi-drugs; substances other than standards and specifications; and substances generated during manufacturing, processing, and distribution. Many cosmetics and quasi-drugs, widely used by entire age groups ranging from children to the elderly, are everyday chemical products applied directly to the human body. In this regard, scientific research is needed to propose human health risk levels and safety standards for solving safety blind spots and preventing ingestion of harmful substances.

In order to support safety management policies for cosmetics and quasi-drugs, MFDS conducted a human health risk assessment on safety concerns involving cosmetics and quasi-drugs. Based on the results, it provided information on the impact on human health and proposed safety standards for relieving consumer anxiety. MFDS analyzed the maximum contents of 84 volatile organic compounds including chlorobenzene contained in sanitary pads and panty liners on the market and published the total risk assessment results, thereby resolving anxiety about women's specialty items. For instance, Nickel is a prohibited substance based

on the safety standards for cosmetic ingredients with limits of use and unintentional pollutants, where the permissible limit by product type is below 10 ~ 35 ㎍/g. Four types of substances such as Etidronic Acid, which has limits of use, were newly added to the compilation of standards. Based on these additions, 「Regulation on Safety Standards, etc. of Cosmetics」 was revised on December 8, 2017.

MFDS conducted a "Broadcasting Interview for Empathy with Policies" based on the results of the survey on the usage of Korean cosmetics to strengthen the basis for cosmetics risk assessment and management. It also distributed promotional booklets on the fine dust cutoff masks to promote the safe use of quasi-drugs. It continues to develop testing methods and publish relevant sourcebooks in order to prepare a rapid testing and inspection system for harmful and prohibited substances in distributed products. MFDS will continuously carry out development and monitoring of guidelines for efficacy evaluation of cosmetics and quasi-drugs and methods for testing of harmful substances. MFDS will also conduct researches to establish the basis for a safety assessment and examination system by means such as development of technologies for assessment of human health risk from hazardous substances.

Son Kyeong-Hun, Cosmetics Research Team
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7. Research on Management of Medical Devices Safety

As the 4th Industrial Revolution has turned into a hot topic of discussion in our society, the development of preliminary evaluation technology is urgently needed for the rapid commercialization, the next-generation convergence, and integration of medical devices. This is crucial to pre-occupy the global market of medical devices to which related new technologies are continuously being applied. It is essential to prepare a globally harmonized policy to quickly respond to changes in regulations according to changes in international safety management standards required for the entire cycle of medical devices ranging from development to commercialization and post-marketing. MFDS developed ways to build a database for the UDI (Unique Device Identification) of medical devices globally harmonized with major countries such as U.S., Europe, Japan, etc. and established methods to utilize the database in Korea efficiently, thereby facilitating Korea's entry into domestic and overseas markets. It conducted a preliminary policy support study for the prevention of false and exaggerative advertisement

for smart media-based medical devices and prepared efficient management measures. In addition, it made efforts to create a safe distribution environment for medical devices by developing guidelines for efficient monitoring through a consumer watchdog system.

In 2017, MFDS joined the International Medical Device Regulators' Forum (IMDRF) to identify worldwide medical device regulatory trends and reflect them to the regulatory system, thereby promoting medical device companies' entry into overseas markets. It established globally-aligned standards and specifications for consistent and scientific evaluation of medical devices through the entire cycle ranging from design, development, production, and distribution to post-marketing. MFDS also prepared globally harmonized safety evaluation measures such as the enactment and revision of reference standards and the development of guidelines for safer and faster monitoring and evaluation.

The electronic medical devices were globally harmonized through the application of the revised international standard IEC 60601-1(Version 3.1). In this regard, MFDS prepared safety evaluation guidelines based on the latest standards and thereby established the basis for strengthening the global competitiveness of domestic medical device manufacturers. As the Korean government expands its support for convergence and integration of medical devices in response to the new paradigm presented by the 4th Industrial Revolution, MFDS plans to prepare policies and systems to facilitate commercialization of R&D to secure the safety of medical devices. The ministry also plans to revitalize the medical device industry by promoting product commercialization through rapid licensing.

Kim Mi-Jung, Medical Device Research Division
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Section 4

Development of Safety Evaluation Technologies for Food and Drugs

1. Government Control of Toxic Substances and International Cooperation in Toxicity Testing Methods

Since the 2015 incident involving Cynanchum Auriculatum, a kind of Cynanchum Wilfordii, the safety of raw materials used in food and medicine has become a hotly debated issue. In view of recent incidents involving detection of pesticides in eggs and VOCs in sanitary pads, the need for preventive research has grown. In addition, after the humidifier disinfectant-related accident, anxiety over household chemical products and substances that come into direct contact with the human body is spreading. Therefore, it is necessary to provide toxicity test data and toxicity information based on reliable methods, and strengthen preemptive safety management in order to reassure the public about food and drug safety-related social issues.

MFDS conducted a toxicity test for Cynanchum Wilfordii and Cynanchum Auriculatum in order to relieve public anxiety over the Cynanchum Wilfordii accident that occurred in 2015 and to secure the safety of health functional food. It has also continuously carried out toxicity tests for ingredients used in food and pharmaceuticals. MFDS has also been operating Tox-info, a system to provide toxicity information to the public. MFDS collects additional toxicity information on chemical substances related to food and pharmaceuticals every year, and 2,187 pieces of information on toxicity and 570 on addition have been collected and provided to public and emergency medical workers so far. In March 2017, MFDS (through National Institute of Food and Drug Safety Evaluation) signed an MOU with the US National Institute of Environmental Health Sciences (NIEHS) for cooperation in the national toxic substance management projects.

In 2018, MFDS plans to expand the test subjects to hygiene products including sterilizer preservatives in order to carry out governmental tasks (No.57-4. Strengthening Integrated Risk and Safety Evaluation of Substances and Products Hazardous to Human Health).

Lee Jong-Kwon, Toxicological Research Division
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2. Development of Alternatives to Animal Testing and the Advancement of Non-Clinical Trials

There is a growing need to develop alternative test methods to safely assess 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 2017 with the goal of prohibit 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 the European Union Reference Laboratory for Alternatives to Animal Testing (EURL ECVAM), the Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM), the Japanese Center for the Validation of Alternative Methods (JaCVAM), and Health Canada in 2011 to join the International Cooperation on Alternative Test Methods(ICATM). In 2017, the MFDS worked on the development of alternative test methods such as an "*in vitro* inhalation toxicity test" and a "skin sensitization test using human keratinocytes" and conducted validation studies on the "developmental toxicity test using embryonic stem cells". In addition, it has recently submitted a Standard Project Submission Form (SPSF) for the "eye irritation tests using the Reconstructed human Cornea-like Epithelium (RhCE) model" to the OECD guidelines after completing a validation study on the assay. A draft Test Guideline on the "Local Lymph Node Assay Using Flow Cytometry (LLNA: BrdU-FCM)", which was already included in the OECD work plan, is likely to be finally approved by the OECD in 2018. It has also been committed towards establishing test guidelines in the "Short Time Exposure Test" and the "*In Vitro* Skin Sensitization Test (h-CLAT)". The MFDS will constantly develop test guidelines 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 the OECD Good Laboratory Practice (GLP) principles. The MFDS has provided non-clinical expert training programs for new drug developers and non-clinical workers since 2008. In 2017, it held a total of 7 workshops including the "Educational Program for Developing Expertise in Non-clinical Studies" and the "Educational Program for Connection from Non-clinical to Clinical Studies". The "introductory training on GLP for medical devices" was offered in those programs as part of GLP regulations that are applied to medical device studies. The MFDS will remain committed to strengthening the foundation for non-clinical trials.

Park Ki-Sook, Toxicological Screening and Testing Division
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3. Research on Predictability of Drugs Safety and Assessment of Pharmaceutical Dependence

MFDS has been conducting researches to develop interaction evaluation tests for combined use of food and pharmaceuticals and to evaluate the impact of health functional foods as they change the intestinal microorganisms and thereby the metabolism of medicines. In the field of narcotics-related business, scientific test researches have been conducted by establishing a regular evaluation system for temporary drugs; operating a supply system for standard substances; and developing rapid predictive evaluation technologies for new drugs for the improvement of domestic drugs. These measures of scientific technology support will contribute towards organizing the domestic narcotics system and provide scientific technology support. MFDS is strengthening the collaboration system with relevant institutions by participating in international drug conferences and sharing information on new domestic and foreign drugs through the Association for Narcotics-related Scientific Information.

Seo Soo-Kyeong, Pharmacological Research Division
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4. Securing Public Safety through Advancement of Clinical Evaluation and Reduction of Side Effects

With the emergence of the 4th Industrial Revolution era, more efforts have been put into creating a patient-oriented customized medical environment in the pharmaceutical industry. Therefore, it is imperative to create a safe environment for proper use of medicines. Domestically, it has become more important to manage side effects due to the increase in chronic diseases and changes in characteristics of diseases as the society ages. Therefore, it is necessary to reinforce the safe use of medicines and form consensus on scientific safety management through prediction of drug side effects and patient-oriented evaluation of pharmaceutical side effects. To this end, MFDS has put efforts to establish the foundations for policies through the verification of safety and efficacy of unlicensed drugs for managing the safety of medical products for vulnerable groups, and provision of a data sheet for the safety assessment and management of medicines for pregnant women.

For stabilization of the system to protect those subject to clinical trials, MFDS also produced and released promotional video clips and SOP for each department regarding the Human Research Protection Program (HRPP). MFDS has strengthened the cooperative network between industry, academia, the research community, and the public by holding a bio-imaging symposium to develop advanced pharmaceutical evaluation technologies. Following revision of the ICH E18 Guideline, amendments (draft) on the Korean-style guideline regarding genome sample collection and management of material for clinical research were also prepared. Along with that, by establishing a metoprolol group pharmacokinetics model, MFDS provided information on the safety of pharmaceuticals and acquired intellectual property rights (registered 6 patents) on a genotype-based technique for prediction of drug reaction among Koreans, in an effort to prepare a precise medical infrastructure.

Based on this, MFDS wants to create an environment where people can predict the safety and effect of customized pharmaceuticals by 1) developing standard tools to measure PRO (Patient-Related Outcomes) in order to provide patient-centered customized medical services, and expanding system infrastructure through GCP revisions (draft) 2) reinforcing scientific infrastructure support for the safe use of pharmaceuticals based on regulatory science by setting the proper dose based on metoprolol exposure-reaction model according to drug genotype; analyzing the drug reaction of Zolpidem (sleep inducer) according to gender and securing pharmacokinetcs information; verifying clinical information and securing contents in order to provide pharmacogenetics information through the next-generation drug integrated information system, and 3) securing scientific evaluation technologies for medical devices that use new technologies through the autophagy image analysis for customized clinical evaluation of medical devices and the development of in-silico model for simulation of drug reaction.

Oh Woo-Yong, Clinical Research Division(acting manager)
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5. Blocking Illicit Food and Drugs through an Advanced Analysis System

The Advanced Analysis Team of MFDS has developed and inspected testing methods to promptly and effectively prevent illegal manufacturing of food and pharmaceuticals. In 2017, MFDS presented analysis results on 655 samples upon the request of relevant departments including the Criminal Investigation Office of MFDS, Korea Customs Service, and Public Prosecutors' Office. MFDS investigated Desmethylpiperazinyl propoxysildenafil and disulfonylchlorosildenafil, the new analogue of erectile dysfunction drug, and Triaminodil, the analogue of minoxidil hair regrowth solutions, and published 12 papers in renowned foreign scientific journals (SCI, Science Citation Index). In addition, in order to ensure the reliability of test results, MFDS acquired ISO / IEC 17025 from Korea Laboratory Accreditation Scheme (KOLAS) and applied the certification to 12 items.

In order to establish the domestic infrastructure for the measurement and disclosure of tobacco ingredients in accordance with the Framework Convention on Tobacco Control (FCTC), MFDS prepared a test method for identifying the harmful components of tobacco (including electronic cigarettes). In April 2017, MFDS disclosed 45 harmful components from 5 cigarette brands in the domestic market and published information on ingredient contents of 7 components from 35 E-Cigarette liquids based on the public's right to know. MFDS participates in the international ACS on harmful components in tobacco and joins TobLabNet activities as an analytical member, thereby enhancing its ability to analyze tobacco components.

Kang Ho-Il, Advanced Analysis Team
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6. Advancement of Development, Preservation, and Utilization of Laboratory Animal Resources

Laboratory animals are essential bio resources for development and evaluation of food and drugs' safety and efficacy. However, laboratory animals and disease models used in Korea depend entirely on foreign countries. Since biological samples such as organs and tissue of the laboratory animals can be utilized as a research resource, it is necessary to establish a system to share them. In 2017, MFDS acquired two species of Korean strain laboratory animals

(BALB/cKorl, DBA2/Korl), and developed 14 disease model animal resources including those for cancer, metabolic disease, circulatory disease, and immunodeficiency through the 「Center for Mouse Models of Human Diseases」. In addition, MFDS completed construction of the "Laboratory Animal Resource Bank", an infrastructure for securing and utilizing laboratory animal resources, in Daegu-Gyeongbuk Medical Cluster, and enacted the "Regulation on the Operation·Management of Laboratory Animal Resource Bank". Future studies will further develop 3 species of model animals with immunodeficiency, and analyze and provide the scientific traits of Korean laboratory animal resources, Korl: ICR and C57BL/6NKorl to the researchers in Korea. Moreover, MFDS intends to collect useful biological samples of laboratory animals through the Laboratory Animal Resource Bank and distribute them to researchers, thereby establishing a sharing system.

Chung Seung-Tae, Laboratory Animal Resources Division
☎ 043.719.5501

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

Korea has implemented the National Lot Release System that examines the quality of biological products such as vaccines and blood products one more time under the responsibility of the National Institute of Food and Drug Safety Evaluation governed by MFDS.

As of Dec. 31, 2017, a total of 218 products are subject to national lot release. A total of 2,467 lots were approved for shipment in 2017, which accounts for 92 additional lots compared to the last year (See table 5-2-1). It is expected that applications for shipment approval will steadily increase based on the increase in the share of domestically manufactured vaccines and the expansion of production facilities for blood products.

[Table 5-2-1] National Lot Release Statistics in the Last 7 Years

(As of Dec. 31, 2017, Unit: lot, Ref. 2017 Annual Report on National Lot Releases)

Category \ Year	2011	2012	2013	2014	2015	2016	2017
Vaccine products	941	900	995	922	856	885	919
Botulinum products	92	152	242	471	536	597	521
Blood products	739	955	1,018	976	942	893	1,027
Total	1,772	2,007	2,255	2,369	2,334	2,375	2,467

MFDS has been operating the 'Biological Drug Delivery System' based on hazard analysis since April 1, 2016. MFDS will set the risk stage for 218 items in 2017, conduct a certification test and review manufacturing and quality control data according to the risk stages.

In order to improve the clarity and efficiency of the national shipping approval procedure, MFDS is in the process of revising the National Shipping Approval Manual. Starting from 2015, MFDS established and revised 10 business manuals by 2017. It also enacted 93 checklists for manufacturing and quality control summary review items to improve the consistency of reviewing data and standardize the review process. From 2015 to 2017, MFDS enacted and

revised 128 test records of full life-cycle test procedures including materials, equipment, and processes at the applicable laboratories. In 2018, MFDS will establish a mid-term roadmap and yearly action plans for the National Lot Release System while organizing the NLRS quality assurance system through test reports and test records.

2. Strengthening Cooperation and Communication through the Operation of a Public-Private Consultative Group

MFDS has formed a Public-Private consultation body to promote quality control efficiency and international harmony through exchange of information and technologies exchange between laboratories. As of now, there are 14 manufacturers and 2 quality inspection agencies participating in the 「Vaccine Quality Control Laboratory Network (Lab-Net)」. In 2017, MFDS carried out a joint research on 3 topics related to the establishment of national reference products. Through these activities, MFDS has established national reference products and upgraded its proficiency in protein content tests. MFDS also held a workshop on the 「2017 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 the establishment and domestic standardization of thrombogenic test methods for immunoglobulin products and the inspection of proficiency between institutions on the human antithrombin potency assay. MFDS also carried out 4 site visits for manufacturers and importers.

In 2018, MFDS will continue its communicative and cooperative activities by producing and establishing national reference products, conducting training for quality control testers, operating proficiency programs, and visiting manufacturers' sites through public-private consultations, with manufacturers, quality inspection agencies, and blood centers.

3. International Cooperation Activities

In order to strengthen capabilities for the safety management of biological products and discuss and exchange information on regulatory issues, MFDS is carrying out various cooperative tasks with foreign national regulatory authorities including the World Health Organization

(WHO), the European Directorate for the Quality of Medicines and Healthcare (EDQM), Germany's Paul Ehrlich Institute (PEI), Japan's National Institute of Medical Sciences Infectious Diseases (NIID), and National Regulatory Labs of the Western Pacific.

Since 2006, MFDS has signed a contract to carry out the WHO's Technical Service Agreement (TSA) and has accordingly been tested for the WHO delivery vaccine. In 2016, MFDS signed an additional contract test for 2 lots of Japanese encephalitis live vaccines, 10 lots of BCG vaccines and 10 lots of pertussis vaccine for two years to be completed by the end of 2017. MFDS implemented potency assays and heat stability tests for 22 lots of vaccines including BCG vaccines under the contract and the results were sent to the World Health Organization to carry out the fiduciary testing work.

Designated in 2011 as a cooperation center in the field of standardization under the auspices of the World Health Organization, MFDS has been carrying out various cooperation activities. The 'Hands-on Training', which was operated as a vaccine quality management education over the last four years from 2012 to 2015, was officially designated as the 'Global Learning Opportunities for Vaccine Quality (GLO / VQ)' in 2016. Following the first training program held in 2016, MFDS implemented the 2nd WHO GLO/VQ training for 10 days from Aug. 30 to Sep. 8, 2017. A total of 48 officials in charge of vaccine quality control from 17 countries in Asia, Middle East, and Africa attended the training.

In addition, the "Western Pacific Lab-Net International Workshop" was held for 2 days from September 20 to 21, 2017 in order to strengthen the cooperation between national regulation laboratories in the Western Pacific region. Quality control experts from Canada, Britain, China, Japan, Vietnam, Malaysia, and Philippines, and WHO Regional Office of the World Health Organization participated

In the international joint research activities for the sharing of the national lot release system and quality control studies of vaccines and blood products by invitation. The participating experts presented and discussed researches on blood coagulation activation of immunoglobulin products, tests for freedom from aggregated immunoglobulin and the establishment of reference products of antitoxin for Mamushi.

MFDS participated in 3 international collaborative studies organized by Britain's National Institute for Biological Standards and Control (NIBSC) to establish the National Reference Standards for Polysaccharide Content Test for Meningococcal Vaccines, the 2nd potency assay on blood coagulation V, and the 3rd activation measurement test for prekallikrein activators.

The major international cooperation activities planned in 2018 include operation of the World Health Organization's International Training Center for National Shipment Approval/Examination for 10 days (in October) for developing countries around the world. Further, starting 2018, the 3rd Western Pacific Lab-Net International Workshop will be held with the Global Bio Conference (GBC). In addition, WHO will conclude new contracts for products and test items for commissioned tests. MFDS will send the final results of the 2nd potency assay on blood coagulation V and the 3rd activation measurement test for Prekallikrein activator to National Institute for Biological Standards and Control and will actively participate in any additional international collaborative research projects.

4. Strengthening the Quality Management Function in National Testing and Operation of the Proficiency Program

In order to ensure 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 testing capabilities, MFDS continuously participates in international proficiency programs and operates a domestic proficiency program to check the quality control of domestic manufacturers.

MFDS is operating 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 2017, it received internal evaluation and external update evaluation and approval for the maintenance of accreditation as an international testing institute. In addition, MFDS took part in the International Proficiency Program organized by the National Institute for Biological Standards and Control and the European Directorate for the Quality of Medicines & Healthcare (EDQM), and received accreditation for its quality inspection capability at the international level regarding hemagglutinin content test for influenza vaccines and activation measurement test for Prekallikrein activators. MFDS also came up with 2 domestic proficiency programs including protein content test in order to identify the testing ability of testing agencies and secure trust in those tests.

MFDS will continue to engage internationally accredited testing institutes (ISO/IEC 17025) for testing personnel for shipment approval, and carry out training for new/existing members,

internal auditors, and evaluators. In 2018, MFDS will receive additional approval for 10 test items such as the human antithrombin potency assay from ISO. In 2018, MFDS plans to participate in the international proficiency program hosted by European Directorate for the Quality of Medicines & Healthcare for potency tests on vaccines for measles, mumps, and rubella, as well as the polysaccharide content test for protein conjugated hemophilus influenza vaccines organized by the World Health Organization. It also plans to perform endotoxin test as a domestic proficiency test. The Ministry of Food and Drug Safety will further develop its international testing and analysis capabilities in the vaccine and blood products sector as a reliable test analysis and research facility.

Ban Sang-Ja, Vaccines Division
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Kang Ju-Hye, Blood Products Division
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VI

Appendix

1. Ministers/Commissioners/Vice Ministers in MFDS

1) Ministers

Name	Terms of Office
Ryu Young Jin	2017. 7.12. ~
Sohn Mun Gi	2016. 3.28. ~ 2017. 7.11.
Kim Seung Hee	2015. 4. 7. ~ 2016. 3.12.
Jeong Seung	2013. 3.23. ~ 2015. 3.12.

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
Choi Sung Rak	2017. 8.20. ~
Yoo Moo Young	2016. 5.11. ~ 2017. 8. 6.
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.
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.

2. Changes in the Number of Staff

<table>
<tr><td>Mar. 30, 2018</td><td>○ Reflected the required number of personnel for 2018 (61 personnel)
– 1 Inspection Center established (Gimpo Imported Food Inspection Center)
– Added 61 personnel (five class-4 officers, six class-4 officers, seven class-9 officers, eight class-10 officers, nine class-10 officers, one senior officer, and 23 researchers)
* Deal with safety management for sanitary goods (11 personnel), Strengthen imported food safety management (1 personnel), Supply national essential drugs (1 personnel), Strengthen safety management of cosmetics (2 personnel), Enhance life-cycle safety management for medical devices (1 personnel), Operate Laboratory Animal Resources Bank (2 personnel), Information Security and Control Center (3 personnel), Imported food inspection (40 personnel)
○ Reshuffle of personnel in 2018: ±10 personnel
– (Interregional, 5 staff) Medicine Inspection Center → Gimpo Inspection Center(six class-1 officer, seven class-2 officers, eight class-2 officers)
– (Intra-organizational transfer, 5 personnel) Division of Imported Food Inspection Management → Inspection Center Busan2, Gyeongin3</td></tr>
<tr><td>Jan. 1, 2018</td><td>○ Deployed 8 personnel for the operation of the Total Labor Cost System (six -class)
* Customer Risk Prevention Policy Division (+1), Communication and Cooperation Division (+1), Food Safety Policy Division(+1), On-site Inspection Division(+4), Dietary and Nutritional Safety Policy Division(+1)</td></tr>
<tr><td>Sep. 28, 2017</td><td>○ Changed name of position: Organization and Management Innovation Office → Innovative Administration Office
○ Added 1 personnel to the employment quota of term-based public officers
* (Current) 1 personnel for promotion → (Amended) 1 personnel for promotion and 1 person for international cooperation</td></tr>
<tr><td>May. 26, 2017</td><td>○ Merged the temporary Pharmaceutical Safety Evaluation Division into the regular organization
– The result of the Ministry of the Interior and Safety's performance evaluation on the Pharmaceutical Safety Evaluation Division, which was established temporarily until May 31, 2017, was reflected in the organization
* Three temporary positions (four class-1 officers, five class-1 officers, six class-1 officers) were turned to regular positions.</td></tr>
<tr><td>Mar. 21, 2017</td><td>○ Reshuffle of bureaus and divisions related to food
– Reshuffled relevant bureaus and divisions to strengthen safety management of imported food and to ensure efficiency of food safety management
* Reshuffled the Food Nutrition and Dietary Safety Bureau to Food and Consumer Safety Bureau
* Reshuffled the Agro-Livestock and Fishery Products Safety Bureau to Imported Food Safety Policy Bureau
<table><tr><th rowspan="2">Classification</th><th colspan="2">Major Reshuffles</th></tr><tr><th>Bureau</th><th>Division</th></tr><tr><td>Food Safety Policy Bureau</td><td>Food Safety Policy Bureau</td><td>· 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)</td></tr></table></td></tr>
</table>

<table>
<tr><td></td><td>
<table>
<tr><th rowspan="2">Classification</th><th colspan="2">Major Reshuffles</th></tr>
<tr><th>Bureau</th><th>Division</th></tr>
<tr><td></td><td></td><td>· Health Functional Food Policy Division (transffered from Food Nutrition and Dietary Safety Bureau)
· Livestock Products Standard Division → Residues and Contaminants Standard Division (changed name)</td></tr>
<tr><td>Food Nutrition and Dietary Safety Bureau</td><td>Food and Consumer Safety Bureau</td><td>· 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, (transferred 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)</td></tr>
<tr><td>Agro-Livestock and Fishery Products Safety Bureau</td><td>Imported Food Safety Policy Bureau</td><td>· Imported Food Policy Division (transferred from Food Safety Policy Bureau)
· Foreign Inspection Division → On-site Inspection Division (changed name)
· Imported Food Inspection Management Division, Imported Food Distribution Safety Division (reshuffled via merger of divisions)</td></tr>
</table>
○ Established R&D policy capabilities on food and drugs. adjusted the number of officers
– One 5th class officer was transferred from Research Planning Management Division to Customer Risk Prevention Bureau
○ Strengthened food microbiology risk analysis capabilities
– Four researchers were transferred from the HQ to Food Microbiology Division
○ Adjustments in Director General level open position system
– Designated Director General of Food and consumer Safety Bureau as an open position system and Director General of Food Nutrition and Dietary Safety Bureau was excluded after the reshuffle.</td></tr>
<tr><td>Feb. 28, 2017</td><td>– Reflected the required number of personnel for 2017 (38 personnel)
• Three divisions were established (Alcoholic Beverages Safety Policy Division, narcotics Management Division, Biopharmaceuticals Review Management Division)
• 38 personnel added: (one class-4 officer, four class-5 officers, eleven class-6 officers, nine class-7 officers, two senior officers and eleven researchers)
* Expand the scope of responsibility of special judicial police (3 personnel), expand food traceability system gradually (2 personnel), strengthen imported food safety management (4 persons), strengthen safety management of alcoholic beverages (1 personnel), implement restaurant sanitation grade system (1 personnel), strengthen safety management of livestock-fishery products (2 personnel), drug approval update, etc. (5 personnel), narcotics management division (6 personnel), strengthen the system for approval of health functional foods (2 personnel), biopharmaceutical review management division (9 personnel), strengthen international cooperation (2 personnel), document controller (2 personnel)</td></tr>
</table>

<table>
<tr><td>Jan. 26, 2017</td><td>- 15 personnel reduced: (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 two 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 personnel)
- One division established (Integrated Food Information Service Division)〈April.26, 2018 temporarily〉
- Added 12 personnel
* HQ: Integrated Food Information Service Division(2personnel), Cyber security(1person), Strengthening safety management of imported food (2personnel), Safety and traceability of drug(1personnel), Traceability of medical devices (1personnel)
* NIFDS: R&D management (1personnel), Biosimilar approval process (1personnel)
* Regional FDA: Food traceability (1personnel), Archives management (2personnel)</td></tr>
<tr><td>Feb. 5, 2016</td><td>- Adjustment in positions in 2016: ±15 personnel (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 personnel (5 personnel from the Headquarters, 3 personnel from the National Institute of Food and Drug Safety Evaluation, 8 personnel 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 was newly designated as an open position.
Post of Director General of Medical Device Evaluation Department is no longer subject to open position</td></tr>
<tr><td>Dec. 4, 2015.</td><td>- Increased the number of personnel for cyber security: 1 personnel (Headquarters)
- Import Food Analysis Division in Gwangju Regional Office of Food and Drug Safety done away with (△ 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)</td></tr>
<tr><td>May 29, 2015</td><td>- Reflected the required number for 2015 (14 personnel)
• Newly established 1 division (Pharmaceutical Safety Evaluation Division) 〈17.5.31.temporarily〉
• Added 14 personnel
* HQ: Food Radiation (2personnel), Archives/Personal Information(1personnel)
* NIFDS: Food Radiation (1personnel)
* Regional FDA: Pharmaceutical Safety Evaluation Division (3personnel), human tissue (2 personnel), Integrated network (1personnel), Food Traceability (2personnel), Archives/ Personal Information (2personnel)
• Adjusted ranks : ±22 personnel (class 3·4 -2, class 4·5 -5, class 5-15)</td></tr>
</table>

	- 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 → The 2nd affiliated agency
Jan. 9, 2015	- Reflected organization diagnosis of 2014 : +9 personnel (class 5 -2, class 6- 3, class 7- 3, class 8 -1) • HQ : △ 21 personnel * (Transfer·abolition) Health Functional Food Standard Division terminated, New Material Food Division → transferred to NIFDS, abolished the Medical Device Quality Division, (created) Health Functional Food Policy Division, Medical Device Safety Evaluation Division • NIFDS : +14 personnel * (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 personnel * (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 personnel (HQ 5, NIFDS 4, Regional FDA 7)
Aug. 27, 2014	- Reflected required number for 2014 (12 personnel) • 1 division established (Quasi-drug Policy Division) • 12 personnel added * Safety management of quasi-drugs reinforced (3 personnel HQ, 1 personnel NIFDS), test inspection quality management reinforced (2 personnel), the Integrated Food Safety Information Network constructed and operated (3 personnel), plasma safety management reinforced (2 personnel HQ,1personnel NIFDS) - Resolved disagreement between job and ranks (1 personnel) : Public Health Operation Assistant Secretary→ Office Operation Secretary
Feb. 20, 2014	- Vice minister for special service transferred to general position according to revision of the 「National Government Organization Act(Dec. 24, 2013)」 - Adjusted number of employees to transfer the successful candidates of administration position test to other job types (3 personnel)
Dec. 18, 2013	- Adjusted the number of employees according to reorganization of job type (Dec. 12, 2013) • Technical post (94 personnel) → General post(94 personnel) • Contract posts (11 open type positions*)→ transferred to term-based public officials * Director level : Director of Food Standard Planning Office, Biopharmaceutical Inspection Office, Medical Device Inspection * Manager level : Spokesperson, managers of the 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 (2personnel)*→ general post (term-based secretary, administrative official) * Emergency and Security Office, facility· equipment class 5 - Removed 17 personnel according to operation plan for integrating the number of officials of Ministry of Public Administration and Security (June 2013)* * HQ (△6 personnel), NIFDS(△3 personnel), Regional FDA(△8 personnel)

Nov. 5, 2013.	- Established Gamcheon Port Imported Food Inspection Center to stabilize the inspection performance of Japanese imported fishery products - Adjusted disagreement between current number and prescribed number and other function posts : ±17 personnel
Oct. 4, 2013	Reflected the required number for 2013 and added personnel for the National Policy Project - Two divisions established : Alcoholic Beverages Safety Management and Planning Division (temporary), Pharmaceutical Approval and Patent Management Division - Added 15 persons • Required number for 2013 : 12 personnel • Dedicated for eradiation of adulterated food : 5 personnel • Transfer radiation safety control personnel (Radiation Safety Division) to Ministry of Welfare (△3 personnel) - Others • Adjusted open type positions (3 director level, 8 manager level) • Changed name and location of Gyeongin FDA* * Incheon Metropolitan City → Gyeonggido, Gwangyang Import Inspection Centers (Yeosu → Gwangyang)
Mar. 23, 2013	Established the Ministry of Food and Drug Safety - Transferred the food and drugs safety policy function 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 the 「National Government Organization Act (Mar. 23, 2013)」 - Personnel : 1483 personnel → 1760 personnel (+277 persons) • Transfer from Ministry of Agriculture and Forestry* : 260 persons * Livestock area (1 bureau, 8 divisions, 171 personnel), fishery area (1 bureau, 87 personnel), area of agriculture(1 personnel) • Transfer of Ministry of Welfare* : 10 personnel * Food area (1 division, 6 personnel), medicine area (2 personnel), common area(2 personnel) • Increase (+12 personnel), decrease (△5 personnel)
Nov. 18, 2012	- Established separate quota for filling up vacancy due to maternity leave for MFDS and agencies (a total of 64 personnel) - Added an open type position of bioequivalence manager - Changed the competent department of the Medical Device Inspection Division (Advanced Medical Device Division) - Established regulation for job division of imported foods of Regional FDA
July 30, 2012	- Increased personnel as necessitated by the reinforcement of safety management of raw materials and introduction of the national lot release approval system • 19 personnel (class 5-3, class 6-2, class 7-3, senior officers-3, researchers-8) - Rearranged jurisdiction of the Uiwang Inspection Center through creation of Gwangju Imported Food Inspection Center in Gyeonggin office - Terminated function class 10 according to revision of Government Officials Act • Changed 33 personnel of functional class 10→ functional class 9 in lump sum
Feb. 3, 2012	- Established the Biopharmaceutical and Medical Device Approval Inspection Division and appointed personnel • Established the Advanced Medical Device Division and Cell Gene Medicine Division

	- Discarded the Manufacturing Quality Research Team of NIFDS and established the Biopharmaceutical Quality Management Division in charge of quality management function of biopharmaceuticals - Renamed the division and reorganized a review division for each clinical trial area of medical devices • 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 the Emergency Planning Office at Director General for Planning and Coordination
Jan. 4, 2011	- Discarded the Side Effects Monitoring Team of NIFDS and established the Medicine Safety Information Team in charge of collection and evaluation of information on side effects of medicine at Administration
Apr. 30, 2009	Reorganized the organization (reduced 6 divisions with application of the project system) - Administration 1 office 5 bureaus (1team·4 bureaus) 65 divisions→ 1 office 5 bureaus (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 • Reorganized 4 evaluation bureaus to 4 inspection bureaus (Food Standards Bureau, Medicine Inspection Bureau, Biopharmaceutical Inspection Bureau, Medical Device Inspection Bureau) - National Toxicity Science Institute → National Institute of Food and Drug Safety Evaluation(3 bureaus 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 FDAs • 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 Food analysis Division • Transferred 101 personnel and added simple tasks of instruction and guidance according to plan for establishment of the Special Provincial Administrative Agency of food and Drug in cities and provinces.
Mar. 6, 2008	Reorganized to the bureau and division (office) system - Created spokesperson under administrators, and Regulatory Reform and Legal Affairs Office under 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 for Harmful Substance Management Center under the Food and Safety Bureau - Abolished Innovation Planning Office, Policy Promotion Team - Adjusted the names of some divisions creatively and transferred the team based system to division based system according to government reorganization policy

Sep. 20, 2007	- Created Performance Management Team under vice minister team, Food Poisoning Prevention Management Team under Food HQ, Medicine Quality Team and 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 a team under Pharmaceutical Research Bureau, Endocrine Disorder Substance Team under Toxicity Study Bureau to Endocrine Disorder Evaluation Team under Risk Evaluation Research Bureau, respectively
Aug. 25, 2006	- Created Inspection and Examination Management Team under the competent 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, and Medical Device Quality Team under Medical Device HQ, respectively - Abolished Inspection Management Team under the 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 high-ranking official positions (22 positions)
Jan. 24, 2006	- Established Harmful Substance Management Team under 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 • 6HQs : Policy Promotion Management HQ, Food HQ, Nutrition Function Food HQ, Medicine HQ, Biopharmaceutical HQ, Medical Device HQ • 4 evaluation bureaus : 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 divisions of 6 Regional FDAs to food safety management teams - Created 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 Office 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 teams 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, removed the Test Analysis Officer position at 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 - Transferred 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 Bioequivalence 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 Division 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 and transferred the execution tasks of Food Policy Bureau, and Medical Device Bureau of Ministry of Health and Welfare • Some tasks such as enactment and revision of laws and determination of policy remained with 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 under Ministry of Health and Welfare → Transferred safety administration to Regional FDA • Safety HQ : 2 bureaus (6 divisions) 5 offices (22 divisions) - 4 divisions of National Institute of Health (Sanitation, Chemicals, Herbal Medicine, Radiation Standard divisions) → reorganized as 5 safety evaluation divisions (Food, Food Additives, Cosmetics, Biological Products, Medical Devices) - National Institute of Health and Safety → reorganized the Toxicity Laboratory

3. 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 middle and long-term policies and plans, direct and coordinate data required by the National Assembly, organize budget, coordinate and settle execution, coordinate and direct R&D projects
	Innovative Administration Office	Manage organization and quotas, establish and inspect performance management plans, direct employment policies, improve the administration system and direct and coordinate improvement of organizational culture.
	Organization and Management Innovation Office	Manage organization and quotas, establish and inspect performance management plans, direct and coordinate improvement of government 3.0, the administration system and organizational culture
	Regulatory Reform and Legal Affairs Office	Draft and review legislation·administrative rule plan, direct regulatory reforms, support cabinet·vice-minister meetings, support legislation of National Assembly, direct administrative appeals and litigation affairs
	International Cooperation Office	Direct and coordinate international cooperation projects 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 for food and drugs; operate, maintain and repair the 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 centers
	Emergency Planning and Safety Office	Control and coordinate the overall plan and training to cope with national emergencies, manage mobilization resources for responding to emergencies (supplies, companies)
Audit and Inspection Office		Audit MFDS, its agencies and groups under MFDS, and handle audit results
Criminal Investigation Office		Investigate criminal acts involving food and drugs, identify and investigate habitual and intentional crimes related to food and drugs
Affairs Division		Documents, general affairs, personnel, use, accounting, facility work
Consumer Risk Prevention Bureau	Customer Risk Prevention Bureau	Develop consumer policies for protection of consumer rights and interests in food and drugs, develop policies for prevention of risks related to 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 on food and drugs
	Risk Information Division	Collect risk information related to food and drugs at home and abroad, construct a risk information collection and analysis system and develop techniques

Department			Main Functions
	Integrated Food Information Service Division		Establish and coordinate policies regarding utilization of food safety information among government agencies. In charge of managing and supporting the Integrated Food Safety Information Network.
	Laboratory Audit and Policy Division		Direct and coordinate system improvement, enact and revise laws and regulations related to inspection and examination of food and drugs, establish plans for enhancement of result quality and comprehensive development of inspection and examination agencies
Food Safety Policy Bureau	Food Safety Policy Division		Establish sanitation and safety management policies for utensils, containers, and packaging; food additives; health functional foods; and food. In charge of coordination for improvement of regulations.
	Food Safety Management Division		Establish a comprehensive plan regarding guidance and crackdown on operation of food business. Establish and manage a food collection and inspection plan.
	Food Safety Labelling and Certification Division		In charge of labeling standards for food, etc., and labeling and advertisement approval standards for infant/baby foods, and weight control foods; and coordinate comprehensive plan regarding HACCP; in charge of the Food Traceability System.
	Health Functional Food Policy Division		Develop policies regarding health functional foods and improve relevant regulations; establish and implement a comprehensive safety management plan; in charge of relevant regulations regarding approval and notification of health functional food businesses
	Alcoholic Beverages Safety Management and Planning Division		Establish and coordinate a comprehensive plan on policies regarding safety management of alcoholic beverages, improve and amend relevant laws and regulations, promote alcoholic beverages safety management and provide educational programs, impose administrative penalty.
	Food Standard Planning Office	Food Standard Division	Establish and execute a total plan for improving food standards and specifications
		Residues and Contaminants Standard Division	Establish and implement a comprehensive plan to improve standards and specifications on hazardous material in food.
		Food Additives Standard Division	Establish and execute a total plan for operation and establishment of standards and specifications for sterilizers and utensil disinfectants, etc., utensils, containers and package and food additives
Imported Food Safety Policy Bureau	Imported Food Policy Division		Establish a comprehensive plan for safety management of imported food and enact and amend the act with a view to improving regulations and notifications.
	On-site Inspection Division		Establish a comprehensive plan for safety management of manufacturers located in foreign countries, and conduct import sanitation assessment.

Department		Main Functions
	Imported Food Inspection Management Division	Establish and coordinate a plan for inspection of imported food. Designate products subject to inspection.
	Imported Food Distribution Safety Division	Establish a comprehensive plan for guidance and crackdown on businesses related to imported food. Establish and manage a plan for collection and inspection of imported food. etc.
Food and Consumer Safety Bureau	Nutrition Safety Policy Division	Establish and implement food nutrition safety policies and comprehensive plan. In charge of children's food safety management and matters related to nutrition and safety of children's favorite foods.
	Agro-Livestock and Fishery Products Policy Division	Manage a sanitation and safety control scheme for domestic agro-livestock and fishery products and establish countermeasures.
	Agro-Livestock and Fishery Products Safety Division	Establish and manage a safety management plan for safety research, and collection and inspection of agro-livestock and fishery products. Establish guidance and crack down plan.
	Foodborne Diseases Prevention and Surveillance Division	Establish and implement a comprehensive plan for prevention of food poisoning Operate a pan-governmental committee for responding to outbreaks of foodborne diseases Educate, promote, and evaluate measures for prevention of food poisoning.
Pharmaceutical Safety Bureau	Pharmaceutical Policy Division	Develop policy for safety management of medicine, enact and revise notice and laws on medicine, operate the medicine approval system and develop policies
	Pharmaceutical Management Division	Establish and coordinate a plan for monitoring pharmacists, operate labeling and advertisement system of medicine, designate and manage medicines likely to be abused or misused
	Narcotics Policy Division	Establish and coordinate policy development and total plan for narcotics and substance materials, enact and revise related laws and notices, establish and coordinate distribution and monitoring of the framework plan
	Narcotics Management Division	Establish and pursue a comprehensive narcotics safety management plan. In charge of the Narcotics Information Management System. Establish and coordinate a basic plan for distribution and surveillance of narcotics and raw materials of narcotics, etc.
	Pharmaceutical Quality Division	Establish a plan related to manufacturing and quality management standards of medicine, operate system, establish education plans and promote international cooperation
	Clinical Trials Management Division	Direct coordination and establishment of policies related to clinical trials, approval and management of clinical trial plans for medicine

Department		Main Functions
	Pharmaceutical Approval and Patent Management Division	Operate registration, management and related systems of medical patents, enact and revise regulations
	Pharmaceutical Safety Evaluation Division	Collect, manage and evaluate information on the side effects of medicines and quasi-drugs, operate a medicine damage relief system
Biopharmaceuticals and Herbal Medicine Bureau	Biopharmaceutical Policy Division	Establish and coordinate policies related to biological products, gene recombination medicine, gene medicine, cell medicine, tissue-engineering medicine, and human tissue and plasma safety
	Biopharmaceutical Quality Management Division	Establish manufacturing and quality management standards for biopharmaceuticals, manage and operate change, establish and coordinate plan for monitoring of human tissue transplants
	Herbal Medicine Policy	Establish and coordinate policies related to the safety of herbal medicine and medicinal herb products, enact and revise related laws and regulations.
	Cosmetics Policy Division	Establish and coordinate cosmetics related policies, enact and revise related laws and regulations, establish a total plan for cosmetics manufacturing and quality management standards
	Quasi-drug Policy Division	Establish and coordinate policies related to quasi-drugs, enact and revise related laws and regulations, establish and coordinate plan for monitoring of quasi-drugs
Medical Device Safety Bureau	Medical Device Policy Division	Establish and coordinate policies related to distribution of medical devices; operate the system for approval, classification, and designation of medical devices; and develop policy.
	Medical Device Management Division	Establish and coordinate a plan for monitoring of medical devices, establish and coordinate instruction and enforcement plan for medical device handlers, preliminary deliberations on advertisement of medical devices
	Medical Device Safety Evaluation Division	Management of side effects of medical devices, management of safety information of medical devices, re-evaluation and review of medical devices

4. Number of Staff

1) Prescribed Number

As of March 30, 2018 (Unit: persons)

Position / Agency, Division	Total	State	General Posit											Management Operation Post		
		Minister	General·Research high ranking	3·4	Class 4	4·5	Class 5	6	7	8	9	Senior officer	Researcher	7	8	9
Total	1,858	1	23	12	49	31	210	314	321	148	62	158	494	9	2	24
HQ	598	1	10	10	35	20	122	128	114	8	7	36	87	7	2	11
Agency	1,260	-	13	2	14	11	88	186	207	140	55	122	407	2	-	13
NIFDS	423	-	7	-	6	1	28	13	11	19	5	107	223	2	-	1
Regional FDA	837	-	6	2	8	10	60	173	196	121	50	15	184	-	-	12
Seoul Regional Office	127	-	1	1	1	2	9	28	31	12	7	5	25	-	-	5
Busan Regional Office	216	-	1	1	4	-	17	44	51	44	10	2	40	-	-	2
Gyeongin Regional Office	290	-	1	-	3	2	18	58	57	35	18	5	89	-	-	4
Daegu Regional Office	53	-	1	-	-	2	4	11	14	9	4	1	7	-	-	-
Gwangju Regional Office	74	-	1	-	-	2	7	14	21	11	6	1	10	-	-	1
Daejeon Regional Office	77	-	1	-	-	2	5	18	22	10	5	1	13	-	-	-

2) History of Change in Prescribed Numbers

Mar. 30, 2018 1,858 personnel (61 personnel added)

- ▸ required personnel for 2018 : 61 personnel
  - Deal with safety management of sanitary goods: 11 personnel
  - Strengthen safety management for imported foods: 1 personnel
  - Supply national essential drugs: 1 person
  - Strengthen safety management of cosmetics: 2 personnel
  - Enhance life-cycle safety management for medical devices: 1 personnel
  - Operate the Laboratory Animal Resource Bank: 2 personnel
  - Information Security and Control Center: 3 personnel
  - Imported food inspection : 40 personnel

Feb. 28, 2017 1,797 personnel (added 38 personnel)

- ▸ required manpower for 2017: 38 personnel
  - Expanded the scope of responsibility of special judicial police: 3 personnel
  - Expanded the food traceability system gradually: 2 personnel
  - Strengthened safety management of imported foods: 4 persons
  - Enhanced safety management of alcoholic beverages: ±1 personnel
  - Implement a restaurant sanitation grade system: 1 personnel
  - Strengthen safety management of livestock-fishery products: 2 personnel
  - In charge of pharmaceutical approval updates, etc.: 5 personnel
  - Enhanced the safety management of narcotics: 6 personnel
  - Enhanced the approval capability of health functional foods: 2 personnel
  - Approval and Review of Medical products: 9 personnel
  - Enhance international cooperation: 2 personnel
  - Document controller: 2 personnel

Jan. 26, 2017 1,759 personnel (removed 15 persons)

- ▸ Removed 17 personnel according to the integrated operation plan of MOPAS (13 June)
  - HQ: △5
  - NIFDS : △4
  - Regional offices : △6

May. 19, 2016 1,744 personnel (added 12 personnel])

- Required manpower for 2016: 12 personnel
- Personnel for Integrated Food Information Service Division: 2 personnel
- Personnel for cyber security: 1 personnel

- Personnel for strengthening safety management of imported foods: 2 personnel
- Personnel for safety and traceability of drug and medical device management: 2 persons
- Personal for R&D management and biosimilar approval process: 2 personnel
- Personnel for food traceability and archive management: 3 personnel

Dec. 30, 2015 1,762 personnel (reduced by 16)

- ▸ Cutback 16 positions 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 personnel (increased by 1)

- Added a new staff for cyber security (1)

May 29, 2015 1777 personnel (added 14 personnel)

- ▸ Required manpower for 2015 : 14 personnel
  - Personnel for Pharmaceutical Safety Evaluation Division : 3 personnel
  - Personnel for human tissue : 2 personnel
  - Personnel for operation of the Integrated Food Safety Information Network : 1 personnel
  - Personnel for food traceability : 2 personnel
  - Personnel for management of food radiation : 3 personnel
  - Personnel in charge of records and personal information : 3 personnel

Jan. 9, 2015 1763 personnel (removed 7 positions)

- ▸ Frequent position of 2014 : 9 personnel
- ▸ Removed 16 positions according to the Integrated Operation Plan of MOPAS (June 2003)
  - HQ : △5 personnel
  - NIFDS : △4 personnel
  - Regional FDA : △7 personnel

Aug. 27, 2014 1770 personnel (added 12 positions)

- ▸ required manpower for 2014 : 12 personnel
  - Personnel for quasi-drug safety management : 4 personnel
  - Personnel for test and inspection quality management : 2 personnel
  - Personnel for operation and construction of the Integrated Food Safety Information Network : 3 personnel
  - Personnel for plasma safety management : 3 personnel

Dec. 18, 2013 1758 personnel (removed 17 positions)

- ▸ Removed 17 positions according to the Integrated Operation Plan of MOPAS (June 13)
  - HQ : △6 personnel
  - NIFDS : △3 personnel
  - Regional FDA : △8 personnel

Oct. 4, 2013 1775 personnel (added 15 positions)

- ▸ Frequent position of 2013 : 6 personnel
- ▸ Additional personnel in charge of eradication of adulterated food : 5 personnel
  - Additional personnel of Government 3.0 : 1 personnel
- ▸ Required manpower for 2013 : 12 personnel
  - Personnel for management of alcoholic beverages: 2 personnel
  - Personnel for medicine approval and patents: 4 personnel
  - Personnel for follow-up management of cosmetics: 3 personnel
  - Personnel for local inspection of medical device GMP: 2 personnel
  - Personnel for protection of personal information: 1 personnel
- ▸ Transfer of radiation safety management personnel from the Ministry of Welfare: △3 personnel

Mar. 23, 2013 MFDS established, 1760 personnel (added 277 personnel)

- ▸ Personnel transferred from Ministry of Agriculture and Forestry: 260 personnel
- ▸ Personnel transferred from the Ministry of Welfare: 10 personnel
- ▸ Increased imported food inspection staff: 12 personnel
- ▸ Common division: △5 personnel

5. Laws and Regulations under the Ministry of Food and Drug Safety

Name of Law(18)	Enforcement Ordinance(20)	Enforcement Rule (Ordinance of Prime Minister)(23)
Framework Act on Food Safety	Enforcement Decree of the Framework Act on Food Safety	
Food Sanitation Act	Enforcement Decree of the Food Sanitation Act	Enforcement Rule of the 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 the Health Functional Foods Act	Enforcement Rule of the Health Functional Foods Act
Special Act on Safety Control of Children's Dietary Life	Enforcement Decree of the Special Act on Safety Control of Children's Dietary Life	Enforcement Rule of the Special Act on Safety Control of Children's Dietary Life
Livestock Products Sanitary Control Act	Enforcement Decree of the Livestock Products Sanitary Control Act	Enforcement Rule of the Livestock Products Sanitary Control Act
Agricultural and Fishery Products Quality Control Act	Enforcement Decree of the 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 the Pharmaceutical Affairs Act	Rules on Safety of Medicine, etc
	Regulation on Damage Relief for Side- Effect of Medicine	Enforcement Rule of the Regulation on Damage Relief for Side-Effect of Medicine
	Decree on Facilities of Manufacturers and Importers of Medicine, etc.	Enforcement Rule of the Decree on Facilities of Manufacturers and Importers of Medicine, etc.
		Rule on Manufacturing, Sales Management of Biological Products
Act on the Control of Narcotics, ETC.	Enforcement Decree of the Act on the Control of Narcotics, ETC.	Enforcement Rule of the Act on the Control of Narcotics, ETC.
Cosmetics Act	Enforcement Decree of the Cosmetics Act	Enforcement Rule of the Cosmetics Act
Medical Devices Act	Enforcement Decree of the Medical Devices Act	Enforcement Rule of the Medical Devices Act
Laboratory Animal Act	Enforcement Decree of the Laboratory Animal Act	Enforcement Rule of the Laboratory Animal Act
Safety, Management, etc. of Human Tissue Act	Enforcement Decree of Safety, Management, etc. of the Human Tissue Act	Rule on Safety of the Human Tissue
	Ministry of Food and Drug Safety and its Organizations	Enforcement Rule of the Ministry of Food and Drug Safety and its Organizations
		Rule on Establishment and Supervision of Non-Profit Corporations under MFDS
		Enforcement Rule of the Emergency Resource Management Act under MFDS
Food and Drug Examination and Inspection Act	Enforcement Decree of the Food and Drug Examination and Inspection Act	Enforcement Rule of the 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
Cleasing and Hygiene Products Act	Enforcement Decree Cleansing and Hygiene Products Act	Enforcement Rule of Cleansing and Hygiene Products
Act on Labelling and Advertising of Food, ETC.		

Contributors

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A Message from the Minister / Contents	ICT Management and Statistics Office/ Na In-Mook	Kim Jong-Wook
		Lee Gyeong-Min
Ⅰ. Outline		
1. Vision·Objective·Core Strategies	Planning and Finance/ Jang Min-Su	Park Seon-Yeong
		Namkung Jong-Hwan
2. Organization·Affiliated Organizations	Organization and Management Innovation Office/ Ju Seon-Tae	Kim Jin-Hwi
3. History		Joo Chang-Joo
Ⅱ. Food		
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2. Strengthening of Safety of Food Production·Manufacturing		
A. Establish Safe Food Manufacturing Infrastructure	Food Safety Labelling and Certification Division/ Oh Jeong-Wan	Kang Seung-Keug
		Kim Mi-JA
	Food Safety Management Division/ Choi Soon-Gon	Kim Sung-Il
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B. Safety Management of the Production and Distribution of Agricultural, Livestock and Fishery Products	Agro-Livestock and Fishery Products Safety Division / Rhee Seong-Do	Byun Seong-Keun
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	Residues and Contaminants Standard Division / Lee Soon-Ho	Jeong Ji-Yoon Yune So-Young
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