Government Innovation for a better (healthy)life
Better MFDS

2019
Ministry of Food and Drug Safety
White Paper

Ministry of Food and Drug Safety

Foreword

The Ministry of Food and Drug Safety strives to keep our people safe and healthy by ensuring the safety of food and drugs that people consume in their everyday lives.

In the year 2018, our ministry made various efforts aiming at eliminating the blind spots associated with food and drug safety for more stringent safety control. To enhance the safety of food on the Korean market, we fully enforced Positive List System (PLS) that only allows registered pesticides within the accepted threshold with a view to prevent the misuse and abuse of pesticides. Also, we established a new requirement to label the spawn date of the egg on its shell. In the field of drug safety, we increased the transparency of narcotics control by obliging clinics and hospitals to report supply details of medical narcotics electronically. Furthermore, we enacted the Hygiene Products Control Act for safety control of cleaning and hygiene products used in our daily lives such as cleaning products and hygienic wet towels.

MFDS introduced the National Petition Safety Inspection System this year to better understand and serve the safety needs of our people. Under the new system, products that were petitioned for inspection, such as hygienic wet towels, vinegar drinks for weight loss and noni products were inspected. We then published the results and took necessary administrative measures on them. In addition, MFDS ramped up our monitoring and inspection on products in high demands or trending online, such as fine dust masks, konjac jelly and hydrogen water and has been promptly blocking the illegal websites selling these products.

Also, building on our last year's effort to intensify safety monitoring on sanitary products for women, this year we permitted the import of cannabis for medical purpose in order to provide patients an opportunity to treat rare conditions. Moreover, we established a country-led procedure to enable the supply of emergency medical devices including synthetic blood vessels for rare disease patients. All of our efforts are

dedicated to achieve our mission of inclusive country where people are provided with safe food and drug wherever necessary.

To respond to the era of the 4th industrial revolution we are living in, MFDS will strive to innovate ourselves. We will provide our support in fast forwarding the release of state-of-the-art new drugs and medical devices. We are also laying the foundations for creating new markets by introducing certification system for natural and organic cosmetics.

The 2019 White Paper sets out comprehensive policies led by the Ministry of Food and Drug Safety. We hope this white paper will be helpful for the readers to understand our policies. We pledge to continue to strive in keeping up with changes and better understanding our people's need to ensure the safety and health of the people.

June 2019
Minister of Food and Drug Safety

Eui Kyung Lee

01 Outline

02 Food

Section 1. Strengthening the Food Safety Management System

Section 2. Internationalization of Scientific Food Standards and Specifications

Section 3. Expansion of a Healthy Dietary Environment

Contents

03 Medical Products

Section 1. Medicines

Section 2. Biopharmaceuticals and Cosmetics

Section 3. Medical Devices

04 Risk Prevention

Section 1. Establishment of Foundations for Preemptive Risk Prevention and Crisis Response System Focused on Customers

Section 2. Building Consumer Trust through Reinforced Communication on Food and Drugs with the Public

Section 3. Expansion of Sharing · Publicizing · Utilizing Food and Drug Safety Information

Section 4. Enhancing International Competitiveness through the Advancement of Testing and Inspection Agencies

Contents

05 Research & Development for Food & Drug Safety

Section 1. Research and Development that are Directly Linked to Safe Life

Section 2. Expanding Risk Assessment for Scientific Food Safety Management

Section 3. Research for Safety Management and Supporting Commercialization of Medical Products

Section 4. Development of Safety Evaluation Technologies for Food and Drugs

Section 5. Advancement and Strengthening of Expertise in the National Lot Release System

06 Appendix

Table/Image of Contents

chapter 1

Outline

1. Vision · Objective · Core Strategies

Safe Food and Drug, Healthy People

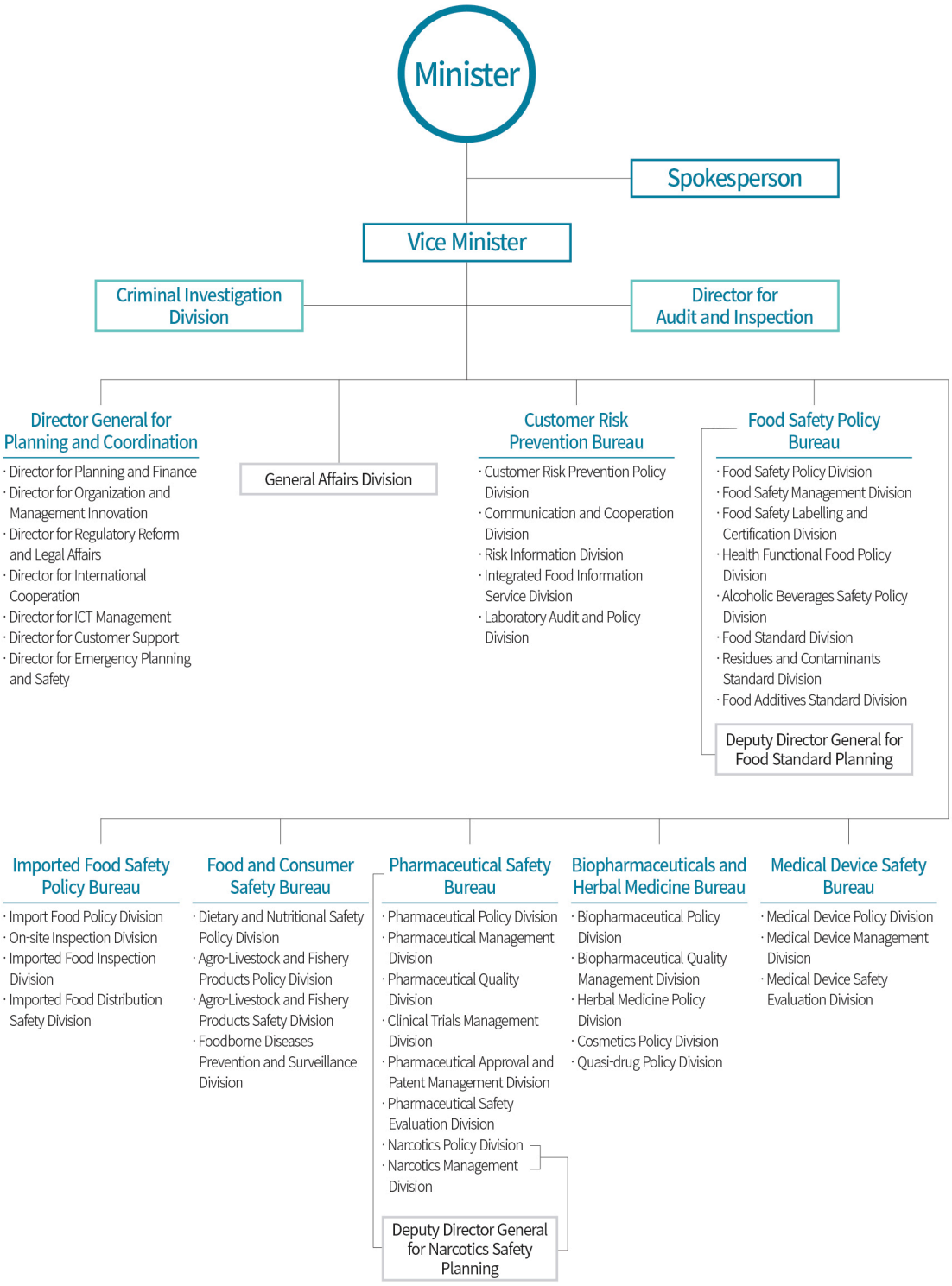
Smart Leader

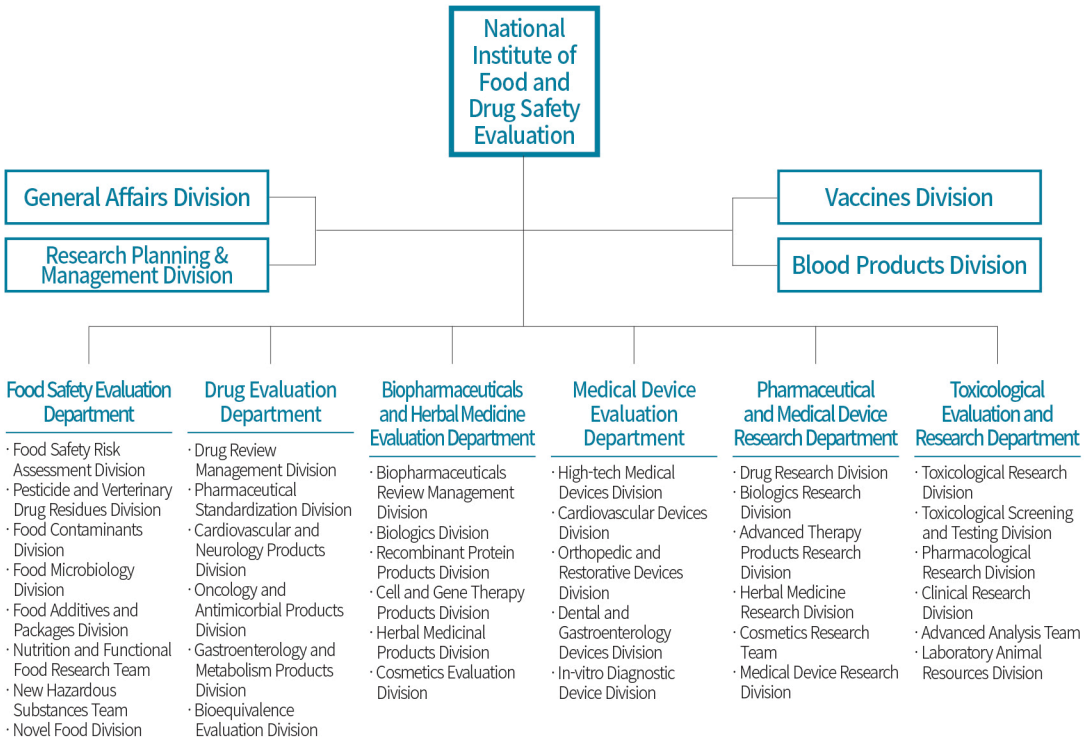
Smart Coordinator

Smart Supporter

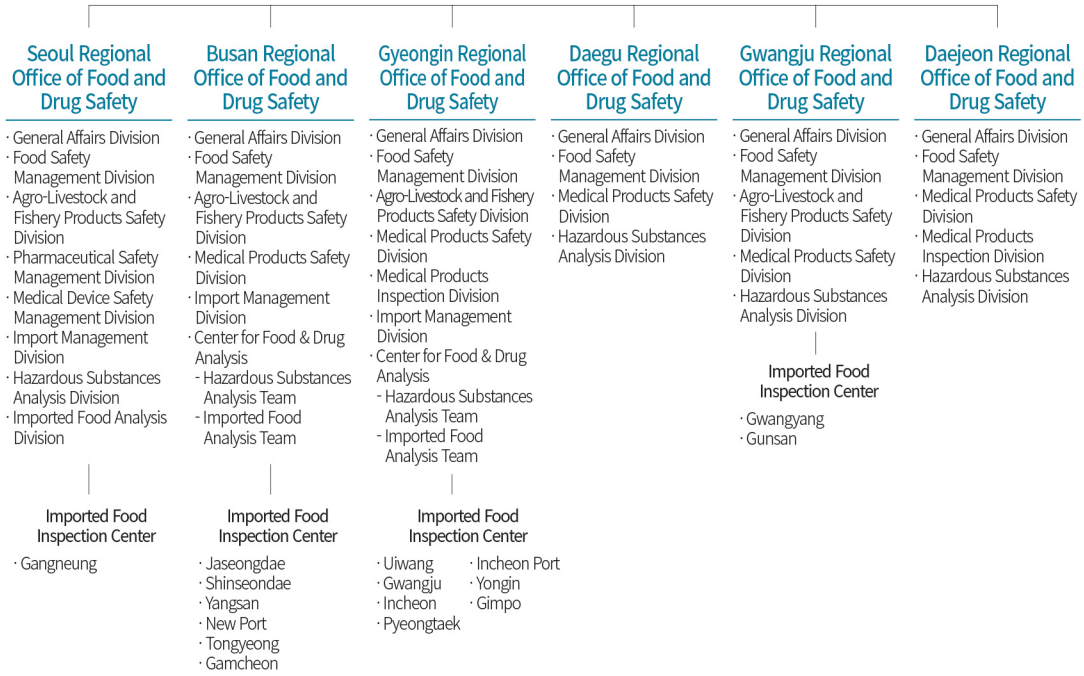
1	Food safety with a robust basic foundation	① Arrest food safety accidents at the fundamental level ② Manage imported food methodically before and after customs clearance ③ Manage food to ensure that only safe agro, livestock and fishery products are distributed ④ Prompt response to changing food trends
2	Reliable drugs, medical devices and living supplies	① Manage drugs thoroughly from the stage of sourcing raw materials ② Arrange the manufacturing and distribution environments of medicine, etc. ③ Enhance safety management in a user-centered manner ④ Raise the safety level of cosmetics and feminine items in daily life
3	Warm and communicative safety	① Protect health of the vulnerable demographic groups ② Supply vaccines and essential drugs in a stable manner ③ Reinforce consensus and communication with the public
4	Energetic, innovative growth based on customized regulations	① Support commercialization through smart audit of licenses ② Cooperate internationally and implement R&D for the future ③ Realize a sharing economy and increase jobs

2. Organization · Affiliated Organization





Regional Office of Food and Drug Safety



3. History

2019.05
Establishment of the Narcotics Safety Planning Directorate (Headquarters)

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)

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

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)

2012.07

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

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

2013.10

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

2013.11

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

2014.08

Establishment of Quasi Drug Policy (Headquarters)

2001.10

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

2001.03

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

1998.02

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

1996.04

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

chapter 2

Food

section 1

Strengthening the Food Safety Management System

1. Securing of Safety in Online Distribution of Food and Drugs

A. Growth of Online Markets and Rampancy of Illegal Activities such as Unlawful Distribution, Etc.

1) Growth of Online Markets

With advancements in technology, the center of product advertisement and sale is rapidly shifting from offline to online (Internet/mobile). The scale of online markets has been expanding at a rapid pace lately, making regulation of online markets more important than ever before.

Moreover, with the growing rate of online purchase by which consumers directly buy foreign products, etc., food and beverages and cosmetics subject to management of the MFDS are on the rise.

The Internet/mobile markets have lowered transaction fees and entry barriers remarkably; thus, they heighten economic utility for consumers while serving as an opportunity to create business profits for sales people. Against this backdrop, the scale

of online markets is expected to keep growing in the future.

2) False/Exaggerative Online Advertisements and Rampancy of Illegal Activities such as Unlawful Product Distribution, Etc.

Given the characteristics of online markets e.g. anonymity, lack of face-to-face transactions, the ability to function across national borders, and convenient market entry, illegal activities are hard to specify and the effectiveness of sanctions are meager. This generates serious social issues caused by false/exaggerative advertisement and rampant illegal activities such as unlawful product distribution, etc. through online markets.

* Illegal advertisement and sale of food & drugs: 50,093 cases in 2015 → 79,905 cases in 2015 (60% ↑ from 2015)

Especially, products that boast their effect on human health relying on science, there is a concern about damage to consumers. Now that false/exaggerative advertisement is rampant with no verification about cosmetics and beverages promoted as blocking particulate matters, it is necessary to strictly monitor them online.

B. Achievements in Eradicating Online False/Exaggerative Advertisements and Unlawful Distribution

1) Establishment and Operation of the Cyber Investigation Bureau (T/F)

As false/exaggerative advertisements tend to increase along with bullish online markets, the MFDS established the Cyber Investigation Bureau in Feb. 2018 and has been operating the Bureau by integrating online monitoring functions unlike the existing management method.

The Bureau started with 10 cyber monitoring personnel from each division and some personnel of the Task Force for Eradicating Unwholesome Food.

The main tasks of the Cyber Investigation Bureau are: 1) formulate and operate a

plan to tackle illegal online advertisements and manage unlawful products; 2) prepare criteria to define false/exaggerative advertisements in online and print publications, and uncover and block them; 3) quickly cut off products distributed online that raise concerns of health and safety hazards; 4) construct a cooperation system among consumers, related ministries and companies; 5) educate consumers and companies on illegal online advertisements; and 6) handle complaints on illegal online advertisements, etc.

The Cyber Investigation Bureau selects monitoring targets and devises a monitoring plan through civil reports published via e-People, 1399 and social issues. It also searches and monitors open markets, individually operated shopping malls and posts on the portals, and reviews illegality of the outcome. If violates violation of law is identified, the Bureau requests the Korea Broadcasting Commission or portal operator to close the relevant website.

The process may involve framing of charges, request for investigation and on-site examination by case.

2) Stricter Inspection of Blind Spots and Products Closely Connected with People's Lives

The MFDS took action including shutting down of a total of 95,789 sites by intensively inspecting products related to consumers' daily life/health (24 times) through the Public Communication Bureau and e-People.

Table 2-1 **Results of Uncovered Websites by Area**

(As of Dec. 31, 2018, Unit: Case, Source: Cyber Investigation Bureau)

Sum	Food	Health Functional Food	Drugs (Quasi-drug)	Cosmetic	Medical Device etc.
95,789	35,677	14,149	36,089	4,574	5,300

The MFDS rapidly blocked foreign products (167 items, 3,817 cases) with hazardous substances e.g. those from which microorganisms or harmful ingredients were detected. Moreover, the Ministry performed planned inspection of industrial products like pinhole glasses given that consumers may view them as medical devices or quasi-drugs on account of their advertising about medical effectiveness.

3) Eradication of Unlawful Online Distribution, and Establishment of the Basis for Swift Shutoff

The MFDS contributed to eliminating illegal drugs by introducing the "Prohibition of Mediation for Advertising Medicine and the Right of the Minister of Food and Drug Safety to Request Data from Online Business Operators" to facilitate basic investigation of illegal sellers (amended Article 61 (2) of the Pharmaceutical Affairs Act, effective in Dec. 2019). The ministry has been continuously and repeatedly carrying out crackdowns to end the illegal distribution of drugs such as abortion pills that are in high demand owing to social issues.

Table 2-2 **Results Of Uncovering Illegal Distribution Of Abortion-Induced Drugs**

(As of Dec. 31, 2018, Unit: Case, Source: Cyber Investigation Bureau)

Sum	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
2,197	238	215	185	216	127	150	66	76	712	135	41	36

In addition, the MFDS signed MOUs with 31 agencies in 2018 (one in 2017) regarding eradication of false/exaggerative advertisement and illegal distribution, in an attempt to set up a safe and sound basis for distribution of food and drugs. As a part of this drive, MFDS monitored illegal advertisement on cosmetics that claimed to prevent hair loss in public-private cooperation with "Naver", "Homeshopping Association", "GS", etc., uncovered 6,607 cases, and worked together to induce online shopping malls at unlawful sites to close on their own (41,766 out of 97,276 cases).

Such action led to a dramatic shortening of the duration necessary for shutting down illegal sites from 88 days in 2017 when ordered by the Korea Broadcasting Commission to 27 days in 2018 by public-private cooperation.

4) Change in Monitoring and Public Relations Methods to Expand Public Consensus

The MFDS carried out inspections that could validate efficacy/effectiveness to remove people's doubt. To that end, the MFDS disclosed information in areas such as efficacy/effectiveness, precautions, etc. about advertising articles at the time of result presentations. The Ministry forged consensus on online illegal distribution with consumers including adolescents through the first "25 Seconds Film Festival" held by the MFDS, and provided useful information for consumers, e.g. cautions to be taken while purchasing online, deploying card news and planned reports (Segyeilbo [Korean daily newspaper], Aug. to Sep.).

* Shared consumer damage related to exaggerative advertisement through ultra-short films and relayed them live to the public on Facebook.

Furthermore, the MFDS removed consumers' doubts by inspecting fields seemingly fraught with false/exaggerative advertisements and illegal distribution, and pushed ahead with an "idea contest" to assess consumer demand as a precondition to beef up policy responsiveness.

* Carry out this inspection (activity) for online safety of food and drugs. ('18.11.26~12.14)

C. Plan to Intensively Implement the Online Security Project

1) Increase Planned Investigation into Products of Interest to Consumers

With more online shopping markets, false/exaggerative advertisement and illegal distribution continue to recur by means such as changing a sale website regularly etc. despite constant crackdown. Given of the recent trend of increasing particulate

matters, false/exaggerative advertisement concerning related products like masks is widespread. In response to this trend, the MFDS chose five areas directly connected to consumers – diet, particulate matters, hair loss, women's health and vulnerable areas – and will enforce regulations and monitoring until we achieve complete eradication of false/exaggerative advertisement and illegal distribution.

Apart from this, the MFDS will authenticate content of commercials and deliver specific information including cautions at the consumers' eye level with a focus on non-conforming cases that violate the law. To this end, the Ministry will regularly announce inspection results and disclose names of the non-compliant companies and products.

2) Crackdown of Online Illegal Drug Sale/Advertisement

To fight illegal distribution of drugs such as the diet drug (Saxenda) and GHB which have caused major issues recently, the MFDS has mapped out and implements pan-governmental management measures led by the Prime Minister's Office. The measures are carried out smoothly by building an inter-ministry cooperation mechanism. The MFDS Cyber Investigation Bureau monitors illegal online drug advertisements/sale posts at SNS like Twitter, collects related information like advertising posts and site addresses and unlawful seller IDs and requests investigation so that the National Police Agency can implement crackdown, etc.

The MFDS plans to actively promote a channel on the MFDS website to report illegally distributed drugs and by doing so, encourage reporting by citizens and bolster monitoring of online drug advertisement.

3) Reinforcement of Objective, Scientific Verification for Products Claiming Medical Effectiveness

With a growing interest in health, consumers are likely to suffer more damage from

products sold and advertised based on information that has never been authenticated scientifically.

Since the MFDS recognizes the need to set up an objective verification system regarding unverified medical efficacy/effectiveness to prevent consumers from being cheated by false/exaggerative advertisement, it has organized a pool for the "Private Advertisement Verification Group" to validate efficacy/effectiveness of food and cosmetics against the claims made by their advertisement. The pool has experts objectively, scientifically inspect advertising to verify claims.

The main targets are commercials claiming scientifically unverified diet value, treatment/prevention of disease, or addition of natural/organic ingredients. The MFDS will review advertisements on its own or select them at the request of the "Private Advertisement Verification Group."

The Ministry pursues fair and reliable assessments by holding expert meetings in the relevant field, verifying content of advertisement through thesis analysis and data survey and announcing the results.

4) Provision of Consumer-Friendly Information and Stronger Self-Monitoring by the Industry

As the online market is growing fast owing to the convenience offered by online transaction, there are more management targets that the government cannot handle on its own. Furthermore, the existing monitoring system cannot overcome the limitations to arriving at fundamental solutions to issues such as secret illegal distribution, to accelerate fundamental change in advertisement markets*.

* (Media) Internet shopping malls, home shopping → Mobile, SNS (YouTube, Facebook, etc.)
(Advertisement) Text, search ads → Video, SNS review of experience, etc.

In this vein, the MFDS will prevent purchase of illegal products by providing information of particular interest to consumers e.g. cautions to be taken while making online purchase. Information regarding illegally distributed online products, sellers, sale types

and verification results of advertised effectiveness shall be shared in easy-to-understand forms such as card news and planned reports and steadily posted on the MFDS website.

Besides, the MFDS will enhance self-monitoring based on business agreements with online shopping malls, etc. to eradicate illegal distribution, strengthen private-public collaboration by means including periodically operating a council, and continue to educate sellers and consumers on false/exaggerative advertisement.

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2. Strengthening of Food Production · Manufacturing Safety

A. Establishing Safe Food Manufacturing Infrastructure

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

A) Background

Korea established regulations on Hazard Analysis and Critical Control Points in the「Food Sanitation Act」in 1995 and introduced the HACCP system by enacting the「Hazard Analysis and Critical Control Point」in 1996. Furthermore, in August 2003, six items including fish cakes were designated as mandatory items that should apply HACCP (Kimchi cabbage was added in Dec. 2006). The HACCP system was enforced from 2006 to 2014 in multiple phases, based on annual sales and the number of employees at the assessed business entities.

In May 2014, 8 items including kids' favorite foods were added in the list of mandatory items that should conform to HACCP standards. HACCP is mandatorily being applied to them phase-by-phase from 2014 to 2020, based on the annual sales and number of employees as determined in 2013.

Korea started to mandatorily apply HACCP to livestock slaughter business in January 2001, milk collection and dairy 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-contaminated eggs were detected, the MFDS newly established an edible egg packaging system and designated it as a mandatory item to apply HACCP standards in order to enhance sanitation quality of the egg distribution & management system. Going further, mandatory application of HACCP 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

To unify the HACCP certification process, efficiently carry out HACCP-related tasks, and minimize inconveniences to businesses, the Korea Institute for Food Safety Management Accreditation (KIFSMA) was established (Feb. 13, 2017) by integrating individually operated HACCP certification organizations.

Table 2-3 **Management System including HACCP Certification of Foods and Livestock Products and Follow-Up Management**

(As of Dec. 31, 2018, Unit: 100 million/business entity, Source: 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 required by the HACCP system	(Mandatory) Regional FDA Quarantine Agency
	(Voluntary) KIFSMA	(Voluntary) KIFSMA

※ Tasks including HACCP certification of 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 foods and livestock manufacturing businesses, encourage voluntary participation in application of HACCP and enable small businesses acquire HACCP certification smoothly, 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 and technical assistance for HACCP operation, training and promotion. As a result of these consistent efforts, the number of HACCP-certified businesses increased significantly from 4,487 in 2010 to 18,491 in 2018.

* 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 2-4 **HACCP Certification Status**

(As of Dec. 31, 2018, Unit: business entity (cumulative), Source: Food Safety Labelling and Certification Division)

Category	2011	2012	2013	2014	2015	2016	2017	2018
Total	5,851	8,161	10,461	12,024	13,991	15,566	17,152	18,491
Food	1,163	1,809	2,408	3,029	3,734	4,358	5,031	5,762
Livestock	4,688	6,352	8,053	8,995	10,257	11,208	12,121	12,729

In order to strengthen follow-up management of HACCP, along with the revision of the「Food Sanitation Act」in August, 2015, the MFDS introduced a regulation that provides a legal basis for immediate cancelation of HACCP certification for businesses that do not abide by the food safety standards, receive less than 60 % in the periodic inspection/assessment, or acquire HACCP certification by unlawful means. After the regulation was introduced, the MFDS canceled HACCP certification of 79 businesses by the end of June 2018.

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 by end of 2018, MFDS completed reexamination of a total of 3,668 business entities (160 food items, 3,508 livestock products) to extend certification.

In addition, the MFDS conducted TV publicity and hosted events for terrestrial and

cable broadcasting, and increased the level of broadcasting exposure while determining the method of publicity by age. The MFDS also continues to actively promote the HACCP system in coordination with consumer groups and food-related associations.

Table 2-5 **Consumer Awareness Survey of the HACCP System**

(As of Dec. 31, 2018, Unit: %, Source: Food Safety Labelling and Certification Division)

Category	2008	2009	2010	2011	2012	2014	2016	2018
Ratio (%)	18.1	25.6	30	40.2	48.3	51.6	64.7	68.9

C) Implementation plan

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

In 2019, the scope of mandatory HACCP certification is being expanded (Dec. 2014 – Dec. 2020) to 8 food items including kids' favorite foods. Also, the certification system is being applied gradually (Dec. 2018 – Dec. 2420) to meat processing businesses depending on their sizes.

Table 2-6 **Mandatory HACCP Application Status of Foods since the Scope of Mandatory HACCP Application was Expanded**

(As of Dec. 31, 2018, Unit: Business entity, %, Source: Food Safety Labelling and Certification Division)

Category	Enforcement Date	Size of Target Businesses	Number of Businesses
Convenience foods, 8 categories of kids' favorite foods (6,581 businesses)	2020.12.01	With annual sales under 100,000,000 won and number of employees fewer than 5	5,799
Meat processing industry (2,224 businesses)	2020.12.01	With annual sales more than 500,000,000 won	348
	2022.12.01	With annual sales more than 100,000,000 won	691
	2024.12.01	Other businesses	1,115

(2) Enhancing HACCP Follow-Up Management (Periodic Inspections·Assessments)

In the aftermath of the incident where HACCP-certified chocolate cakes caused

food poison to a group of people in Sep. 2018, the MFDS is implementing a "Plan to Improve HACCP Management" in an effort to appropriately run the HACCP system and substantiate follow-up management. The Ministry endeavors to intensify the system by conducting random assessments on all related businesses without notice throughout the year to ensure that they operate HACCP standards all the time.

(3) Strengthening HACCP Support Projects

To ease the burden of small manufacturing enterprises subject to mandatory HACCP-application, the MFDS offers budgetary assistance nationwide to improve their facilities (50 % of investment amount, up to 10 million won), and provides technical support for HACCP certification and operation of those businesses through the Korea Institute for Food Safety Management Accreditation (KIFSMA). In addition, MFDS strives 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

To properly stabilize the HACCP system, it is necessary for the general public to recognize its superiority and buy only HACCP-certified foods, 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 not only the scope of its TV commercials, but also advertising customized to consumers and industries.

2) Management of Foreign Substances in Food

In order to promptly take necessary measures to investigate and deal with consumer complaints regarding foreign objects in food and to resolve distrust and disputes between food businesses and consumers, it is mandatory to immediately report any foreign substances detected in food to the Ministry of Food and Drug Safety and to the

competent Si/Gun/Gu office when a business operator receives a consumer report.

In 2018, there were 3,061 reports on foreign matters found in food: worms (27.6%), mold (12.5%), metals (9.8%) and plastics (7.9%).

Table 2-7 **Status of Foreign Substance Reporting by Year**

(As of Dec. 31, 2018, Unit: Case (%), Source: Food Safety Management Division)

Year	Total (Number of Cases)	Reported by Businesses	Reported by Customers
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%)
2018	3,061	980 (32.0%)	2,081 (68.0%)

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

1) Background

There is only a limited number of ways to reduce or eliminate hazardous elements associated with agricultural, livestock, and fishery products at the stage of the distribution process, etc. Given this, chances are high that the end consumer will have to cope with hazardous elements they are not blocked at the production stage including cultivation, breeding, farming, etc.

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

2) Achievements

A) Safety Management of Agricultural Products

In 2018, as part of efforts for safety management of agricultural products, the MFDS inspected products for pesticide residues and heavy metals, etc. for a total of 126,647 cases of commonly consumed and frequently non-compliant items and those transacted in the public wholesale markets. Among them, 1,417 cases (1.1 % of the inspected items) were found to exceed the permitted limits. The Ministry took action such as deferred shipment or disposal of the non-compliant products.

Also, 53,276 agricultural products that are commonly consumed and frequently found to be non-compliant at distribution · sales stages were investigated for pesticide residues, heavy metals, sulfur dioxide, etc.; among the products thus inspected, 489 non-compliant items (0.9 % of the inspected items) such as angelica root leaves, pigweeds, pepper leaves, etc. were disposed of as they exceeded the limits.

The MFDS constructed a mechanism to prevent distribution of non-compliant agricultural products by securing a budget of 4.9 billion won and 52 dedicated personnel to increase the number of on-site inspection stations in public wholesale markets, which serve as a distribution channel of agricultural products from across the country.

The MFDS has concentrated its safety management efforts on hazardous items in foods such as agricultural products supplied to children' meal services at the time of schools reopening, local specialty agricultural products, agricultural products for holidays and gifts, seasonal agricultural products that are commonly consumed, etc. Besides, to cut off illicit distribution of inedible agricultural products, the MFDS intensified its safety management on the blind spots by instructing and examining 385 places including food retailers in eight herbal medicine markets in Korea.

In view of the rising public anxiety over Japanese products as well as domestic foods in the aftermath of the nuclear disaster in Fukushima, the MFDS inspected radiation levels of 541 agricultural products such as green onions and cabbages grown outdoors at the production stage and also examined 3,485 agricultural products distributed in

domestic markets, such as onions and carrots at distribution · sale stages. The results showed that only a single case of neungi mushroom from Kyrgyzstan exceeded the permissible limit. Information on agricultural products with traces of radiation below the standard level were transparently disclosed to the public through the MFDS website and mobile apps, etc.

B) Safety Management of Livestock Products

Safety inspections · investigations on livestock products were carried out for a total of 519,706 items including 494,356 items in the production stage and 25,350 in the processing · distribution stages. For items in the production stage, inspections focused on the hygiene levels of slaughterhouses (meat) and dairy farms (raw milk).

Residual substance tests on meat were carried out by 17 city (Si)/provincial (Do) livestock testing · inspection agencies for a total of 163,455 livestock products including beef, pork, chicken, duck, lamb (goat meat) and horse meat to check the presence of 175 toxic substances including 47 types of antibiotics, 58 synthetic antibacterial products, 3 hormone drugs, 7 other medicinal products, and 61 types of agricultural pesticides. The tests revealed that 511 out of 163,455 livestock products had residual substances at levels in excess of the permitted range (the violation rate was 0.31 % for residual substances). Preventive measures such as restriction of shipment and postponement of release were imposed on the non-compliant farms in question.

Apart from this, 13,380 cases of egg production units (including overlapped farms) were inspected for 79 residual substances including antibiotics, pesticides, etc. A total of 17 violation cases (15 farms) were detected (the violation rate of residual substances was 0.11 %) and preventive measures such as postponement of release were taken.

In relation to insecticides illegally used on edible eggs, lot tests were conducted to all egg farms and eggs at the distribution stage. As a result, the MFDS designated non-compliant farms as farms that violated residual substance standards and carried out follow-up action to withdraw and dispose of the inedible eggs. Furthermore, the Ministry conducted pre-shipment inspection of eggs produced by the non-conforming

farms, securing the safety of eggs reaching the market.

C) Safety Management of Fishery Products

In 2018, a total of 29,569 cases, e.g. commonly-consumed fishery products (by producing area, item, and season) or those with a history of non-compliance, were tested for veterinary drugs, heavy metals, shellfish toxins, vibrio parahaemolyticus, Norovirus, etc. and 532 items (the violation rate of residual substances was 1.8 %) were found to have exceeded standards. Measures such as restriction · postponement of shipment, withdrawal · disposal and administrative measures were enforced on the non-compliant products to secure food safety.

The MFDS laid a foundation to systematically manage residues in commonly-consumed/much produced fishery products through the National Residue Program (NRP). The Ministry also prevented circulation of fishery products polluted with vibrio parahaemolyticus by carrying out unscheduled on-site screening of water quality at seaside sushi restaurants and gathering and inspecting fishery products in summer.

The MFDS made efforts to forestall the spread of food poison stemming from vibrio parahaemolyticus in marine products by analyzing marine environmental factors to forecast the possible occurrence of microbes that cause vibrio vulnificus septicemia.

Table 2-8 Results of Investigation and Inspection Implemented in 2018 on Safety of Agricultural, Livestock, and Fishery Products

(As of Dec. 31, 2018, Unit: Case, Source: Agro-Livestock and Fishery Products Safety Division)

Category	Total		Agricultural Products		Livestock Products		Fishery Products	
	No. of cases	Non-compliance	No. of cases	Non-compliance	No. of cases	Non-compliance	No. of cases	Non-compliance
Total	675,922	4,253 (0.6%)	126,647	1,417 (1.1%)	519,706	2,304 (0.4%)	29,569	532 (1.8%)
Production Stage	584,081	3,561 (0.6%)	73,371	928 (1.3%)	494,356	2,153 (0.4%)	16,354	480 (2.9%)
Distribution/ Consumption Stage	91,841	692 (0.8%)	53,276	489 (0.9%)	25,350	151 (0.6%)	13,215	52 (0.4%)

3) Implementation Plan

A) Safety Management of Agricultural Products

In 2019, MFDS will execute safety inspections on some 110,000 agricultural products commonly consumed and frequently found to be non-compliant.

In an effort to safely manage agricultural products at the distribution · sale stages, the Ministry will designate top 15 hazardous · troublesome items that are most commonly consumed and reported for recurring non-compliance every year as subjects for special management. The MFDS will collect and test 50,000 items distributed in the public wholesale markets.

To manage safety from radiation, which is a major concern for the public, MFDS plans to conduct radiation tests on 2,400 items 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.

The MFDS will also provide guidance · inspection to block 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 and sold online, the Ministry has plans to provide thorough guidance and examine the distribution centers of online shopping malls.

B) Safety Management of Livestock Products

With regard to safety inspection of livestock products, the MFDS operates a collaborative system with several institutions including MAFRA, Regional Korea Food & Drug Administrations, and city and provincial testing & inspection centers. In consultation with these entities, the MFDS re-evaluates the overall inspection targets, volumes and items, and reflects the results in the safety inspection plan for livestock products for the following year.

In addition to this, rather than simply increasing the number of test cases or items, efforts are being made to efficiently test the most commonly consumed veterinary

drugs in the domestic market, with a special focus on the items with frequent detection records of non-compliance. The MFDS will also carry out a pilot survey to introduce and operate the NRP for milk in 2019 as it did in 2018.

In addition to the regular collection and inspection of products, the MFDS will monitor livestock processing facilities that have non-compliant histories or implement self-quality tests, and specially remain vigilant to false advertisements and exaggerated claims on the Internet in order to prevent food incidents caused by hazardous substances.

C) Safety Management of Fishery Products

In 2019, to control the safety of fishery products, the MFDS will intensively manage the most commonly consumed veterinary drugs, unchecked fishery products, and the articles and items with non-compliant histories, and guide and train the producers on the safety of fishery products.

For fishery products at distribution · sale stages, the MFDS will collect and carry out inspection for a total of 10,000 marine products. In doing so, the Ministry will examine the articles and items with recurrent records of being unfit for consumption; place priority of safety management on fishery products on the Internet market in line with the consumption trend; inspect commonly consumed products by producing area, item, and season regarding shellfish toxins, vibrio parahaemolycius, norovirus, etc.; and expand the scope of NRP evaluation for marine products.

The MFDS plans to prepare and disseminate sanitation management guidelines to heighten the voluntary sanitation level of fishery product manufacturers for simple processing and thereby block the distribution of hazardous fishery products. The Ministry will also strengthen autonomous inspection of fishery products at production and distribution stages by way of educating autonomous inspectors at producer organizations on inspection methods for veterinary drugs, heavy metals, and microorganisms.

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

A. Nationwide Joint Crackdown

In cooperation with the local governments, MFDS regularly conducts joint crackdowns on food facilities that will have a large impact in the event of an incident or those under poor sanitary conditions. Such enforcement aims to prevent food incidents and ensure food safety. In 2018, nine joint crackdowns were carried out on 52,037 businesses including facilities supplying holiday · summer foods, school cafeterias preparing for a new semester, and youth training centers. The MFDS identified 1,001 businesses (violation rate: 1.9 %) with poor sanitation levels and took administrative and improvement measures for them.

Table 2-9 **Results of Joint National Crackdowns by Year**

(As of Dec. 31, 2018, Unit: Business entities, %, Source: Food Safety Management Division)

Year	2014	2015	2016	2017	2018
Number of Inspected Businesses	28,528	32,829	31,492	44,915	52,037
Number of Detected Businesses	995	740	780	1,227	1,001
Violation Rate(%)	3.5	2.3	2.5	2.7	1.9

B. Reinforcing Collection · Inspection of Foods at the Distribution Stage

In order to secure food safety and promote public health, the MFDS, local food& drug safety administrations, cities and provinces (Si/Gun/Gu) collect and inspect foods distributed in the domestic markets. The MFDS implements customized seasonal (periodic) collection · inspection on commonly consumed foods of which consumption increases in summer or during holidays such as New Year's day, Korean

Thanksgiving day, etc. The ministry also carries out planned collection · inspection reflecting the consumption trends including overseas information.

In 2018, the MFDS collected and inspected 172,132 items of agricultural · livestock · fishery products and processed foods, and seized or disposed of 957 batches/items non-compliant with food safety standards and quantities. 0.6 % of the non-compliance rate remains unchanged from the last year.

Table 2-10 **Results of Collection · Inspection by Year**

(As of Dec. 31, 2018, Unit: Case, %,
Source: Food Safety Management Division, Health Functional Food Policy Division, Imported Food Distribution Safety Division, Agro-Livestock and Fishery Products Safety Division, Alcoholic Beverage Safety Policy Division)

Year	No. of Cases Collected	No. of Non-Compliant Cases	Non-Compliance Rate (%)
2016	189,198	1,176	0.6
2017	168,096	1,064	0.6
2018	172,132	957	0.6

C. Operation of the Food Traceability Management System

The MFDS operates the Food Traceability Management System to provide accurate food traceability information to consumers. This is how it works: the MFDS tracks, records and stores information on food traceability from the manufacturing · processing stages to the sale stage, and when food safety problems occur, it rapidly takes measures such as cause analysis, recalls, etc.

The system was mandatorily applied by phase to: 1) businesses manufacturing and processing (including import and sale) baby foods and health functional foods and other retailers that directly sold food to the customers from 2014 to 2017; and 2) businesses dealing with infant formula milk from 2016 to 2018. Focus was placed on these products as they can be especially hazardous in the event of a problem. In 2018, foods for pregnant and lactating women, special-purpose foods and diet foods were

designated as food categories to be registered for the management of food traceability. Enforcement of the system on manufacturers · importers of infant foods and other retailers was completed in 4 phases (Dec. 2017), and, as of the end of 2018, a total of 7,341 food-related businesses were registered in the system. In addition, the MFDS aims to conduct inspection · evaluation every 2-3 years to ensure that the information is correctly linked even after the businesses are registered with the system.

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

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

The MFDS discloses information on foods subject to recall on the MFDS website and the food safety information portal sites for promptly withdrawing hazardous food and notifying consumers. In 2018, the Ministry recalled 193 hazardous foods, etc.

Table 2-11 Recall Status of Nonconforming Processed Food by Year

(As of Dec. 31, 2018, Unit: Number,
Source: Food Safety Management Division, Health Functional Food Policy Division)

Category	2014	2015	2016	2017	2018
Total	287	324	283	202	193
Food	269	310	252	169	177
Health Functional Food	18	14	31	33	16

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

1) Background

Given the rapid changes occurring in the food consumption environment, food labels are becoming more important to consumers concerning whether to select the food. In view of this, the MFDS works hard to provide accurate labels containing factual information on foods, health functional foods, food additives, utensils, and containers · packages.

The MFDS is not only strengthening food labeling standards to protect consumers' safety and guarantee their rights to know, but also working to improve unreasonable or ambiguous provisions to promote the food industry.

2) Achievements

Up till now, the Korean labeling of food had been governed by three statutes: Article 10 of the「Food Sanitation Act」, Article 17 of the「Health Functional Foods Act」, and Article 6 of the「Livestock Products Sanitary Control Act」. In the interests of a more streamlined management, MFDS integrated these acts and enacted and promulgated the「Act on Labels and Advertisements of Food, Etc.」on Mar. 14, 2018. By doing so, the MFDS expects to have in place better processes to prevent consumer damage from false labels and advertisements and secure the consumers' rights to know.

Table 2-12 **Act on Labels and Advertisements of Food, Etc.**

Food Sanitation Act	Act on Labels and Advertisements of Food, Etc.
Article 10 (Standards for Labeling) Article 11 (Food Nutrition Labelling) Article 12-2 (Indication, etc. of Compared Sodium Content) Article 12-3 (Deliberation on Labels and Advertisements) Article 12-4 (Filing Objections with Regard to Deliberations on Advertisements) Article 13 (Prohibition against False Labelling, etc.)	Article 4 (Standards for Labelling) Article 5 (Nutrition Labelling) Article 6 (Indication, etc. of Compared Sodium Content) Article 7 (Standards for Advertisements) Article 8 (Prohibition of False Labelling and Advertising) Article 9 (Substantiation of the Content of Labels or Advertisements) Article 10 (Autonomous Deliberation on Labels or Advertisements)
Livestock Products Sanitary Control Act	
Article 6 (Standards for Labelling of Livestock Products) Article 32 (Prohibition of False Labelling, etc.)	
Health Functional Foods Act	
Article 16 (Deliberation on Labels or Advertisements regarding Functionality) Article 16-2 (Filing Objections to Deliberation on Advertisements) Article 17 (Labeling Standards) Article 18 (Prohibiting False, Exaggerative, or Negative Labels or Advertisements) Article 25 (Prohibition against Sale, etc. of Health Functional Foods which Violate Labeling Standards) Article 26 (Prohibition against Similar Labels, etc.)	

Furthermore, the MFDS integrated the standards for food and livestock products into the「Standards For Food, Etc.」to apply the same criteria throughout the range of products. The MFDS also came up with a plan to improve the reliability of labeling by adding pine nuts as a subject of allergen labeling, and by labeling “Example of Cooking” around the photos of cooked foods and “Ginseng Fruit” in case of using it, and mention the content of soybeans in fermented soybean lumps.

To ease the impact of enforcement on sellers, the MFDS did away with the regulation on the sum of more than two kinds of raw materials required to use general names like fruit, etc.; omitted the need for extra labeling when the name of a product composed of a single raw material is subject to allergen labeling; and devised an exemption provision in character sizes for health functional foods to which the instructions for use can’t be attached. The Ministry introduced an eggshell labeling

system, too. In 2018, the MFDS began labeling for egg producer IDs and breeding conditions and promoted details of the system through electronic display boards at multiplexes, subway train destination equipment and so on.

Image 2-1 Eggshell Labeling System

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 2018, a total of 60 training sessions were conducted for 3,648 persons.

3) Implementation Plan

The MFDS intends to contribute to improving consumers' living quality. To that end, the Ministry will prevent consumer damage from false labels and advertisements based on a consumer-centered food labeling system in line with the「Act on Labels and Advertisements of Food, Etc.」, and continuously upgrade the labeling system to provide accurate information and help consumers to choose products that are suitable for them.

F. Establishment of a Public-Private Joint Monitoring System

1) Operation of the Consumer Food Sanitation Supervisory System

The MFDS is operating a "Consumer Food Sanitation Supervisor" system in order to

encourage active participation of consumers in food sanitation monitoring activities and to ensure fairness, reliability, and transparency in these activities by working with members of consumer groups or people with expertise on this field.

In 2018, 9,510 people were newly appointed as consumer food sanitation supervisors, and a total of 100,976 supervisors participated in monitoring activities on a yearly basis. Inspections were carried out on sanitation conditions of 590,783 food service businesses including restaurants and cafeterias providing food services. The inspections also identified businesses without a license, violation of labeling standards, as well as false·exaggerative advertising activities.

Table 2-13 Activities of Consumer Food Sanitation Supervisors by Year

(As of Dec. 31, 2018, Unit: Person, Case, Source: Food Safety Management Division)

Year	No. of Appointed Persons	No. of Active Persons per Year	No. of Inspected Businesses	No. of Violating Businesses	Details of Violation			
					No License	Labeling	Advertising	Other Charges
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
2018	9,510	100,976	590,783	7,275	415	132	21	6,731

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

In order to facilitate consumer-driven monitoring of food safety and expand consumers' participation, the MFDS operates a report-reward system on unclean · adulterated food, which gives a reward in the range of 10,000 won to 10,000,000 won Act in accordance with the current reward standard and depending on the details of violation. In addition, the MFDS has established a system to reward whistle-blowers on unclean · adulterated food in active cooperation with the Anti-

Corruption & Civil Rights Commission. In 2018, the MFDS accepted 7,885 reports on food suspected to be unclean · adulterated, investigated the status, took administrative measures accordingly, and gave rewards of 1,616,000 won on 218 reports.

Table 2-14 **Reward Payment Status by Year**

(As of Dec. 31, 2018, Unit: Number, 1,000 won; Source: Food Safety Management Division)

Year	Number of Reward Payments	Amount of Reward Payment
2014	535	37,500
2015	332	24,990
2016	307	19,431
2017	78	4,340
2018	218	16,160

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4. Reinforcement of the Safety Management System for Imported Foods

A. Bolstering the Foundations for the Safety Management of Imported Foods and Countering the WTO Dispute on Japanese Foods

1) Bolstering the Institutional Foundations for the Safety Management of Imported Foods

The MFDS introduced the "System for Deferring Import Declaration" in scenarios where a significant hazard breaks out or there is a concern about a potential hazard to public health, and enlarged the One-Strike Out System, which immediately filters

businesses committing serious violations such as falsifying expiration dates or weight of imported foods. The Ministry also prepared a basis for evaluating the sanitary status of by-products, etc., which are defined as edible food in Korea but not abroad (frozen fish head/offal, etc.), before such foods are imported.

The MFDS simplified the requirement for documents to be submitted to declare imported foods and eased facility standards so that ordinary households can serve as online purchase agencies. Such measures are intended to reform unreasonable regulations (10 cases) with no direct impact on safety of imported foods, etc. In this regard, MFDS revised 11 cases of institutional requirements to make sure that business operators voluntarily sell safer food.

The MFDS enabled reliable business operators that keep importing safe food to quickly pass a customs clearance procedure without inspection. With this "Rapid Clearance System for Planned Import", the MFDS induced businesses to thoroughly manage safety of imported foods in advance. As demonstrated by these efforts, the Ministry aims to preemptively respond to changing environments at home and abroad, and going further, create an institutional foundation for guaranteeing the safety of imported foods and public health based on consumers' and experts' opinions.

2) Countering the WTO Dispute Appeal on Japanese Foods

The MFDS restricted the import of Japanese foods in the aftermath of the nuclear disaster in Fukushima in Mar. 2011 (Mar. 11, 2011). It also implemented stronger interim measures after Japan announced in Aug. 2013 that contaminated waste water was being leaked from the crippled nuclear plant; The MFDS introduced a blanket ban on all Japanese seafood from eight prefectures on Sep. 9, 2013 and imposed more testing requirements for presence of other nuclides in case of detecting cesium.

Since then, Japan filed a complaint on our food regulations with the World Trade Organization (WTO) on May 21, 2015 and the international body ruled against Korea in the first ruling. In response, the Korean government filed an appeal on Apr. 9,

2018, pointing to the importance of food safety and on-going radiative contamination in the areas affected by the Japanese nuclear plant debacle. The appeal was prepared by cooperation among multiple ministries such as the Ministry of Trade, Industry and Energy, MFDS, Ministry of Oceans and Fisheries, Nuclear Safety and Security Commission, etc. under the leadership of the Office for Government Policy Coordination. As a result, on Apr. 11, 2019, Korea achieved a brilliant feat of winning the dispute in all major issues in question except some concerns about transparency.

Supported by this WTO ruling, the Korean government will maintain its current import restrictions on Japanese seafood and more strictly manage its safety from radiation to import only safe food.

3) Active Public Communication on the Policy to Safely Manage Radiation Present in Imported Foods

The MFDS reformed the "Safe Management of Food Radiation" section in the MFDS websites to relieve public anxiety regarding Japanese foods and improve public awareness of radiation. Moreover, the Ministry offered information on radiation, its criteria, disclosure of test results at the import stage, WTO dispute procedures and so on. The Ministry also held the "International Symposium on Safe Management of Food Radiation" with participation of British, German and Chinese government officials, and promoted the related policy with two web talks on WTO dispute developments, etc. and two PR videos on safe management of radiation, using buses, train stations and media boards of large shopping malls as platforms for maximum exposure.

The MFDS will pursue two-way communication with the public by increasing the number of "hands-on experiences of radiation test sites" to four times in an attempt to help people understand the radiation policy. Furthermore, the Ministry will share relevant information with the public via online/offline channels to boost their confidence in the government's radiation policy.

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

1) On-Site Inspection of Foreign Food Facilities

Customs clearance tests alone are not adequate to assure the safety of imported foods, given the continually growing volume. In this regard, precautionary measures to manage food safety before import, by means such as on-site inspection of foreign food facilities, have become more significant.

The MFDS selected foreign food facilities (237 facilities) from 21 countries (as of 2018), using test results implemented at import clearance and distribution stages, based on the analysis of their risk including a history of manufacturing non-conforming products and information on food hazards. After the MFDS performed on-site inspection on these facilities, the Ministry imposed import suspension on non-compliant food items or took corrective action on the articles in need of improvement. For the latter, the MFDS executed more comprehensive inspections until the corrective action was fully implemented. In these ways, the MFDS substantiated precautionary safety management of imported foods.

The MFDS will make more efforts to manage the safety of potentially hazardous foods in advance through on-the-spot inspection of foreign food facilities. In addition, the MFDS will implement amendments to the related institution for the efficient operation of this system, so it can suspend import of the foods produced by the foreign facility that refuses, hinders, avoids or does not respond to such investigation requests without due reasons.

2) On-Site Inspection of Establishnents for Livestock Products of Exporting Countries, and Import Sanitation Assessment

For imported livestock products, the MFDS permits their import after assessing the sanitary control systems of the exporting countries. As of 2018, the MFDS evaluated

12 cases of livestock products from 10 countries including Italy. Evaluations of 97 imported items from 49 countries including Finland are presently in the process. The MFDS also examined the sanitary management of 84 registered foreign establishments in 10 countries like the US, Brazil, China, etc.

In case of imported meat, the MFDS improved the evaluation mechanism and stipulated that exporting countries first prove that their sanitary management is of the same level as Korea. The new mechanism will also be applied to processed livestock products such as dairy products and egg products in the future.

Furthermore, the Ministry will implement on-site inspections for 1) livestock products of new exporting countries that have passed sanitation assessment for import and 2) foreign establishments selected as priority items/countries based records of non-compliance and information on food hazards.

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

In 2018, the MFDS carried out sanitary inspection on 86 processing facilities for marine products and requested corrective and improvement measures such as facility renovation, in order to address the matters pointed out during inspection.

Frozen fish heads, offals, etc. are defined as edible food in Korea based on the unique eating habits of the Korean people but this is not so abroad. Hence, the MFDS will designate these items as foods for special sanitary control; decide whether to import them through sanitation assessment like livestock products; and expand and reinforce on-site inspection of foreign food facilities in exporting countries in instances where export of items under special sanitary control has been allowed.

The MFDS will increase the number of signatories involved in sanitary agreements to strengthen the accountability of the exporting countries in terms of safety management of fishery products. This will also enable MFDS to directly check how they manage product safety by inspecting local facilities.

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C. Reinforcement of Safety Management of Imported Food at the Customs Clearance Stage

1) Reinforced Customs Inspection on Imported Food

As of 2018, the number of import cases was 728,114 and the volume of imports reached 18,553,000 tons, up by 47.4 % and 19.4 % respectively from 2013. For more selective and focused inspection, the MFDS analyzed the histories of hazardous substance detection, etc. of imported foods by country · item; differentiated their random sample testing rates depending on the hazard levels; and selected the items that required in-depth inspection. For random sample testing, MFDS utilizes the Observation & Prediction by Endless Risk Analysis (OPERA) mode designed for in-depth inspection of potentially hazardous imported foods.

Table 2-15 **Inspection Status on Imported Foods (including Livestock and Fishery Product)**

(As of Dec. 31, 2018, Unit: case, thousand ton, million dollar, Source: Imported Food Inspection Management Division)

Classification	2014	2015	2016	2017	2018 (p)
Inspection	554,177	598,082	625,443	672,273	728,114
Weight	16,358	17,064	17,261	18,296	18,553
Amount	23,112	23,295	23,438	24,972	27,402
Reject	1,242 (0.22)	1,397 (0.23)	1,250 (0.20)	1,279 (0.19)	1478 (0.20)

* Numbers in the parenthesis ( ) indicate the rate of non-conformance (%), (p) is an estimate.

In addition, the MFDS is presently in the process of establishing an “Intelligent Integration System for Imported Food.” The system will help to remove conflicts and inefficiency arising from the systems being separately operated by area (food, livestock products and fishery products), and support works in the clearance stage, precautionary safety management before import (on-site inspection) and affairs in the distribution stage. The Ministry will adopt a “Risk Analysis System based on Big Data,” which is designed to automatically review the content of the goods declaration for import and analyze accumulated inspection and hazard data. Thus, the MFDS intends to make clearance

inspection of imports more efficient and examine potentially hazardous imported foods more intensively.

2) Wider Range of Inspection Orders for Importers of Potentially Hazardous Foods

The MFDS applied the "Inspection Order Policy" to 11 cases (snacks from Indonesia, products containing puffer fish, litopenaeus vannamei from India, etc.) as of the end of Dec. 2018. The policy was designed to require the importers to prove the safety of the foods they import, to ensure that they take more responsibility for food safety. Meanwhile, the MFDS plans to additionally designate the subjects of "Instructed Inspection (supported with state budget)", which are currently managed under "Inspection Orders (where costs are paid by business operators)." The Ministry will select priority subjects for inspection orders in the clearance stage among the items with a high occurrence rate of hazardous ingredients or a high risk.

In addition to these, the MFDS will specify and streamline the procedures for designating or cancelling the subjects of inspection orders for imported food; prepare a rapid response system to manage non-compliance; and revise existing regulations to establish the inspection order system for the distribution stage.

3) Reinforcement of Capacity of Importers to Safely Manage Imported Food

For securing the safety and quality of imported food, the MFDS issues an education order upon finding non-conforming imported food during customs inspection or distribution inspection. With a view to securing the effectiveness of the Food Safety Education Order Policy, the MFDS has initiated education programs for not only business operators but also hygiene personnel designated by the business operators. Under this program, the MFDS trained a total of 1,105 people under 16 training sessions in 2018.

The MFDS will expand the Education Order Policy to prevent recurrence of nonconformity, educate more people to reap more practical effects, and establish an easy-

to-access online course.

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D. Reinforcement of Safety Management at the Distribution Stage of Imported Foods

1) Systematization of Management Infrastructure at the Distribution Stage of Imported Food

The MFDS carries out safety inspection for ever increasing volumes of imported food during the stage of distribution in domestic markets after customs clearance. This acts as a double safety net along with customs inspection.

The MFDS set up the "Imported Food Distribution Safety Division" to systematically manage the safety of imported food (Mar. 21, 2017), and has implemented a system for comprehensive post-management of imports, which was separately handled by several ministries. According to nonconformity records during customs inspection and overseas hazard information, the Ministry swiftly collects and examines imported foods in the market that might pose a harm; examples include American chicken with nitrofuran metabolites, berries contaminated with radioactive cesium and others. The MFDS took measures like withdrawal or disposal of the contaminated items in the above examples.

Collected/inspected imports during distribution include 1) items that passed through the customs only with documentation for a long period, 2) foods with overseas hazard information, 3) commonly consumed products, and 4) foods with a history of nonconformity. While instruction and examination for imported food sellers focus on entities with a past history of nonconformity, inspection efforts of the MFDS will be mainly focused on potentially hazardous items. Though this, the MFDS will prevent recurrence of hazard and eliminate illegal operations.

2) Systematization of Safety Management for Abnormal Imported Food

In order to block directly purchased overseas food containing hazardous substances, the MFDS carries out joint inspections with the Incheon Airport Customs (from Mar. 1, 2017) and also buys and examines them. In collaboration with the Customs, the Ministry will continue to shut off entry of directly purchased overseas food with hazardous substances; monitor the websites selling these items and buy/examine them; and educate customers on "cautions against direct purchase of overseas food", etc.

When so-called peddlers bring in food for the purpose of self-consumption, inspection prior to the import stage is difficult to be conducted. To overcome such safety management problems, the MFDS has expanded the scope of inspections to twice a week by port (Incheon Port, Pyeongtaek Port, and Gunsan Port). In cooperation with the Incheon Airport Customs, the Ministry prohibits non-conforming products identified during the inspection process from being imported for three months. The MFDS plans to forge a distribution environment where only safety-certified imports can be let in through joint efforts with the Customs.

Table 2-16 Collection and Test Status for Overseas Directly Purchased food over the Recent 5 year

(As of Dec. 31, 2018, Unit: case, Source: Imported Food Distribution Safety Division)

Classification	2014	2015	2016	2017	2018
Inspection	255	444	902	1,002	1,300
Non-conforming	74 (29.0)	99 (22.3)	107 (11.9)	163 (16.3)	107 (8.2)

* Numbers in parentheses ( ) indicate the rate of non-conformance (%).

Table 2-17 Collection and Test Status for Food Carried by Peddlers over the Recent 5 year

(As of Dec. 31, 2018, Unit: case, Source: Imported Food Distribution Safety Division)

Classification	2014	2015	2016	2017	2018
Inspection	368	897	1,230	1,166	1,182
Non-conforming	6 (1.6)	49 (5.5)	33 (2.8)	22 (1.9)	16(1.4)

* Numbers in parentheses ( ) indicate the rate of non-conformance (%).

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

1) Establishment of the 3rd ('18~'22) Safety Management Plan for Genetically Modified Organisms

Based on Article 7 of the「Transboundary Movement, Etc. of Living Modified Organisms Act」, the MFDS crafted a basic policy on safety management of GMOs under the food category; the policy is slated to be executed over five years from 2018 to 2022. The main content of the policy is classified into two. The first covers matters about safety evaluation: improving evaluation criteria for GMOs under the food category and formulating a plan to reevaluate their safety after the passage of 10 years after safety approval. The second part address matters related to safety management: increasing regular inspection of the firms handling GMOs (once → twice a year) to prevent their release into the environment and performing a voluntary inspection system by tapping into corporate self- monitoring.

The MFDS will systematically manage the safety of GMOs under the food category, by creating an annual implementation plan that contains a safety evaluation plan, detailed safety management measures, safety management measures by production process as well as strategy for public communication and public relations, etc.

2) Safety Evaluation of Genetically Modified Foods

The MFDS mandates only genetically modified (GM) foods safety-certified through safety evaluation to be imported, and inspects unapproved items in the import clearance stage before they enter Korea.

In 2018, the MFDS approved 15 GM foods in total – 13 cases of initial evaluation and 2 cases of reevaluation. The Ministry added evaluation items such as base sequence analysis materials for gene stacking events, and effects of gene products on metabolic pathways.

Table 2-18 Approval Status of GM Foods

(As of Dec. 31, 2018, Unit: case, Source: Novel Food Division)

Classification	Agricultural Products	Microorganisms	Food Additives Originating from GM Microorganisms
Approved Items	169	6	24

* Agricultural Products (169): corn 87, cotton 29, bean 29, canola 14, potato 4, sugar beet 1, alfalfa 4

The MFDS will reconfirm safety of three GM foods subject to reevaluation as of 2019, and gather more opinions by improving the open process to collect opinions from the general public regarding the Safety Evaluation Report (draft) on GM foods.

3) Safety Management Including Import of GM Foods

To prevent environmental damage occurring from improper handling of GMOs for food or their discharge (release) into the environment, the MFDS increased the frequency of its instruction and inspection from one time to two times a year. The inspections are conducted to assess whether businesses related to import (production), unloading (storage) and transport of GMOs follow their own safety management plan and whether they comply with the procedures to cope with emergencies such as discharge (release) into the environment. The Ministry has requested relevant businesses to implement their own safety management measures for handling and storing GMOs, along with an environment monitoring plan.

Table 2-19 Import Status of GM Agricultural Products for Food

(As of Dec. 31, 2018, Unit: case, thousand ton, thousand dollar, Source: Imported Food Distribution Safety Division)

Classification		2014	2015	2016	2017	2018
Total	Case	116	121	105	123	116
	Weight	2,233	2,145	2,004	2,254	2,207
	Amount	922,449	662,484	596,899	664,639	692,540
Soybean	Case	38	39	40	40	40
	Weight	1,021	1,029	982	1,043	1,049
	Amount	555,043	433,144	397,757	436,455	451,958
Maize	Case	78	82	65	83	76
	Weight	1,212	1,116	1,022	1,211	1,158
	Amount	367,406	229,340	199,142	228,184	240,582

For import approval, the MFDS plans to keep reviewing the safety management status by business including measures to prevent release into the environment, category management measures, etc. concerning GM agricultural products for food. It is expected that these measures will strengthen safety management of GMOs under the food category.

Furthermore, the MFDS will implement regular instruction and inspection on GM agricultural products by handling phase (import/manufacturing, storage, transport) and by object (facility/equipment, worker, workplace), and perform on-site inspections for every import. The Ministry will also continue to enhance the safety management capabilities of related workers through training programs and devote itself to follow-up management.

4) Follow-up Management Including Labeling of GM Foods

The MFDS and local governments have carried out continued education and examination on labeling of GM food, etc. in the manufacturing · distribution stages in order to guarantee their safety and raise consumer confidence. Inspection results in 2018 revealed 10 cases involving violation of labeling standards.

The MFDS will conduct year-round instructions and examinations on raw materials subject to labeling under the GM foods category, etc. (soybean, corn, cotton, canola, sugar beet and alfalfa), and monitor manufacturing · processing firms using them as raw materials. The Ministry will support the persons concerned to acquire better capabilities by holding education sessions and workshops nationwide.

5) Education · Campaign on GM Foods

In order to provide the public with accurate information on GM foods, the MFDS worked with consumer groups to conduct customized education programs for elementary school · middle school · high school · college students, office

workers, homemakers, school meal managers, etc. In addition, the MFDS developed educational content that external bodies such as local governments and associations can harness for GM food education.

Moreover, MFDS carried out a GM Foods knowledge sharing event on its page, in order to provide accurate information on GM foods and create an opportunity for posting comments.

The Ministry will implement customized outreach/education programs and organize and operate support groups for novel foods, delivering correct information through a variety of communication channels including Blogs, Facebook, etc.

6) Temporary Standards · Specifications for Novel Food Ingredients

From 2010, regarding raw food materials to be used for the first time in the country, the MFDS has been examining the safety data submitted by the applicant and holding expert meetings. MFDS approves the use of novel food raw materials only for individual applicants based on the results.

In 2018, the MFDS held 18 briefing sessions such as "Technical Consulting Outreach" for government agencies and local governments to facilitate development of novel raw food materials, and approved 9 cases including pine cone extracts and noni leaves. Besides, the MFDS canceled the temporary requirements for allulose (10 cases) and acer tegmentosum extracts (2 cases) among novel materials and registered them to the Korean Food Standards Codex, changing them to materials available to all.

The MFDS will expand services by means of preliminary consultations to improve convenience for people, and collaborate with other ministries like the Rural Development Administration especially to support use of novel raw materials with high added values e.g. approved plants and insects.

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5. Reinforcement of Safety Management for Alcoholic Beverages

A. Background

The MFDS has actively pursued policies for safety management of alcoholic beverages in accordance with changing alcoholic market conditions and in keeping with national interest and requirements for the safety of alcoholic beverages. However, there are still discrepancies in technical education for safety management and quality improvement, and thus it is necessary to develop a systematic and professional support system. In addition, since the alcoholic beverage management system is under supervision of multiple ministries, coordination among the ministries and harmony among laws and regulations on alcohol are required so that effective policies can be devised and implemented.

B. Achievements

To run a "Sanitary Management Grading System" for alcohol manufacturers, the MFDS evaluated safety management levels of the entire alcohol manufacturing industry. In order to prevent alcohol safety accidents, the MFDS has established an off-flavor autonomous management system for beer manufacturers, planned inspection by theme or season, etc. In addition, the MFDS has been continuously raising the hygiene requirements for the alcohol industry by supporting small businesses solve field issues and performing educational programs on sanitary safety management through regional alcoholic beverage safety management centers. The Ministry also assists alcohol manufacturers by means of an autonomous alcoholic beverage safety management nurturing system, which helps enhance their hygiene levels.

1) Continuous Improvement of Hygiene Level of Alcohol Manufacturers

Because hygiene levels of alcohol manufacturers vary by company, the MFDS operates a "Sanitary Management Grading System" that differentiates and manages access/inspection by company to manage the companies efficiently within limited administrative resources, and differently managed them in 2018 according to sanitary evaluation results of the previous year.

The hygienic management compliance rate of the alcohol industry has improved as evidenced in higher hygiene levels and safety of alcoholic beverages thanks to the education and technical support provided for substandard companies. The MFDS offered tailored guidance and education to them, significantly improving manufacturers' awareness of the duties stipulated in the Food Sanitation Act.

The MFDS prepared an "Autonomous Management Manual for Beer Off-flavors" that covers topics such as types of off-flavors, off-flavor management methods by process, etc. By promoting the autonomous off-flavor management system for beer manufacturers, the Ministry was able to bring down the number of reports of consumer complaints on off-flavor beer. Moreover, the Ministry applied the system (May 2018) to small beer (so called homemade beer) manufacturers given the dramatic growth in their numbers of late.

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

The MFDS strengthened the collection · inspection of alcoholic beverages popular within specific classes as well as those commonly consumed by season. The MFDS carried out rapid collection · inspection and inspection · examination of alcoholic beverages by analyzing the status of the gifts exchanged and ancestral rites widely observed during specific periods such as the Lunar New Year's Day and Chuseok (Korean Thanksgiving Day), and took prompt action upon receiving hazard

information and civil complaint reports at home and abroad.

In addition, to forestall safety accidents related to alcoholic beverages, the MFDS established measures to verify that the distribution/sale agents observed the standards for storing and handling alcohol, and took action such that no product is left unchecked from the manufacturing stage to the distribution stage.

The MFDS conducted special inspection on companies using underground water for food, and as part of preventive safety management, investigated their use of underground water and provided an alarm service to them so that they could take inspection within a set period. The Ministry made a water quality manual to promote use of safe underground water and disseminated it to alcoholic beverage manufacturers.

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

The MFDS designated organizations specialized in alcohol beverages as regional "Alcoholic Beverage Safety Management Support Centers" and operated them. Under this system, alcoholic beverage specialists visited small and medium-sized alcohol manufacturing facilities, analyzed the manufacturers' problems and provided them with customized consulting and safety management information. In addition, the specialists educated the manufacturers on food sanitation laws and regulations and had them practice analysis. By doing so, the MFDS was able to establish a systematic support system for alcoholic beverage manufacturers.

The MFDS operated a study tour program for excellent alcohol manufacturers, shared best practices to expand HACCP coverage for alcoholic beverages, and enhanced communication with companies by listening to their issues on the spot and holding civil complaint briefings to enable them introduce amendments.

With the growing popularity of homemade beer, the Ministry hosted technical support seminars to manage its hygiene and safety, generated and disseminated a manual on washing the kegs used for beer distribution and assessed the validity of washing.

The MFDS intends to enlarge the "Autonomous Alcoholic Beverage Safety Manager" system that fosters independent specialists who carry out voluntary safety management activities and take measures to prevent illegal behaviors. To that end, the MFDS has implemented education on quality · safety for newly designated and existing personnel.

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

Using new online channels such as YouTube and Podbbang (At Meal Table It Chatting), the MFDS continues to deliver information on alcohol types that people use in their daily lives. The information thus shared includes: a safe home brewing method, cautions about alcohol made with wasp, hygiene management for homemade beer, avoiding alcohol mixed with energy drinks, appropriate drinking at year end, and how to store alcohol in winter.

Meanwhile, the issues related to the presence of foreign substances arising from reuse of empty alcohol bottles were brought to the MFDS' attention. To resolve this issue, the MFDS organized the "Public Design Unit" (an institution developing and operating policy from people's point of view) and staged campaigns to reduce the number of foreign substances in cooperation with the Korean Alcoholic & Liquor Industry Association under the slogan, "If you use bottles cleanly, clean bottles return to us." These efforts by the Ministry worked to transform consumer behaviors and perceptions.

C. Improvement Plan

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

To improve the efficiency and level of safety management for alcoholic beverage manufacturers, the MFDS plans to classify the manufacturers into autonomous,

general, and priority control grades depending on hygiene levels. This would help to ensure the autonomy of excellent companies and strengthen hygiene management of unsanitary companies. In addition, the MFDS plans to adopt measures for pre-emptive management of commonly consumed alcoholic beverages according to consumption trends by specific period or season. Moreover, the Ministry is working to reinforce the management of foreign materials in alcohol by conducting professional education for the manufactures and performing campaigns to prevent foreign materials from being mixed with alcohol.

2) Support for Alcohol Safety Management and Reinforcement of Promotion

The MFDS plans to reinforce its risk prevention management plan by designating and operating Safety Management Support Centers for alcoholic beverages in 4 regions in support of small-sized businesses, and carrying out consultations on the spot. Customized support for managing sanitation · quality · off-flavor, and an autonomous inspection system for off-flavor beer will be established to facilitate a high-quality, safe manufacturing environment. Furthermore, the Ministry will offer education programs for new and existing "Autonomous Alcoholic Beverage Safety Managers" to improve safety · quality management capacities of alcohol manufacturers. The Ministry will also promote relevant and practical safety information on alcoholic beverages in various forms, covering topics such as healthy drinking habits and safe methods to brew 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

For thorough management of food safety, it is necessary to set the standards for residual substances such as pesticides and veterinary drugs without existing criteria, draw up measures to reduce harmful environmental contaminants, and manage the standards and specifications on a regular basis. As the probability of occurrence of new types of food poison is likely to increase, microorganisms should be safely managed by expanding the scope of management to a greater variety of food poisoning bacteria, etc. There is also the need to resolve trade conflicts deriving from different standards and specifications by country. Given that new toxins and hybrid species are generated as a result of climate change, safety of conventional raw materials used for food is to be reevaluated.

2) Achievements

A) General Foods

The MFDS made efforts to identify and improve regulations on the standards and specifications for food that guide the domestic food industry and enable development of various foods in a safe range as a measure of institutionally supporting their competitive edge. The Ministry added three analogues of anti-erectile dysfunction drugs with a defined structure (isopropyl nortadalafil, descarbonsildenafil, dithiopropylcarbodenafil), an analogue of anti-obesity drugs (chlorosipentramine) and five illegal drug ingredients (yohimbine, icariin, cascaroside, phenolphthalein) to the list of adulterated substances that shall not be reported, and thus created a ground for constant management of these items. The MFDS established the standard for the maximum content of total acids (under 6.0 w/w%) to prevent incidents caused by consumption of sour candies. Apart from this, the MFDS set the standards for how to wash fruits and vegetables to ensure hygienic lunch boxes, stipulated that cooked food be frozen for packaging, and instituted the standards for thawing frozen fishery products. The MFDS also established common standards for infant foods except special purpose food items to support diverse products manufactured and sold as infant food, and newly defined the safety standards for senior-friendly food.

In 2019, the MFDS will safely manage food at a level that can be recognized by the public by generating standards and specifications for meal kit-type products, reflecting consumption trends, and strictly controlling the traces of metal foreign substances present in powder products.

B) Raw Materials

To reassess the safety of raw materials used for food, the MFDS set up DBs on 305 items with information on raw materials, toxicity, and impact on the human body. The DBs include information on food raw materials and food and drug raw materials that can be used in a limited way. The Ministry revised food standards and specifications

so that six fishery products like propeller clams can be used as raw materials.

C) Food Poisoning Bacteria

The MFDS reevaluated 12 specifications for staphylococcus aureus and clostridium perfringens that are detected in ice creams, dried meat, etc. In 2019, the Ministry will reevaluate clostridium perfringens in soy bean sauce, pickled seafood, processed seasonings, etc. to set their specifications in terms of a statistical concept.

D) Pesticide Residue

To prevent misuse and abuse of pesticides and manage imported pesticides, the MFDS set the standards for Maximum Residue Limits (MRLs) of the pesticides legally used at home and abroad. Starting Jan. 1, 2019 the MFDS also fully implemented the Positive List System (PLS) that applies a uniform detection limit (less than 0.01㎎/kg) except those with MRLs (notification no. 2018-8, Feb. 22, 2018). For this, the MFDS organized and operated the "Pan-Governmental Council for the Safety Management of Residues" in cooperation with 11 agencies such as the Office for Government Policy Coordination, Ministry for Food, Agriculture, Forestry and Fisheries, etc. and held 35 domestic and international briefings and meetings for stakeholders to help them prepare for new institutions. In addition, to minimize possible damage from non-standardized pesticides, the MFDS set MRLs for 267 cases of legally used overseas pesticides, such as picoxystrobin for barley, through typical procedures for setting the criteria. The MFDS established group MRLs for 67 cases of 39 pesticides like chlorantraniliprole used for produce cultivated in small areas (leafy vegetables and stalk and stem vegetables), and set the standards for 3,578 cases of temporary MRLs requested by farmers, food companies, embassies, etc. These included 60 MRLs that are applied in instances where pesticides used in the past remain in soil for a long time or when unintentional soil contamination by pesticides occurs due to continuous cultivation.

E) Pesticides and Veterinary Drugs Present in Livestock and Fishery Products

The MFDS enlarged the MRLs for veterinary drugs like novobiocin, ceftiofur, etc. present in livestock/fishery products. The scope was applied to minor species and milk and eggs according to domestic permission, reflecting recent consumption patterns. The MFDS also amended MRLs for veterinary drugs by increasing the range of prohibited materials, etc. to prevent the use of unsafe veterinary drugs in food. Furthermore, the MFDS set MRLs for 23 types of pesticides including methamidophos for livestock products to thoroughly manage insecticides and enable safe distribution of eggs. The Ministry drew up a Comprehensive Plan (draft) for the PLS of livestock/fishery products in consultation with related ministries for their safety management.

F) Food Contaminants

To maintain Koreans' Tolerable Daily Intake (TDI) of 19 contaminants e.g. lead and cadmium at a safe level, the MFDS has been monitoring their contamination levels every year; as a part of this drive, the standards and specifications for dioxins/PCBs and benzopyrene were reassessed in 2018.

The MFDS introduced and toughened up the standards for lead and cadmium and mold toxins to reflect the concerns raised by climate change, environmental pollution and dietary change, established the standards for inorganic arsenic and enforced manufacturing standards for processed food using brown rice, rice bran, rice germ, hijikia, and gulfweed so as to reduce exposure to inorganic arsenic. The MFDS upgraded the standards and specifications for contaminants to maintain reasonable levels by improving heavy metal standards for krill oil and deleting the total standards for tofu, etc. based on opinions by the relevant ministries (Ministry of Agriculture, Food and Rural Affairs (MAFRA) and Ministry of Oceans and Fisheries) and businesses and associations and communications with the field.

3) Improvement Plan

The MFDS plans to continue to implement the Project Phase 1 to Reevaluate Food Raw Materials ('19~'22) for securing safety of plant raw materials, and preemptively respond to future technology by constructing a basis for the safety evaluation of plant raw materials based on new concepts.

In 2019, the MFDS will reassess the standards and specifications for 3-MCPD and melamine; quickly set the MRLs for pesticides so that non-compliant products will not reach the market in the wake of complete enforcement of the PLS for agricultural products grown in small areas (Jan. 2019); and establish MRLs for domestically unregistered pesticides that are frequently found in imported food. The MFDS will also set more MRLs for pesticides at the production stage to deal with a tasks transferred from the MAFRA and manage agricultural products more safely.

Furthermore, the MFDS will apply the PLS to livestock/fishery products for stronger safety management of pesticides and veterinary drugs found in these products and craft a comprehensive management plan. The MFDS will continue setting MRLs for foods (species) with no MRL, though they are on the market, to enhance management of their safety.

To cope with climate change, the MFDS plans to review active safety management measures considering frequency of occurrence, food poisoning cases and major countries' control status regarding food poisoning bacteria without preset specifications. In addition, the Ministry will examine the safety of fish types, which are newly introduced thanks to rising water temperature and advanced fishing technology, review domestic crops for special purposes and approve more food raw materials based on new concepts.

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

A. Management of Food Additive Standards and Specifications

1) Background

The MFDS has reviewed safety of food additives, designated new food additives and revised their use standards so that businesses can conveniently manufacture and provide quality food using food additives.

Meanwhile, given that consumers feel uneasy about the additives owing to negative media reports despite awareness of their necessity, the MFDS stages a campaign to improve public awareness on food additives.

2) Achievements

The MFDS set the standards for the minimum amount of use concerning 14 items such as guar gum, and canceled designation of 20 synthetic flavors/ food additives with safety problems. The MFDS also prepared the standards for use of five aluminum-containing additives including alum to lower the level of aluminum consumption among the public.

The MFDS newly designated peroxyacetic acid as a disinfecting agent, to manage microorganisms in livestock products like poultry during slaughter and handle them hygienically. The Ministry also approved food additives such as propionic acid in the existing range that are accepted as natural origin and not used artificially without documentation, and set up a procedure for substantiating their natural origin. The MFDS deleted acid level standards among ingredient specifications of koji for making traditional alcohol. The MFDS designated nickel, β-Amylase, pearl pigment, and Potassium caseinateo to promote the food industry; expanded uses of cysteine

hydrochloride as a fragrance ingredient; and allowed lactase and β-carotene to be made with microorganisms or materials other than the already permitted ones.

Additionally, to improve public awareness of food additives, the MFDS created professional content to ensure that consumers can easily understand details on their safety, and disseminated this content through the search portal Naver.

The MFDS has been making efforts to improve the awareness of food additives among restaurant and cafeteria attendants, school meal personnel, food hygiene-related civil servants and hygiene inspection agencies through intensive education and promotion sessions (15 times in total).

3) Improvement Plan

There was a case where people inhaled nitrous oxide to experience its hallucinogenic properties far from its original use as a food additive or spray. In response, the MFDS set the standards to enable prohibition of manufacturing/import/distribution of nitrous oxide in small cartridge forms while allowing its manufacturing/distribution using 2.5 L high pressure metal containers. The Ministry will register about 100 synthetic flavors whose safety has been recognized internationally, and ease the standards for using sorbic acid and gilt since their necessity was approved at the request of the food industry.

As regards 34 items including fragrance ingredients with a daily standard for consumption, the MFDS will review their ingredient specifications and reassess the suitability of the standards for use scientifically, and if necessary, amend them.

The MFDS will keep making and providing online campaign videos containing accurate information on food additives, to improve public awareness.

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

1) Background

The MFDS has improved the standards and specifications for utensils, containers, and packaging by examining hazard information posted by major states and reviewing the safety of new hazardous materials. Besides, the Ministry delivers safety information to prevent anxiety from spreading among consumers affected by inaccurate media reports, etc.

2) Achievements

The MFDS integrated the "Rules on the Specifications of Containers, Etc. for Livestock Products" with the "Rules on the Standards and Specifications for Utensils, Containers, and Packaging for Food." Furthermore, the MFDS expanded the ban on the use of Bisphenol A (BPA), Dibutyl Phthalate (DBP) and Benzyl Butyl Phthalate (BBP) in feeding bottles (including pacifiers), infant utensils, containers, and packaging to assure preventive safety and match the Korean standards with international ones. The MFDS changed the specifications for polyethylene and polypropylene materials to permit all food makers to use damp-proof containers for dry food. These were approved as temporary standards, and specifications and revised expressions and provisions related to recycled synthetic resin were provided to clarify them.

The MFDS provided professional information on how to properly use "metal dishes", "foil, wrap and refrigerated containers", "PTFE and PFCs" and "infant dishes."

3) Improvement Plan

The MFDS will reevaluate contaminants that might come from utensils, containers,

and packaging, and arrange material categories and standards for raw materials such as synthetic resin based on the status of their management in major states and domestic/international use cases. The Ministry will keep delivering useful information for everyday life such as how to use disinfectants and sterilizers for utensils, containers and packaging.

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section 3

Expansion of a 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, it is essential to provide something safe and healthy to eat. During infancy and childhood, cognitive abilities develop dramatically along with brain and physical development. 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 essential for growing children.

Meanwhile in Korea, the increasing participation of women in economic, social, cultural, civil and political activity, the government's review of its policy of providing free child care for children and the increasing parental demands for professional

child care services have led to a dramatic increase in the number of children cared in kindergartens and child care facilities from 0.8 million children in 2005 to 2.14 million children in 2018. While interests in child care services have grown due to the increase in the number of children attending these facilities, parents are also experiencing increased anxiety regarding children's meal services as there has been media coverages on usage of expired and/or spoiled foods in the meal service industry. Most of children's meal services are doing their best to provide children the safest and healthiest food possible. However, small-sized businesses face difficulties employing experienced professional dietitians and this in turn increases the risk of food safety issues. For the safety management of children's meal service facilities, MFDS established the Center for Children's Food Service Management in cooperation with local governments and carried out sanitary and nutritional management of children's meal service facilities with the experts and dietitian at the center.

B) Achievements

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

Beginning with 12 Centers for Children's Food Service Management in 2011, MFDS established and has been managing 22 centers in 2012, 88 centers in 2013, 142 centers in 2014, 190 centers in 2015, 207 centers in 2016, 215 centers in 2017 and 220 centers in 2018. MFDS is also supporting food safety management for a total of 34,292 children's meal service facilities and 124 ten thousand children.

The main roles of the Centers for Children's Food Service Management include regular visits to daycare centers and kindergartens to guide sanitation safety and nutritional management, provision of sanitation and nutrition management assistance for targeted audiences (children, facility, principal, parents), development of diet plans for children, and consultations on sanitation and nutrition.

The surveys on directors and teachers at daycare centers and kindergartens that are supported by the Centers showed high satisfaction scores of 86.8 points in 2013, 89.6 points in 2014, 91 points in 2015, 91.0 points in 2016, 90.4 points in 2017 and 88.2 points

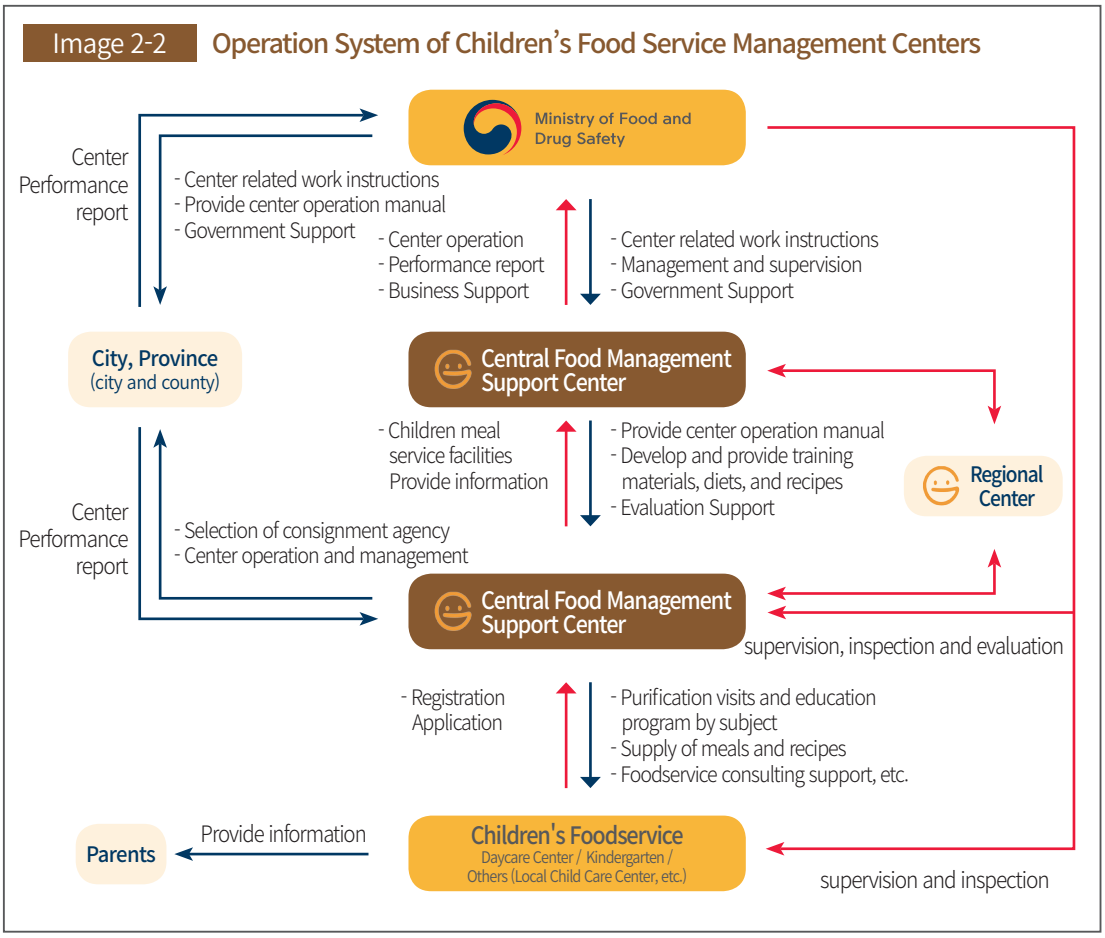
in 2018. The Center's efforts received a lot of support and positive responses, with 87.0 points in 2015, 88.9 points in 2016, 89.9 points in 2017 and 92.0 points in 2018 from the parents since a large number of children learned to wash their hands before meals and eat balanced meals. A survey on the cost-effectiveness of the Centers' efforts showed results at around 11.1~15.7, which amounts to a maximum of 1.356 trillion won.

To promote the important role that these Centers for Children's Food Service Management carry out to ensure the safety, sanitation and nutritional quality of our children's meals, MFDS developed booklets, posters, leaflets and activity booklets for the directors at daycare centers and kindergartens and parents.

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

To effectively support and manage the Centers for Children's Food Service Management that are being established across the country to reach 220 Centers in 2018, MFDS needed an exclusive organization that can supervise the centers. Also, the regional centers' works related to providing educational materials about sanitation and nutrition, meal menus, recipes and sanitary food information were plagued by inefficiency and inconsistency. To solve this issue and to improve the works of the regional centers, the「Special Act on Safety Control of Children's Dietary life」was revised (Jan. 28, 2014, effective on Jan. 29, 2015) and, by securing budget for 2016, the National Institute of Food and Nutrition Service (NIFNS) was established. With these changes, the regional centers were able to focus on field-oriented works while the headquarters management center provided support and supervision for efficient, standardized services of the regional centers.

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



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

C) Implementation Plan

With the Centers for Children's Food Service Management established to support all children at child care facilities and kindergartens and the CCFSM Headquarters established to supervise the regional centers' operations, MFDS will strengthen the

system for supporting the regional centers and meal service facilities across the country, improve the quality of meal services and establish an efficient food safety management system that can assure parents of their 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 on a steady rise, and the phenomenon acquires graver dimensions considering that it 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 the recent incidents related to children, the MFDS recognizes the need to establish comprehensive and systematic measures for children's food safety and plays its role as a control tower for all related work.

B) Achievements

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

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

As of Dec. 2018, the MFDS granted permits to 2,160 exemplary shops not selling

"high-calorie·low-nutrition food" or "high-caffeine food" in 8,357 Green Food Zones around nationwide schools to apply the MFDS logo or use it in advertising.

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

In Korea, snacks high in sugar, fat and sodium e.g.; similarly, confectionery, drinks, bread, ramen etc. are popular than fruits and milk and such change in dietary patterns has resulted in a growing number of overweight and obese kids since 2008. Especially, the consumption of carbonated drink by primary school students increased 1.8 times compared to 1998. The World Health Organization (WHO) and UN Food and Agriculture Organization (FAO) warned that, if sugar intake is not limited under 10% of total calories, kids will be at risk of chronic disease like obesity.

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

The standards to publish nutrition facts of high-calorie·low-nutrition food were set based on the opinions of experts and various stakeholders. Consumers can now figure out whether a food is of the high-calorie·low-nutrition category using the labels on nutrition facts and food types. The MFDS operates a program (web-version) to determine high-calorie, low-nutrition food on the "Food Safety Korea" homepage at http://www.foodsafetykorea.kr. to help consumers conveniently use the information.

In Jul. 2013, the MFDS amended the "Special Act on Safety Management of Children's Dietary Lifestyle", prohibiting schools and exemplary shops from selling high-caffeine food along with high-calorie·low-nutrition food, and restricting and banning their commercials via broadcast, etc. In addition, the Ministry forbade the sale of high-caffeine food at schools from Sep. 2018. The MFDS regularly updates and notifies a list of high-calorie·low-nutrition food on its homepage to guarantee consumers' right to know and provide convenience to sellers.

The MFDS has made continued efforts to promote healthy eating habits to children. In doing so, the MFDS prohibited sale, etc. of alcohol bottle-shaped foods that might

induce children to start drinking at early age, foods that may stir up a speculative drive or sexual curiosity in children and thereby cause harm to their soundness of mind, as well as foods with such pictures or phrases.

The MFDS operates the "Quality Certification System for Children's Favorite Foods" to encourage businesses to manufacture, process, circulate and sell safe and nutritious food for children.

For quality certification, the MFDS evaluates whether a food conforms to standards for safety, nutrition and use of food additives. The relevant logo and letters can be labeled on the containers and packages of certified products.

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

Based on the "Special Act on Safety Management of Children's Dietary Lifestyle", Korea limits and forbids TV commercials for high-calorie, low-nutrition food and high caffeine food, as well as advertisements that are likely to lure children to buy goods. 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. With regard to the ads likely to entice children to buy goods, if broadcast or online advertising is found to offer toys other than food at no charge or provide giveaways likely to seduce kids to make purchases, such adverts are immediately is banned.

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

According to Article 23 and 24 of the "Special Act on Safety Management of Children's Dietary Lifestyle", the MFDS established the Children's Dietary Safety Index by objectively monitoring and assessing efforts and environmental improvement of local governments to manage children's diets more safely. The MFDS harnesses the indices to improve and implement policies for the safety of children's dietary life.

The nation's statistical indices, surveyed every three years, are based on 29 detailed indicators in three areas of safety, nutrition, and recognition·practice of children's dietary guidelines, which are helpful in understanding children's eating habits. The

indices serve as an assessment tool for local governments to understand the safety and nutritious levels in children's meals.

According to the results of the 2017 survey, children's diet safety and nutrition levels generally improved compared to those of 2014 (scores: 67.55 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 children's diet safety levels have become similar regardless of the areas where they live.

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

Since children lack knowledge of food and nutrition, and do not recognize the importance of health, they tend to prefer 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 Safety Management of Children's Dietary Lifestyle" specifies the requirements for education and publicity campaigns related to children's favorite foods, so that all children can develop healthy and safe dietary habits. Under the Act, the heads of elementary schools in particular are required to regularly conduct education on safety and nutrition as necessary for managing children's dietary habits.

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

Further, in 2018, the MFDS developed various educational instruments e.g. a card game for reducing sugar, educational workbook, drink cards, etc. to facilitate dietary education, and produced an e-book to support online education and help people use educational texts more conveniently.

The MFDS operated a professional course to reinforce school nutritionists' (nutrition teachers') capabilities and skills to heighten the quality of food safety and nutrition education. The best classes were identified by holding the 7th Best Class Contest in order to facilitate and promote dietary education and motivate participants.

The Ministry continues to educate the general public through exhibitions and hands-on experience pavilions to make children and their parents understand the safety policies governing children's diet. Ultimately, the initiatives aim to forge a healthy eating environment for children and develop their ability to select food wisely.

C) Implementation Plan

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

The MFDS as a control tower of children's food strives to protect them from safety incidents and create an environment for sale of safe and healthy food by means of stronger hygiene and safety control. To that end, the Ministry plans to implement multiple food safety policies, such as strengthening supervision of business establishments susceptible to poor hygiene and guiding the owners to strictly comply with food safety guidelines on their own in conjunction with local governments.

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

The MFDS has been making efforts to 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 learn about and buy certified foods, and reasonably amend institutions including certification standards.

In an attempt to prevent children from excessive consumption, the MFDS is also

trying to expand the scope of the current ban on sale of children's foods with high caffeine levels in school to a ban on all high caffeine foods like coffee, starting Sep. 2018. The Ministry plans to oversee and inspect its implementation.

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

The MFDS intends to induce companies manufacturing children's favorite foods to improve the ingredient mixture ratios and manufacturing processes, and thus create an environment where they offer safe and nutritionally balanced foods. For this, the MFDS will constantly monitor not only the sale prohibition and ad restriction of high-calorie, low-nutrition food and high caffeine food at schools and exemplary shops, but also continue with the restriction of TV commercials and banning of advertisements that lure kids to make purchases.

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

With a view to improving the safety level of children's eating habits, the MFDS plans to survey, evaluate, and publicize the "2020 Children's Dietary Safety Index", which will objectively confirm and evaluate 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

The MFDS will continue to proactively promote the safety management of children and adolescents' diets by offering stronger support in terms of materials and tools for food safety and nutrition education. This is intended to make sure that children and adolescents can choose safe and healthy foods for themselves.

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2. Prevention of Food Poisoning through Building up Hygienic Surroundings for Restaurant and Meal Services

A. Strengthening of Measures to Prevent Food Poisoning and Supervision on the Safety of Group Meal Services

1) Adoption of prompt measures to prevent spread of food poisoning

A) Background

Outbreaks of collective food poisoning have shown an oscillating trend between increase and decrease every year and in 2018, 363 cases in which 11,504 food poisoning patients were reported. The sharp increasement was shown due to the large-scale incident caused by chocolate cakes, particularly. Among the causative agent of food poisoning average of the recent five years), norovirus has been the biggest with 14.7 % (52 cases), followed by E. coli with 13.1 % (46 cases), and parasite like Kudoa with 7.3 % (26 cases). Among reports (cases) of norovirus for the recent two years (2016-2017), the infection rate between persons represented 45 %. Against this backdrop, there is a growing need to rapidly counter its spread through vomitus, feces, and air.

B) Achievements

Last September when the food poisoning incident due to chocolate cakes took place, the MFDS organized a Crisis Response Headquarters, quickly identified the food item that caused food poisoning by pan-government cooperation with the Korea Centers for Disease Control and Prevention (KCDC), Ministry of Education, etc. and quickly arrested the spread of the disease. After a report on a suspected food poisoning patient (12 p.m. on Sep. 5, landline), the MFDS analyzed the relevant school meals, checked the same batch of chocolate cakes, issued a “warning against eating cakes” to all schools (4 p.m. on Sep. 5) and banned the distribution/sale of related products (5 p.m. on Sep. 6). The Ministry then confirmed the match of DNA fingerprints of salmonella

detected from the affected students' bodies, etc., chocolate cakes stored at the school and distributor's facility, and liquid egg whites as their raw material, and swiftly finalized the same *Salmonella thompson* as the cause of food poisoning (5 p.m. on Sep. 10). This is how the MFDS defined the cause of the food poisoning outbreak.

During the Pyeongchang Olympic Games in Feb. 2018, patients infected with norovirus were reported. The MFDS made all-out efforts to contain further infections: investigated underground water, group meal services and patients to find the cause in coordination with related ministries including the KCDC, and inspected food & beverages in advance during the event by mobilizing fast investigation vehicles. As a result, the number of infected patients were only seven – four athletes and three coaches, which was far smaller compared to the number of occurrences at the previous Olympics.

The MFDS holds a pan-government consultative meeting for food poisoning countermeasures three times a year to respond to food poisoning efficiently and quickly. This serves as a close collaboration system among relevant bodies in the event of an emergency.

C) Implementation Plan

The MFDS plans to heighten the reliability of administration by reviewing the detailed procedures adopted by implementation agencies for the investigation on foodborn outbreaks to make sure that they could consistently conduct the procedures. In order to quickly inspect suspected foods and surroundings on the spot and conduct preliminary examination of food raw materials at international events, etc. a mobilizing fast investigation vehicle will be introduced, developing its capacity for the inspection on foodborn outbreaks.

By means of an early warning system, the MFDS will provide specific information to help persons related to meal services more actively prepare against foodborn outbreaks when they receive text messages.

2) Performance of safety management activities to prevent food poisoning

A) Background

During the summer of 2018 (Jun. 1~Aug. 16.), the nationwide average period of heatwave recorded an all-time high of 29.2 days since 1973 when statistics started to be compiled Given the climate-change related rise of temperature at cooking places, etc. food poisoning bacteria are also highly likely to increase and lead to more incidents of food poisoning. Therefore, it is necessary to proactively prevent food poisoning by occurrence timing, cause and subject. Now a day, school meal services are the more provided with a ready-made format, and not cooked food at schools, there is a higher possibility of large-scale food poisoning outbreaks across the country.

Although foodborn illness occurs most frequently at schools, kindergartens/daycare centers and companies are also not safe. In this context, there is a need for close cooperation between related ministries to remove blind spots in preventive action. To fundamentally forestall food poisoning, it is necessary to establish a more scientific basis that can improve the rate of precisely determining food poisoning causes.

B) Achievements

To promote methods for prevention of food poisoning, the MFDS produces and broadcasts videos on how to prevent food poisoning arising from common bacteria such as E. coli, Campylobacter, Salmonella, Vibrio parahaemolyticus and norovirus in foods. In addition, in preparation for seasonal weather issues and a possible increase in norovirus food poisoning, the Ministry promoted monthly information on cautions, produced a series of videos and held a UCC contest to induce people to practice “Let’s wash hands all together.”

In 2018, the MFDS jointly examined schools and food suppliers (15,523 places) together with the Ministry of Education and local governments at the start of school terms in spring and fall, and implemented special inspection of schools, etc. with a history of violating the Food Sanitation Act (919 places in 2018).

The MFDS also provided education to (688 times) to personnel (78,535 persons) concerned with school meals—such as school principals, dieticians (nutrition teachers), cooks, etc. in conjunction with city/province education offices, and conducted training on prevention of food poisoning for meal service managers and cooks (22,692 persons) at social welfare facilities.

The MFDS thoroughly examined whether there are food poisoning bacteria in agricultural/livestock/fishery products at the production stage, analyzed production conditions like soil and water at farms, ranches and slaughter houses, and laid a foundation to acquire advanced information on genes of food poisoning bacteria by introducing the Whole-genome Analysis Equipment. The MFDS regularly inspects the normal operation of the school devices, etc. used to sterilize underground water, and monitors food makers (684 cases in 2018) using underground water regarding norovirus, etc.

C) Implementation Plan

In order to address the issues caused by climate change including the drastic increase in the number of scorching hot days last summer, the MFDS will provide manuals tailored to each facility considering the status of food poisoning outbreaks, e.g. E. coli in summer and norovirus in winter. Especially, the MFDS is working to develop alternatives to be used for school meals instead of diets with a high possibility of food poisoning in summer, and deliver related information.

As the possibility of large-scale foodborn outbreaks exists owing to the nature of food materials supplied to schools, the Ministry will obtain information on the materials and select the main suppliers so as to strictly manage the quality and hygiene of food materials supplied to school, and forestall food poisoning more effectively.

The MFDS will prepare the grounds to inspect more vulnerable facilities like daycare centers and kindergartens, and enhance education/promotion to guide people to practice the rules for personal hygiene such as washing hands. By doing so, it will be possible to prevent secondary infection in case of a outbreak originated from norovirus.

The MFDS will also make efforts to acquire more professional capabilities to detect small but frequent foodborn illness at restaurants early on and thereby respond to food poisoning in an early stage. The Ministry will consolidate the scientific infrastructure to raise the rate of precisely determining food poisoning causes.

B. Building up a Control System for Creating Favorable Hygienic Surroundings at Restaurants

1) Improving the hygiene level of restaurants by activation of a hygiene grading system and reformation of the food culture

A) Background

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

B) Achievements

In order to enforce and facilitate the hygiene grading system and secure a sufficient number of evaluation personnel, the MFDS operated a systematic education program for evaluators and nurtured 471 evaluators. In addition, the MFDS provided field-customized technical support for evaluation items and standards for 1656 small business owners who wanted to join the system (106.3% compared to the goal of 1,557 business places). In 2018, 4,597 general restaurants applied for the designation of a hygiene grade and 1,359 restaurants received it.

To promote the restaurant hygiene grading system and smoothly implement a project for improving the kitchen culture, the MFDS held nine briefing sessions for public officials and business operators. Besides, the MFDS formed a consultative body composed of about 30 participants including consumer group members, 17 city/province public officials and experts from relevant associations and academia, and held quarterly

meetings to gather opinions from the parties concerned and share information.

The MFDS amended the "Rules (Notice) on Managing Designation and Operation of Restaurants", deleting evaluation items irrelevant to hygiene such as welfare benefits for employees and the subscription to insurance policy for protecting consumers (amended on May 29, 2018), and came up with a procedure and method to extend the expiration date of the hygiene grading system (amended on Dec. 28, 2018). The MFDS enlarged the scope of the system from general restaurants to include cafeterias and bakeries.

To ensure that the public recognizes the hygiene grading system as a brand symbolizing improved sanitation, the MFDS has created promotional videos and publicized them through various media like TV and movie theaters. Apart from this, the MFDS promotes designated restaurants using Internet banner ads and a delivery app (*baedal-ui-minjok*, The People of Delivery) to help people easily access eateries certified for hygiene. Going further, the MFDS intends to share information on best restaurants via SNS so that more people can experience better sanitation on the field and form consensus about its importance.

C) Implementation Plan

In 2019, reflecting the needs of the public, the MFDS will consolidate the hygiene grading system by reforming institutions and streamlining the procedures for designation of a grade and evaluating sanitary status, etc.

The MFDS will expand briefing sessions for public officials and business operators, provide consulting services for small restaurants looking to upgrade their sanitary levels and promote the hygiene grading system for restaurants. To implement post-management of the hygiene grading system, the MFDS will train more evaluators and draw up/disseminate a "Voluntary Sanitation Management Checklist" so that restaurant operators can voluntarily check the sanitary status of the cooking place, storage of food materials, etc.

The MFDS will promote the core message of the slogan of this system (check cleanliness, check everything) to consumers by exposing the CM song via mass media,

YouTube, etc.; and share and spread awareness of the improvement of sanitary levels by inducing consumers to personally visit designated restaurants.

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3. Strengthening Safety Supervision on Health Functional Foods and Introducing Reasonable Improvement to Regulations

A. Reinforcement of Safety Supervision for Health Functional Foods

1) Background

Given the massive rise of aging populations and the resulting personal demand for a "healthy life" and interest in self-health care, the health functional food industry have had an average growth rate of more than 10 % a year for last five years. Based on related studies, the US and EU have taken cognizance of the fact that health functional foods can potentially reduce national medical costs, and evaluated that consumption of health functional foods contributes to improving the welfare of the aged population.

The first Korean institution established to manage health functional foods was the 「Health Functional Foods Act」, which was enacted in August 2002 and put into effect in January 2004. The MFDS focuses on thorough safety supervision from their manufacturing to distribution to provide safe and functionally guaranteed health functional foods in the market, aiming to promote the national health and protect consumers.

2) Achievements

A) Stepwise Application of Conformance to Good Manufacturing Practices (GMP)

In February 2016, the "Health Functional Food Act" was amended to enforce gradual

mandatory application of Good Manufacturing Practice (GMP). In 2018, GMP was mandated for health functional food makers with 2017 sales of more than 2 billion won, and accordingly GMP designation rate of health functional food makers rose from 58 % in 2017 to 64.9 % in 2018. This means that arrangement for a safety management groundwork is systematically being processed to manufacture health functional foods with assured quality and safety. In order to facilitate early consolidation and participation in the system, the MFDS is providing on-site technical support and consultations for 20 small or medium-sized companies equipped to acquire GMP designation.

Furthermore, the MFDS set out in the enforcement regulations (Sep. 28, 2018) to observe and reinforce GMP compliance management by annually conducting survey and assessment over manufacturing and storage facilities, operation of documented product standards and their maintenance, education and training status of employees, etc.

B) Improvement of the Examination System Regarding Functional Raw Materials Certification

After the cynanchum wilfordii incident (Apr. 2015), approval for novel raw materials was dull. In order to measure this situation, the MFDS developed a "Plan to Promote Approval of Functional Raw Materials in Health Functional Foods" (Feb. 2018). Moreover, the MFDS revised the rules with simplified submission of manufacturing process related articles, clarification of toxicity test materials requirements, and cancelling licenses in case of false data submission on materials, etc. The MFDS provisied internal manuals upon functionality for raw materials examination to guarantee objective and fair process and disclose its results (examination reports) through a Food Safety Information portal to secure consumers and industries' confidence in the system.

C) Management of Standards and Specifications for Health Functional Foods

The MFDS newly established cautions for consumption of four notified functional raw materials such as garcinia cambogia extracts, etc. by reflecting the results of

reevaluation on health functional foods conducted in 2017, and ensured the safety and functionality of using strains of Enterococcus genus as probiotics again by revising their manufacturing method.

D) Reevaluation of Safety and Functionality of Functional Raw Materials

Reevaluation of functional raw materials can be classified into two: 1) regular reevaluation of raw materials for which 10 years have passed after they acquired approval as functional raw materials and 2) frequent reevaluation that is rapidly implemented when new information on safety/functionality is confirmed. In 2018, the MFDS selected 9 functional raw materials including xylitol, sardine peptite SP100N, etc. as subjects for regular reevaluation, and conducted their reevaluation. On the other hand, the MFDS also selected and reevaluated 7 materials such as glucosamine, vitamin D, etc. as frequent reevaluation subjects on which new safety/functionality information was reported. The MFDS transparently disclosed the 2018 reevaluation results for these 16 functional raw materials on the MFDS website and based on the results, took follow-up actions such as changing details of functionality (5 types), daily amount of consumption (9 types), and cautions (16 types).

E) Tightened Supervision on Abnormal Cases and Information Disclosure

In the interests of better consumer protection, MFDS prepared a legal basis (amended on Jun. 12, 2018 enforced Dec. 13, 2018) to "immediately change or establish the cautions for consumption" when a possibility of hazard is noticed as a result of inspection and analysis of abnormal cases.

In the current law, there is no basis for gathering and analyzing information on abnormal cases related to health functional foods, making it difficult to identify the causal relationships between the health functional food and abnormal case and to handle it. However, a new legal draft was proposed (on Nov. 28, 2018) to address this problem; it obliges a business operator who manufactures or sells health functional foods to report any abnormal case to the MFDS, and mandates the Ministry to inspect

and analyze the safety and causal relationship of the relevant health functional food with abnormal cases and publicizes the outcome. This law will strengthen the safety supervision of health functional foods.

The MFDS is doing its best to manage abnormal cases by means of disclosing analysis results of reported/accepted abnormal cases due to health functional foods intakes on its website every month and holding a deliberation committee on health functional foods (abnormal case evaluation department) twice a year, and thereby disclosing information on products in need of consumers' attention.

3) Improvement Plan

A) Ensuring Substantiality of the Good Manufacturing Practices (GMP) System

In 2019, the MFDS will support health functional food makers with 2017 sales of more than 1 billion won and less than 2 billion won (10 companies) to achieve mandatory application of GMP, and implement on-site technical support to enforce GMP as soon as possible. Though this, the MFDS will endeavor to complete application of GMP to all manufacturers by 2020.

Furthermore, the MFDS submitted (Jan. 11, 2019) to the National Assembly an amendment proposal to upgrade the "GMP" system currently in place. This proposal was intended as a notice to an enforcement rule to prepare for the completion of GMP's mandatory application by 2020. The MFDS will actively support its amendment and promulgation within the year in order to meet the principle of regulation by acts.

B) Strengthening the Traceability Management System throughout the Distribution Chain

Since 2016, manufacturers with item-wise annual sales of more than 1 billion won are required to register with the traceability management system. But traceability information is disconnected at the distribution step, making it difficult to recall the products. Accordingly, on Nov. 13, 2018, MFDS pre-announced a legislation

amendment that would require health functional food distributors with annual sales of more than 1 billion to register themselves with the traceability management system. The MFDS plans to promulgate the amendment in the first half of 2019 and thereby provide traceability information from manufacturing to distribution/sale and enable the fast recall of unwholesome products.

C) Organized Supervision of Abnormal Cases and Enhancement of Information Offering

As Koreans are consuming more foreign dietary supplements through increasing direct purchase or proxy purchase from foreign countries, supervision on abnormal cases of foreign dietary supplements has become important. Hence, the MFDS intends to collect information on abnormal cases and disclose it on the Food Safety Korea portal to notify consumers and prevent damage.

D) Improvement of the Examination System Regarding Functional Raw Materials Certification

The MFDS will introduce flexible evaluation techniques by facilitating "Systematic Review" (SR), etc. to boost predictability in the approval stage of health functional foods and be able to adopt new technologies. Along with this, the MFDS will make a "checklist for functionality examination" to raise consistency and apply evaluation methods for functional raw materials through gradual, comprehensive and flexible review on quality and quantity based on animal/test tube tests and human body application tests.

E) Implementation of Re-evaluation for Health Functional Foods

In 2019, the MFDS will conduct frequent reevaluations on nine health functional food vitamins and minerals including beta-carotene with no prescribed upper limit for consumption. Among items that have passed 10 years since the their previous approvals, eight items such as L-glutamine are slated for regular reevaluation in 2019; however, their reevaluations are put off since they have no production record, or their item manufacturing reports were not made. Reevaluation experts shall review

details on approval of safety and functionality of the subject materials for 2019 based on data prepared by business operators, etc. and the health functional food deliberation committee shall determine whether to maintain, change or cancel those materials on the basis of reevaluation drafts. Reevaluation is made in order of notice (Feb.), implementation (Mar. – Oct.), reading and submission of opinions (Nov.), and finalization and notification of results (Dec.).

B. Reasonable Improvement of Regulations Regarding Health Functional Foods

1) Background

The health functional food area is popular as a high added-value industry. In this regard, the MFDS aims to leave regulations essential toward protecting life/safety intact, but implement reforms to regulations associated with product development, manufacture and sale in an open, flexible, and reasonable manner by preparing the minimum safety standards, to simultaneously promote consumers' health as well as industrial growth.

2) Achievements

In 2018, the MFDS took several measures to stimulate online sale of health functional foods. To do so, the MFDS improved facility standards by allowing residential houses to be used as sales offices of e-commerce/mail order businesses that buyers do not visit personally. The MFDS also allowed health functional foods manufacturers to omit one of the self-quality tests based on overlapping standards and specifications in cases where they make finished products using functional materials or ingredients made at the same business place, etc.

As part of the drive to implement positive analysis of laws, the MFDS excluded

canteens (group meal services) from the subjects of business report for the general sale of health functional foods, considering the characteristics of the health functional foods included in the meals. Consequently, the MFDS was able to achieve improved consumer health, expand an opportunity for new markets and present the move on Regulatory Reform Sinmungo as a best case (Dec. 27, 2018).

3) Improvement Plan

In 2019, the MFDS will specify ways to introduce "personalized health functional foods" fit for the domestic reality so that people can consume essential health functional foods aligned to their dietary patterns, health status and gene tests. Moreover, the Ministry will ease the burden of management of records and substantiation/investigation/evaluation for HACCP-certified food makers when they operate GMP. To do so, the MFDS will reform regulations by simplifying similar and overlapping documents and carrying out simultaneous investigation/evaluation of HACCP and GMP.

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4. Strengthening of Safety Management for Nation's Nutrition

A. Leading Koreans to Moderately Consume Potentially Hazardous in Moderate

1) Background

On account of the rising participation of women in economic activities and the increasing number of one-person households, a large number of people prefer or are

compelled to eat out and enjoy HMR (Home Meal Replacement) and meal services more frequently. In most instances, this leads to unbalanced nutrition and resulting hikes in the risk of various chronic disease like obesity, stroke, diabetes, etc. and concerns about such a situation have become a social issue.

In response, governments and entities around the world including the WTO as well as Korea are actively implementing a policy to reduce the use of potentially hazardous nutrients e.g. sodium, sugars, trans fat and so on, whose long-term consumption is known to be relevant to chronic disease.

2) Achievements

The MFDS successfully reduced sodium intake and raised awareness of the risks associated with sodium through a program to reduce use of potentially hazardous nutrients. For Koreans, the daily average sodium intake decreased by about more than 27% from 4,879㎎ in 2010 to 3,478㎎ in 2017. National awareness of the necessity for sodium reduction increased from 59.8% in 2017 to 61.1% in 2018 while that for sugar increased from 43.0% in 2017 to 51.2% in 2018.

In 2018, the MFDS worked hard to implement education and promotion to improve consumers' perception of reduction and expand their practice. In May, the Ministry hosted the 'Sam-sam' (meaning, not salty or mild in Korean) Low Sugar Health Festival at Gwanghwamun Plaza for general public, and some 20,000 citizens enjoyed various experiences at 25 booths such as 'Sweet and Salty Taste Test', Nutrition Consultation, Comparative Sampling named 'Taste vs Taste' and 'Playground that Fulfills the Five Senses'. The MFDS operated a regional relay campaign named "Low Sugar & Sodium Promotion Outreach Team" for youths, office workers and seniors to help take the campaign to their regions. At the Low Sugar & Sodium Dining Lab, chefs prepared food based on low sodium/sugar recipes and participants sampled their dishes. Through projects such as these, the MFDS held many events to induce people to take interest in a healthy dietary life. The Ministry integrated recipes of the "Sam-

sam Diet Ⅰ-Ⅵ" published as a series, and turned them into a searchable database (DB) and posted it on the food safety information portal (www.foodsafetykorea.kr) so that individuals and companies can tap into the database for a better dietary life and product development. Apart from these initiatives, the MFDS implements active two-way communication via SNS like Facebook (https://www.facebook.com/mfdsna) and a blog (https://blog.naver.com/mfds_nadown) in an effort to improve consumer awareness of the necessity for reducing potentially hazardous nutrients.

From 2013 to 2018, the MFDS operated 2,359 sessions (approximately 60,000 persons) of the "Strong Eating & Drinking Exploration Team", a field-based diet experience program in which educational vehicles expandable to the size of a classroom visit primary schools and daycare centers, training 18,165 children to participate in the practice of reducing sodium and sugar while cooking. The Strong Eating & Drinking Exploration Team guided children to consume sodium and sugar moderately and provided education on dietary life based on experience. To prevent nutritional imbalance and obesity among children and youth, the training included practice on how to read nutrition labels and cooking based on low sodium and sugar recipes. To make sure that seniors could manage their dietary habits in preparation for an aged society, the MFDS operated the "Nutrition Management Classroom for Healthy Centenarians", educating the elderly improving nutrition and dietary life. The classroom covers topics such as how to manage excessive and insufficient nutrients, good shopping methods, ways of storing food materials, and preparation of healthy snacks, etc.

The MFDS develops and disseminates content on sodium and sugar reduction such as tools for assessment of salty & sweet taste, sugar reduction teaching tools and guidebooks for primary school teachers, sugar reduction camp programs and practice/game tools connected with curricula. The MFDS also holds three national contests by quarter for posters, UCCs and handwriting/calligraphy to promote policies for sodium and sugar reduction and strengthen practice of dietary safety among kids.

The MFDS is also committed to cutting sodium and sugar in food as well. The Ministry developed a technical guidebook for reduction of sodium and sugar in

hamburgers and soup/stew among ready-made meals and delivered on-site technical consulting services especially to small businesses who are making sauces and kimchi which are high in sodium to induce them to produce less salty products. Through these programs, 130 processed foods were produced with less sodium in 2018. In terms of sugar reduction, the MFDS developed a technical guidebook for fruit & vegetable drinks, coffee and fermented milk, and provided technical information to businesses who voluntarily joined the program by analyzing the environment for producing less sugar-contained products, etc.

To reduce sodium and sugar in group meal services and eat-outs, the MFDS is drawing up, distributing operation guidelines for Sam-sam (meaning, not-salty or mild in Korean) Group Meal Services and restaurants who wish to serve low-sodium dishes, and providing on-site consulting, etc. for nationwide meal services and restaurants to help them implement sodium reduction. For franchise restaurants, the MFDS developed a sodium reduction technology in 2018 for menus like hamburger, pizza and pork cutlet by identifying steps to apply sodium reduction in the cooking process. To cut sugar content in food served at those restaurants, the MFDS assisted in developing, promoting and marketing less sodium contained menus as well as soft drinks that come with set menu could be made less sweet. The MFDS also helped to forge an environment where consumers could select additional sugar when ordering a drink.

3) Implementation Plan

The MFDS will steadily implement sodium and sugar reduction policies to manage the intake of potentially hazardous nutrients and ensure that the public consumes them at a safe, recommended level. The MFDS endeavors to spread the policy and allow consumers, suppliers and nationwide local governments to reap benefits.

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

1) Background

We now live in the era of healthy centenarians, thanks to the advances in medical technology delivering significant increases to the average life expectancy. However, the number of eat-outs has rapidly grown due to changes in dietary habits. The increasing number of working couples and higher incomes have contributed to this trend. Due to over-nutrition or nutritional imbalance caused by changes in Koreans' dietary patterns including adoption of a westernized diet, chronic conditions such as obesity and cardiovascular diseases are emerging as a major cause of death. Therefore, public interests in health and the demand for personalized nutrition and dietary information for self care are increasing day by day.

2) Achievements

The Nutrition Labeling System enables displaying nutrition information of processed food on the packages of foods in accordance with certain standards. The goal of the system is to improve public health by helping consumers to select suitable healthy foods based on nutrition information provided.

Since the Nutrition Labeling System was first introduced in Korea in 1995, the types of foods required to have nutrition labels have been gradually expanded. According to the "Act on Labeling and Advertising of Food, etc.", currently, food groups including retort foods, confectioneries (snacks, candies and sweetened ice), breads and dumplings, cocoa products, chocolates, jams, edible oils, noodles, beverages, special purpose foods, fish sausages and instant foods, instant cooking foods, cereals, coffee (excluding roasted coffee and instant coffee), and pastes (excluding Korean Meju(fermented soybean block), Korean traditional soy sauce, Korean

Doenjang(soybean pastes) and Cheonggukjang(fermented soybean paste), health functional foods, processed milk products (milk, processed milk, fermented milk, and cheese), and processed meat are required to provide food nutrition information on their labels.

In 2006, four nutrients (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 can now check the serving size and nutrition facts on the nine nutritional components, 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, regulating foods packaged and sold as one serving for a meal be labeled with nutrition information per container, so that consumers can understand nutritional information more clearly of the food they consume. Furthermore, the MFDS introduced a online "Serving Size Notification System" in order to help businesses set the serving size of the foods they sell.

In 2015, the Enforcement Rule of the "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 had not been provided with a serving size until then; and change the serving size of foods such as coffee and teas whose intake has changed greatly in recent years.

In 2016, the unit and format used in labels were revised to make them easy-to-understand and comfortable for consumers.

Further, as the "Korean Nutrient Intake Standard" was revised in Nov. 2015, nutrient standards were changed to reflect people's current nutritional requirements as follows: vitamin D (5μg → 10μg), chromium (50μg → 30μg), carbohydrate (330g → 324g), and fat (51g → 54g) and the daily reference intake of sugar (100g) was newly set so that consumers could 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 better food, and enabling businesses to develop and distribute healthier food.

The MFDS also established the sodium content comparative claim for popular foods that are 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 design of the "Detailed Standards and Methods for Sodium Content Comparative Claim" were revised to display the sodium contents in a graph format and make use of QR codes when the area on the food package is less than 50㎠.

In the meantime, there have been difficulties in observing permissible labeling errors in products with mixed types of food like lunch boxes; or in trace elements (trans fats, saturated fats, cholesterol, etc.) due to the significant differences in raw materials used for manufacturing/processing vary their nutrient contents based on farming sites and/or harvesting periods. Therefore, the MFDS established a new rule to exempt the products indicating the average value inspected every 6 months by more than two accredited institutes from application of the permissible errors, so as to reasonably implement post-management of labeling.

The result of the consumer awareness survey conducted in May 2017 on the "Detailed Standards and Methods for Sodium Content Comparative Claim" showed that only 5.6% of consumers were aware of the standards and that consumers thought it was difficult to understand. In order to improve ease for consumers, the MFDS will enforce a new method from 2020. Based on the "daily sodium reference (2,000㎎)", a half-round model is divided into 8 sections, and if the amount of consumption exceeds the daily reference, it will be marked in red color to help consumers easily understand the hazard.

As part of the comprehensive measures for children's food safety, the MFDS implemented voluntary nutrition labeling first for fast food companies, and then 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 made mandatory

for businesses (with more than 100 stores) preparing and selling hamburgers, pizza, confectionery, bakery products, and ice cream to indicate the per serving content of calories, sugar, protein, saturated fat and sodium from January 2010. Further, from 2008, the MFDS has been making efforts to induce the industry to join voluntary nutrition labeling by running multi-use eat-out facilities.

The Food Nutrient Database built by MFDS to provide information on the nutrient content for raw material, processed food and menus from franchise restaurants. By using these databases, hosted by the portal site www. FoodSafetyKorea.go.kr, consumers can now easily find the nutrient content of the foods they consider buying. In addition, the web-site includes "Calorie Cody" which operates to support consumers to manage personal nutrition based on such databases. To make the food nutrient database more useful, raw material database was updated, its system was improved and the processed food database was renewed to include single portion nutrition data. The "Calorie Cody" initially started as a mobile-app, now has transformed into a website and its system stabilized through continued maintenance.

Furthermore, the MFDS offered tips to choose better food for patients, to help promoting health-related industries, and to help the nutritionally vulnerable demographics such as seniors and persons suffer from chronic conditions. The MFDS developed a guidebook to support health experts who serve foods for patients, established a method for using patient foods for patients and their caregivers, and communicated among hospitals and public health centers. The Ministry also created and distributed an export guide for patient foods to encourage the industry to join the market and compiled cooking manuals for dysphagia patients and patients with difficulties in chewing.

3) Implementation Plan

The MFDS will continue to work hard to set up an environment to deliver detailed nutrition information and induce producers to label it voluntarily; expand the scope

of nutrition facts labeling by analyzing social trends such as overseas developments and changing dietary habits of Koreans; and safely manage foods for children, offer nutrition databases, and introduce a dietary nutrition guide for patient foods.

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chapter 3

Medical Products

section 1

Medicines

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

A. Efforts to achieve international harmonization in pharmaceutical GMP standards

1) Establishment and Improvement of GMP for Medical Products

A) Background

The World Health Organization (WHO) announced the Good Manufacturing Practices (GMP) (1969) and recommended that member states adopt and apply them to international trade of medical products (1975). Accordingly, Korea promulgated the KGMP in Mar. 1977 as an established rule (No. 373) of what is now the Ministry of Health and Welfare, and announced the KGMP guidance in Jul. 1978 to have manufacturers voluntarily implement the GMP.

In Jul. 1994, the country mandated manufacturers of finished medical products to comply with the GMP and made it a rule to evaluate the GMP practice by dosage form

as a product approval requirement for finished medical products. Additionally, Korea adopted a GMP an evaluation system based on six groups of dosage forms in 1997 to streamline the evaluation procedures and in 2002, made GMP compliance mandatory for Active Pharmaceutical Ingredients (APIs).

In Jan. 2008, the amended Enforcement Rule of the Pharmaceutical Affairs Act introduced a "new GMP" that requires pre-approval GMP evaluation by product instead of evaluation by dosage form. This amendment added fresh concepts such as validation of the manufacturing process, product quality review and change control, and established an advanced GMP system at a global level.

Since then, Korea has sought to revise regulations for manufacturing high quality medical products, along with ongoing efforts to harmonize them with international regulations on account of 1) continuous amendments of GMP standards by pharmaceutically advanced countries to use new technologies and facilities, 2) increase in export by domestic pharmaceutical companies; and 3) enlarging global markets with aging populations and higher incomes.

B) Achievements

(1) Internationally Harmonized Improvement of GMP Rules

Since Korea's accession to the Pharmaceutical Inspection Cooperation Scheme (PIC/S) in 2014, the MFDS has actively engaged in improving the GMP system by revising relevant GMP rules to be aligned with international standards, etc.

(a) Establishment of GMP Standards by Medical Product Category

The MFDS established GMP standards considering the nature of each category of APIs, herbal medicine, radiopharmaceuticals, medicinal gases and investigational medicinal products. The Ministry published the GMP guidelines to help the industry better understand new rules while supporting robust implementation of the GMP system.

In 2018, the MFDS established the "Guidelines for Computerized System" including details on system validation, storage and management of records, change control and

"Guidelines for The Medical Product Quality System" to promote quality assurance throughout the lifecycle of medical products. Furthermore, the MFDS prepared the ICH Q7 Q&A to provide more detailed explanation of GMP standards for APIs and the information on international GMP regulations.

(b) Introduction of the GMP Compliance Certification System

The MFDS introduced a system to assess the GMP compliance of each manufacturing site every three years and issue a certificate of GMP compliance of a manufacturer with 3 years of the expiration period. With this, the focus of the quality control system for medical products shifted from product approval to post-approval surveillance , thereby improving the safety of the products manufactured and distributed. In addition, the MFDS gained international credibility of the KGMP and assisted domestic pharmaceutical companies in entering the global markets by introducing the GMP compliance certification system equivalent to that of the PIC/S.

(c) Establishment of "Regulation on Pharmaceutical GMP"

The MFDS reflected 16 Annexes of the PIC/S GMP in establishing the "Regulation on Pharmaceutical GMP" in Jun. 2015 to implement an internationally harmonized GMP system. In Nov. 2016, the Ministry established [Annex 17] Manufacturing of Finished Medical Products, amending the regulation.

(d) Mandating Isolation of Production Areas for Carbapenem and Monobactam Antibiotics

In line with the PIC/S action to strictly control manufacturing facilities, the MFDS separated production areas for carbapenem and monobactam antibiotics from other production areas, reducing the risk of cross-hypersensitivity reaction.

(e) Mandating Pre-approval GMP Evaluation in Case of a Significant Change in Production Facilities for Sterile Products, Etc.

Sterile products have greater impact on the human body compared to other

products. Therefore, for thorough manufacturing and quality control of products, the MFDS made it mandatory for production facilities to receive GMP compliance certification each time when the facilities are built, re-built, extended or altered remodeled, or and any significant change such as replacement of air conditioners, etc. is made, thereby assuring the product quality.

(2) Advancement of Quality by Design (QbD)

The MFDS created a roadmap to introduce Quality by Design (QbD) to give domestic medical products a competitive edge on the global market, and has been developing the QbD application model and basic technology year by year since 2015. The MFDS made the results available on its homepage for the pharmaceutical industry and held QbD workshops for training of MFDS staff and those from the industry.

C) Implementation plan

(1) Continuous International Harmonization of GMP Standards

The MFDS plans to organize a private-public consultative body with the pharmaceutical industry for continuous international harmonization of the GMP system and periodically review and reflect PIC/S amendments in domestic GMP regulations and guidelines. Among others, the Ministry will reflect amendments to of Annex 15 of the PIC/S Guidelines in revision of Annex 13 (Qualification and Validation) of the "Regulation on Pharmaceutical GMP" (Sep. 2019), and pursue more communication and cooperation with the industry through private-public consultative meetings and briefings and conferences to promote understanding of the pharmaceutical industry on new regulations, etc.

(2) Advancement of Quality by Design (QbD)

To support implementation of the QbD system in Korea, the MFDS will continue to develop QbD example models and study the basic technology. The MFDS will also expand training and assistance appropriate to each step by hosting QbD workshops, and

improve the regulatory environment, etc. to realize QbD-based GMP system.

2) Support for the Korean Pharmaceutical Industry Going Overseas, Deploying the PIC/S Membership Status

A) Background

The Pharmaceutical Inspection Co-operation Scheme (PIC/S) was organized to harmonize the GMP internationally and improve the quality system for inspection, considering the difficulties in export/import arising from the different GMP regulation systems adopted by countries.

As of Dec. 2018, 53 regulating agencies from 49 states have joined the PIC/S and from Asia Korea, Japan, Taiwan, Singapore, Indonesia, Malaysia, Tai, Hong Kong, and Iran have joined the Scheme. Thanks to exhaustive preparation, the MFDS received an on-site assessment conducted by an audit team in Jan. 2014, and was approved (effective on Jul. 1) at the PIC/S committee regular 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.

After PIC/S accession, the MFDS has been implementing supportive policies to lead the Korean pharmaceutical industry to enter overseas markets based on its membership status. First, as an active PIC/S member, the MFDS is holding joint PIC/S workshops on APIs and expert committees on blood, tissue and advanced medicine, etc. From 2015, the MFDS has held Korea-ASEAN GMP conferences for medical products with participation from a large number of people at ASEAN regulation authorities, constructing a collaborative relationship with ASEAN countries regarding GMP standards. Going further, to raise reliability of Korean APIs and expand Korea's presence in the European market, the MFDS is striving to register Korea with the EU whitelist (countries exempt from submission of written GMP confirmation for APIs). The MFDS is also implementing programs including a pilot project conducted from Sep. 2017 to sign a Korea-Switzerland GMP mutual trust agreement.

B) Achievements

(1) PIC/S Member Activities

The MFDS as a qualified PIC/S member attended the regular committee held in Geneva, Switzerland in the first half of the year (April) and another committee held in Chicago, the US in the second half (September) in addition to annual seminars. The MFDS grasped GMP trends of the members as well as other latest information shared at the meetings.

(2) Registration as an EU Whitelist State

To register Korea as one of non-EU states exempt from submission of written GMP confirmation, the MFDS held a cooperation meeting with the European Commission (EC) in Jul, after an on-site inspection in Dec. 2016. The MFDS shared with the EC the improvements it had made to insufficient matters, and discussed on-site reevaluation scheduled for the second half of 2018. In Nov. 2018, an audit team including representatives of the EC visited Korea and conducted the reevaluation procedure for the headquarters and three regional offices of FDS.

(3) Korea-ASEAN Cooperation Program

The MFDS invited ASEAN GMP auditors two times in 2018, organizing a study tour to local pharmaceutical companies and sharing latest GMP trends by country as well as GMP investigation cases of Korean producing facilities. Furthermore, the Ministry held Korea-ASEAN cooperation meetings and prepared a draft of Terms of Reference (ToR) for Korea-ASEAN cooperation. This demonstrates the formation of a collaborative foundation between the two entities.

(4) Korea-Switzerland Cooperation for Mutual Trust in GMP

The MFDS carried out a GMP pilot program in cooperation with Swissmedic from Sep. 2017 to Jun. 2018 and submitted a report on the program in Sep. 2018. By doing so, the MFDS was able to devise measures by which both countries acknowledged

their GMP levels were on a par and thus could exempt the other from inspection on its producing facilities until the conclusion of an agreement.

C) Implementation plan

(1) PIC/S Member Activities

To strengthen the prestige and reputation of the Korean GMP system, the MFDS will increase its PIC/S activities by attending the PIC/S expert committee as well as its regular committee and annual seminars.

(2) Registration as an EU Whitelist State

After successful on-site evaluation, the MFDS plans to rapidly execute recommendations from the auditors as parts of efforts to register Korea as a country exempt from submission of written GMP confirmation. The MFDS aims to conclude final registration in 2019 in cooperation with the EC.

(3) Korea-ASEAN Cooperation Program

The MFDS will invite representatives of the ASEAN regulation authorities to educate GMP auditors and hold the fifth Korea-ASEAN GMP conference. In addition, the Ministry will elicit concrete cooperation measures by conducting comparative analyses on the GMP systems adopted by ASEAN members and review the impact on the domestic industry while exploring measures to prevent overlapped GMP investigation between the two entities.

(4) Korea-Switzerland Cooperation for Mutual Trust in GMPs

The MFDS is working to generate a final written agreement to conclude the Korea-Switzerland agreement on mutual trust in GMPs. The MFDS will also push ahead with related domestic procedures together with the Ministry of Foreign Affairs and Ministry of Government Legislation and make efforts to have the agreement officially signed by 2019.

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2. International Harmonization and Advancement of Pharmaceutical Regulations

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

1) Development of Assessment Guidelines through International Harmonization

The MFDS provides guidelines for the review of pharmaceuticals in order to clearly specify the screening criteria and improve the predictability of the review process for drug approval. To this end, MFDS continuously reflects scientific and technological advancements as well as amendments to the guidelines provided by the International Council on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) in domestic drug regulations and guidelines, towards strengthening the global competitiveness of the domestic pharmaceutical industry. Since 2004, the MFDS has been operating 'Good Review Practice' (GRP) to ensure the consistency, transparency, and reliability of the drug screening process. The MFDS has been continuously revising the guidelines so that the inspectors and applicants can utilize them for screening and applying for approval.

In 2018, the MFDS established and revised a total of 27 guidelines and commentaries guidances / Q&As the "Q&A on the Evaluation Guidelines for API Development and Manufacturing Quality" by reflecting ICH guidelines. Further, 46 medical examination manuals (27 examination criteria, 8 license tasks, 8 other types of duties, 1 disclosure of information, 1 education & training) were enacted or revised in order to improve predictability and consistency of the process.

The MFDS will continue to enact and amend the guidelines regarding the evaluation of drugs for conformance with international standards, by actively implementing ICH guidelines. In addition, the MFDS plans to develop and implement the Pharmaceutical Affairs Excellence Assessment Standards Operational Manual and revise it regularly.

2) Disclosure of Drug Approval Screening Results

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

The MFDS used to disclose the screening results for safety and efficacy and those related to standards and methods separately. However, the MFDS has now integrated them in the 'Drug License Report' by adding screening results and licensing matters for new drugs (2014) and data submission medicine (2015), and expanded the number of disclosed items.

Since Jan. 2017, the MFDS has been disclosing the full text of the safety and efficacy screening review on newly approved drugs as well as the results of the bioequivalence study on generic drugs. The MFDS will continue to disclose information on product licensing and screening results and thereby strive to enhance the consistency, transparency, and reliability of the licensing process.

3) Providing Medical Safety Information

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

In 2018, the MFDS diversified the formats for providing information using the MFDS SNS, electronic displays, etc., helping consumers to easily access information. The MFDS delivered information on 10 cases e.g. cold medicine, high blood pressure, motion sickness medicine, constipation medicine, etc. and published a series of 18 special articles in the daily newspaper "Healthy Centenarian" to provide information on how to use painkillers and cold medicine, etc. In addition, the MFDS used the card news format to provide information of interest to consumers, regarding 19 frequently used drugs for Parkinson's disease, osteoarthritis, acne, hepatitis, etc. including antibiotics.

In 2019, the MFDS plans to offer information on the safe use of medicines for chronic diseases such as hepatitis and diabetes; and distribute card news on the risk management system for medical specialists like doctors and pharmacists and ordinary people, and disseminate educational materials for vulnerable demographic groups such as adolescents and multicultural immigrants.

4) Efforts for International Harmonization of Pharmaceutical Evaluation

A) Korea's Activities Associated with 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) since 2006, and became the 6th member country of the ICH as a drug regulatory authority in Nov. 2016. Since 2011, the MFDS has been participating in the joint development of guidelines for 23 areas identified by the Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use. The MFDS completed joint development of guidelines in 9 areas including "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 the ICH, the MFDS has provided guidelines for the training program on ICH E2 (Safety Information Management) since Aug. 2016 and, since Aug. 2017, worked on guidelines training on quality examination based on pharmaceutical designs (ICH Q8, Q9 and Q10) through the E-learning Center. In 2018, MFDS attended the International Pharmaceutical Regulators Programme (IPRP) to present the status of regulatory improvements in Korea and share the activities and action plans of the Biosimilars Working Group chaired by the MFDS.

The MFDS (National Institute of Food and Drug Safety Evaluation, NIFDS) will participate in the ICH held in Jun.2019 in the Netherlands and in Nov. 2019 in Singapore as a regulatory authority member.

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

The APEC Harmonization Center (AHC), which was established within the MFDS (NIFDS) in Jun. 2009, has hosted and co-hosted a total of 41 workshops CoE (Center of Excellence) pilot workshops until 2018.

In 2018, the AHC hosted four workshops and training sessions for CoE pilot at home and abroad, enhancing the regulatory capabilities of developing countries in the APEC region and facilitating the exports of domestic companies. By co-hosting workshops on supply chain integrity and medical devices, providing training sessions for multi-regional Clinical trials (MRCT) and inspection, medical devices vigilance, and biotherapeutics, the AHC strengthened its position as an organization at the forefront of efforts to promote regulatory convergence.

In 2019, the AHC will co-host workshops for biotherapeutics; hold Policy Dialogue on regulatory convergence policy of the APEC Life Sciences Innovation Forum (LSIF); and conduct CoE training sessions on supply chain integrity and Good Registration Management (GRM). Further, the 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, the MFDS has implemented various international cooperative activities.

The International Generic Drug Regulatory Program (IGDRP) had a total of 7 pilot meetings from 2011 to 2014. The IGDRP started its official activities from 2015. The 2nd IGDRP Assembly was held in Seoul in Nov. 2015, and a total of 6 meetings have been held so far including the 6th IGDRP Assembly held in Nov. 2017. Since Jan. 1, 2018, the IGDRP and IPRF have been integrated into the IPRP (International Pharmaceutical Regulators' Programme). In 2018, the MFDS attended two MC (Management Committee) meetings and quality and bioequivalence working group meetings respectively.

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, the MFDS has participated in a total of 11 PQ sessions (until 2018) of joint evaluation by dispatching Korean evaluators. Also, through a communication channel for providing assistance with WHO PQ Certification (2014) and organizing workshops and tailored technical consultations regarding WHO PQ (2015-2017), MFDS actively helped domestic companies to enter the market of WHO-supplied medicine.

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

D) Renewal of MOU and Strengthening of 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 jointly by the two organizations every year are considered to have enhanced the global competitiveness of the Korean pharmaceutical industry by providing Korean businesses with opportunities to understand the trends of standards in developed countries early on and thereby align their practices with international standards.

The major plans of the MFDS for 2019 are to: jointly develop specifications for Gemifloxacin and herbal medicine (6 cases including angelica root); take part in the joint research on reference standards; support domestic companies to take part in

the project to supply pharmaceuticals that cannot be supplied by the US anymore; support domestic companies to join WHO-PQ projects; help experts to participate in the USPC (United States Pharmacopoeia Convention) Expert Committee (establishment of reference standards, crude drug, etc.); and hold joint symposia 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) Cooperation with the International Coalition of Medicines Regulatory Agencies (ICMRA)

A) Background

Major medicines regulatory agencies agreed to establish the International Coalition of Medicines Regulatory Agencies (ICMRA) for task sharing and information exchange, and organized working groups by areas such as GMP and crisis response to provide a high-level leadership for solving regulatory or safety problems. They have shared the status of each country and discussed their way forward.

In the meeting held in Sep. 2018 with the US, Australia, Brazil, Canada, China, Denmark, the EU, Germany, India, Ireland, Italy, Japan, South Korea, Mexico, the Netherlands, New Zealand, Poland, Russia, Singapore, South Africa, Sweden, Switzerland, the UK, the US, etc.

B) Achievements

For the ICMRA general meeting held in Sep. 2018 in the US, the MFDS joined in the discussion about the cooperation of medicines regulatory agencies for regulatory

affairs/quality assurance in terms of biosimilar statuses and approval review, measures to reflect a patient's opinion on pharmaceutical development, and methods to use the actual basis of clinical trials efficiently. Moreover, the MFDS agreed to hold a regular meeting with Switzerland on common issues; started to discuss about a mutual exchange of chief confidential information on medicine with the EU and the US; and began discussing plans on how to start area-specific consultation.

C) Implementation plan

In 2019, the MFDS will expand the pharmaceutical safety management network and reinforce the credibility of the Korean pharmaceutical safety management systems by attending the preliminary meeting (San Diego, the US) and general meeting in October (Rome, Italy), and sharing tasks and exchanging information between fellow medicines regulatory agencies.

2) Cooperation with the Drug Information Association (DIA)

A) Background

The DIA is a non-profit organization in the pursuit of pharmaceutical safety and the presentation of directions for pharmaceutical development. Recently, it is growing its activity range as a venue to share fast-developing science and technology involving medicine.

The DIA holds an annual meeting in June every year and a closed meeting of the Committee of the Regulators (COR), sharing the regulatory trends of each country and their regulatory issues.

B) Achievements

Since 2017, the MFDS has continued to attend the DIA annual meetings to share her development directions of late, and discussed its main issues with the US, the EU, Japan, and Canada.

C) Implementation plan

The MFDS plans to operate an exhibition booth for promoting the excellent quality of Korean medicine, etc. in the DIA 2019 annual meeting, and attend the COR to discuss regulatory issues with advanced countries in the pharmaceutical field.

3) Expanded Cooperation with Overseas Regulatory Agencies

A) Background

Thanks to the growing R&D capacity of Korean pharmaceutical companies, the overseas expansion of domestically developed medicines with matching world-class competitiveness has been vitalized. For the continued advance of these domestic medicines into the overseas markets, there are preconditions: 1) securing the international credit rating of Korea's pharmaceutical safety management system and 2) cooperative relations such as information exchange with the pharmaceutical regulators of foreign countries.

B) Achievements

The MFDS signed an MOU with Mexico (2016) for their mutual cooperation in the 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.

For Japan, both countries reached a consensus on the necessity to seek more cooperation while joining the Pharmaceutical Inspection Cooperation/Scheme (PIC/S) in 2014. So, the MFDS signed the Agreement between the MFDS and the Japanese Ministry of Health, Labour and Welfare to Establish a Foundation for Dialogue and Cooperation for Regulating Medical Products in 2015 and has hosted the Korea-Japan Director General-level (Annual) Meeting. In addition, the MFDS holds a Public and

Private Joint Symposium with related associations of both states to further private exchanges and shared recent pharmaceutical regulatory trends.

As for China, as the responsible agencies of Korea and China were elevated to minister-level agencies, the MOU signed in Apr. 2009 led to the revision (Dec. 2013) of the Cooperation Agreement on Food, Pharmaceuticals, Cosmetics, and Medical Devices between Korea's MFDS and China Food and Drug Administration (IATF). With regards to Vietnam, which has seen an expansion of Korean pharmaceutical exports, the MFDS amended an MOU with the country in 2018 to hold a regular a director general-level meeting to facilitate regulatory information exchange and cooperation.

Besides, in order to relieve the 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 Apr. 2016. It is expected that this measure will reduce the burdens of time and costs for domestic pharmaceutical companies. In 2016, MFDS agreed with Peru's Ministry of Health to register the Korean Pharmacopoeia (KP) as a reference pharmacopoeia, laying the foundations by which KP can be officially recognized in Peru, like the United States Pharmacopeia or the European Pharmacopeia.

C) Implementation plan

The MFDS will strengthen bilateral cooperation between Korea and Japan, including the Public and Private Joint Symposium and the Director General-level Meeting, and thereby make efforts to improve the credibility of Korean medicine and increase exports.

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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 play a key part in securing capabilities for a 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 the emerging powers in the pharmaceutical industry, emphasis is continuously being placed on the internationally harmonized system.

B) Achievements

In 2018, the MFDS expanded the targets of the exceptional 'use approval of pharmaceuticals' for clinical trials to the patients such as those with no alternative course of treatment, because their treatment timing is very important. Moreover, the MFDS amended and published (Apr. 2018) the Guidelines for the Approval of Pharmaceuticals for Clinical Trials to Be Used for Treatment containing approval application procedures, related diseases and application scopes so that they can be exploited for patients with serious disease.

Going further, the MFDS excluded sponsor-investigator trials from approval subjects of the MFDS Minister (Jun. 2018) only when they are implemented to check the combination therapy, etc. of safe medicines on the market in connection with the Human Research Protection Program. This aims to stimulate pharmaceutical R&D equipped with quality control capacity.

C) Implementation plan

The MFDS plans to devise a Comprehensive Plan for Developing Clinical Trials based on the safety and trust of the targets through various processes to gather opinions. For one, the MFDS is operating the Clinical Trial System Development Unit comprising of Korean experts from the industry, academia, and government (from Jan. 2019).

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

A) Background

In order to safely and scientifically conduct the 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 only by institutions designated by the Ministry of Food and Drug Safety.

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

(As of Dec. 31, 2018, Unit: Number, Source: Clinical Trials Management Division)

Region	Total	Seoul	Gyeonggi-do	Busan	Gyeongsang-do	Chungcheong-do	Jeolla-do
Sub-total	189	57	32	19	14	10	12

Region	Daegu	Daejeon	Gangwon-do	Gwangju	Incheon	Ulsan	Jeju
Sub-total	10	8	5	8	10	2	2

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

B) Achievements

The MFDS has carried out both regular and random inspections for improving the reliability and reinforcing overall competency of clinical trial testing institutions. Last year, the MFDS conducted regular inspections on 30 institutions and additionally carried out random inspections on ta few of the inspected 33 institutions. In addition, MFDS conducted 66 regular and irregular inspections in 2017 and 64 in 2016 in an effort to continuously and systematically manage the clinical trial testing institutions.

C) Implementation plan

For regular inspections of the clinical trial testing institutions, the MFDS will enhance the efficiency of their examination by differentiating inspection intervals and methods, depending on the results of the evaluation conducted starting from 2013 and the added management risks. Especially, the MFDS will intensively inspect a support system, while recruiting notices, written agreements, responses to abnormal reactions, and damage compensation procedures of testing institutions; and keep operating the clinical trial review committee independently and fairly. It is expected that these efforts will expand a self-inspection system of the testing institutions, and reinforce patient-oriented safety and rights.

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, the personnel who conducts

clinical trials, etc. shall complete education courses specified for each person for fixed hours in designated institutions, in order to enhance professionalism and protect the clinical test targets.

Considering their education courses and instructor qualifications, the MFDS designated 42 institutions for clinical trial education (as of Dec. 2018) 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 2019, the MFDS will reasonably its improve education hours and approved range to help the personnel in charge of clinical trials take education courses. Furthermore, the Ministry will provide them with educational convenience by constructing an electronic system through which clinical trial training institutions can report their annual education plans, and by delivering information services for education courses including their search function.

Kim Jeong-Mi, Clinical Trials Management Division ☎ 043-719-1856

3. Strengthening the Safety Management of Approved Pharmaceuticals

A. Stronger Pharmaceutical Safety Management for the Entire Lifecycle from Manufacturing/Import to Distribution/Consumption

1) Background

Owing to higher incomes, aging populations and the increasing number of patients

suffering from chronic diseases, there is a growing interest in pharmaceuticals that support eradication of disease and longer lives, which humankind has always desired.

As people want a healthy and safe life, it is necessary to guarantee the quality of their life by creating an environment where safe, highly beneficial medicine is supplied and the general public can use pharmaceuticals with no worries at all.

It is time to make various efforts to assure a healthier and safer life for people and enable them choose medicines with confidence and peace of mind. Establishing a methodical safety management system at an international level, based on stronger pharmaceutical safety management over the entire life cycle from manufacturing/import to distribution/consumption, is an important step in this direction.

2) Achievements

A) Advanced Safety Management System in Pharmaceutical Manufacturing, Import, Etc.

In the manufacturing area, on-site inspection of domestic manufacturing facilities was first conducted in 2018 according to the 2nd Three-year Plan ('18~'20) under the international standards (PIC/S). A monitoring system based on risk evaluation was also applied for the first time in Korea. Next, the MFDS introduced and implemented qualitative evaluation with a focus on hazards by differentiating inspection of manufacturing facilities depending on potential risks. The MFDS frequently inspected facilities with a high risk in an intensive, repeated manner and inspected facilities with a low risk centering on only the essential areas.

Moreover, unlike the past when the MFDS provided only result notifications on matters identified through monitoring, the MFDS now offers the whole GMP inspection report to pharmaceutical companies when required/upon request for exporting products at the request of an overseas regulatory agency. By doing so, the MFDS supports their export and eases the nuisance of repeating the inspection procedure for an overseas regulatory agency.

Table 3-2 2018 Regular/Frequent Pharmaceutical Monitoring Results

(As of Dec. 31, 2018, Unit: facility, Source: Pharmaceutical Management Division)

Classification	Implementation	Compliance	Violation	Others*
Sum	239	180	59	-
Regular	110	96	14	-
Frequent	129	84	45	-

* Unable to perform inspection, transferring, etc.

In the import area, the MFDS mandated importers to register their overseas manufacturing facilities to enable the systematic and effective post-management of the facilities on par with that of domestic pharmaceuticals. The MFDS also formulated a legal basis for implementing overseas inspection as necessary (amended and promulgated the 「Pharmaceutical Affairs Act」, Dec. 11, 2018). Further, the MFDS inspected 12 overseas manufacturing facilities for analysis of hazard information.

The MFDS selected priority monitoring targets after assessing the risk of importers and examined their facilities over warehousing, storage, and distribution.

Table 3-3 Results of Regular/Frequent Pharmaceutical Monitoring for Importers in 2018

(As of Dec. 31, 2018, Unit: facility; Source: Pharmaceutical Management Division)

Classification	Implementation	Compliance	Violation	Others*
Sum	144	97	42	5
Regular	101	85	11	5
Frequent	43	12	31	-

* Unable to perform inspection, transferring, etc.

In the renewal area, the MFDS started operating a renewal system in earnest in 2018. To tighten safety management of medical products, the Ministry refused to renew the marketing authorization that were not equipped with all materials for renewal due to insufficient safety management after obtaining a license or completing pharmaceutical reporting. The MFDS also enhanced the consistency of how pharmaceutical approval agencies and renewal agencies operated by revising relevant statutes (amended, etc.

「Enforcement Decree of the Pharmaceutical Affairs Act」 and 「Regulations on Safety of Pharmaceuticals, etc.」, Apr. 25, 2018), and clarified the renewal review · handling procedures (「Rule on Renewal of Pharmaceuticals」, Aug. 31, 2018). Through these measures, the MFDS improved the renewal system systematically and efficiently, raising predictability for applicants.

Table 3-4 Results of medical products in 2018

(As of Dec. 31, 2018, Unit: No. of product, Source: Pharmaceutical Management Division)

Classification	Required the renewal application	Renewal	Non-renewal
Renewal	4,806	3,126 (65.0%)	1,680 (35.0%)

B) Reinforcement of User-Centered Safety Management of Pharmaceuticals

In the distribution area, the MFDS made recall of medical products more efficient by disclosing, connecting and expanding recall information including providing images of recall items (amended 「Operating Guidelines for Recall · Disposal of Pharmaceuticals」, Mar. 30, 2018), and installed a system to block the sale of hazardous pharmaceuticals at more drug stores and wholesalers (85.3%). In addition, the MFDS established a regulation to punish individuals who mediate for or promote illegal pharmaceuticals (amended 「Pharmaceutical Affairs Act」 etc., Dec. 11, 2018). Through these measures for preventive cutoff of sale, the MFDS lowered the risk of consumers using hazardous pharmaceuticals. Furthermore, the MFDS continues to monitor product quality by means such as collections and tests of medicinal products with possible risk in cooperation with local governments, forging an environment for safe use of medical products.

Table 3-5 Collection and Test Results of Pharmaceuticals in 2018

(As of Dec. 31, 2018, Unit: No. of products, Source: Pharmaceutical Management Division)

Classification	Total	Manufacturing	Import
Sum	1,460	1,373	87
Regional Office	280	226	54
Local Governments	1,180	1,147	33

In the labeling area, the MFDS allowed only the distribution of pharmaceuticals that provided complete information for the entirety of ingredients (enforced on Dec. 3, 2018) to help consumers understand medical information easily and sufficiently. This also strengthened consumers' right to know by offering information on all ingredients through the MFDS integrated information system. The MFDS also supported labeling of the pharmaceutical industry (Nov. 16, 2018) by developing tips for filling in a standard form for commonly used general pharmaceuticals and improved their readability for consumers.

In advertising, the MFDS improved deliberation procedures. Starting May 4, 2018, deliberators are required to exhaustively manage records and only those with a product license shall be eligible to apply for deliberation. This is intended to fairly and reasonably operate deliberation on advertising of pharmaceuticals.

In the consumption area, while using supplier-centered one-way media like electronic displays, the MFDS expanded its promotion range to pharmaceutical safety management policies such as labeling, instructions for use outside the permitted scope, etc. apart from running campaigns to eradicate illegal distribution of pharmaceuticals. To maximize promotional effects, the Ministry also recruited "Pharmaceutical Safety Keepers" comprising university students, etc. to draw consumers' attention to the safety of pharmaceuticals via communicative media including SNS. Besides, the MFDS shifted from random promotion for the general public to a customized approach, to include on-site campaigns linked to kid events for kids, webtoons for youths and office workers, and accurate information on high blood pressure for adults.

3) Implementation Plan

A) Advancement of Safety Management Systems such as Manufacturing and Import, Etc. of Pharmaceuticals

In 2019, which is the second year of the 2nd three-year cycle ('18~'20) under the

international standards (PIC/S), the MFDS will apply the principle of selection and focus to consolidate differentiated inspection of manufacturing facilities based on risk evaluation; and intensively monitor manufacturing and importing companies by organizing a special inspection team to more appropriately manage API quality.

In the import area, the MFDS will fully implement the preliminary registration system for overseas manufacturing facilities by amending regulations subject to the Pharmaceutical Affairs Act. The MFDS also plans to craft a potential risk assessment system and expand on-site inspection of overseas facilities selected as targets of intensive management for the purpose of safer management of imported products.

In the renewal area, the MFDS will lay the foundations to use data by connecting the system for distribution management of pharmaceuticals, with data including production results submitted to the electronic civil affair system regarding renewal. In addition, the MFDS will devise a renewal system development plan by compiling accumulated research, communication and evaluation results on renewal operations.

B) Reinforcement of User-Centered Safety Management of Pharmaceuticals

In the distribution area, the MFDS will standardize and clarify detailed work procedures by amending the guidelines for recall operations to pursue consistent and efficient recall of pharmaceuticals, and bolster recall skills by training related workers in the government and industry.

In the labeling area, the MFDS will organize FAQs of the industry and make/provide a Q&A book to address relevant questions and in advertising, amend and offer the guidelines complete with advertising cases and standards to prepare for new modes and conditions of advertising.

In the consumption area, the MFDS will formulate control measures to enhance safety management of pharmaceuticals used outside the permitted scope, and actively pursue cooperative, participatory promotion together with the public to establish a culture in which consumers use drugs in a safe manner.

Kim Myeong-Ho, Pharmaceutical Management Division ☎ 043-719-2651

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

1) Background

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 these drug products for a long term, producing side effects that are not possible to observe at the time of the drug license 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 more efficiently. Data thus gathered is ultimately developed into new safety information after they are subjected to 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, recall and disposal, and related information is provided to medical institutions, doctors/pharmacists, and consumers.

2) Achievements

A) Collection of Pharmaceutical Safety Information

In this regard, the MFDS has revised safety management regulations for released drug products by means of measures such as mandatory designation of pharmaceutical safety management officers and specifying their education requirements, and regular and prompt reporting of adverse effects of drug products. In addition, the MFDS established the Korea Institute of Drug Safety Risk Management

(Jan. 2012) dedicated to the collection, analysis, and management of safety information, including side effects of medicines, and also increased the 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 257,438 in 2018, and the number of accrued reports has reached about 1.6 million in total.

B) Safety Measures Based on Domestic Pharmaceutical Safety Information Reports

The MFDS develops safety information after statistical analysis and review of relevant data including literature based on the reports on domestic adverse reactions, and then consultations with Central Pharmaceutical Affairs Council. As a result, safety action such as license changes of 24 ingredients were taken. Such safety measures were implemented for 6 cases in 2012, 25 cases in 2013, 14 cases in 2014, 17 cases in 2014, 21 cases in 2016, 29 cases in 2017 and 34 cases in 2016.

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

The MFDS collects safety information from abroad by monitoring information posted by international organizations, foreign regulatory agencies, and overseas media in real-time. In 2018, the Ministry implemented safety measures to revise the label information of about 4,400 items including 195 ingredients in total (eg. issuing a Letter of Safety regarding extended release tablet of acetaminophen, revising precautions on the label information of anti-hypertensive amlodipine-containing products, etc.).

D) Provision of DUR (Drug Utilization Review) Information

The MFDS has developed and provided DUR information since September of 2005, after the “Service for Development and Provision of Standards of Using Drug Products” was transferred to the Ministry by the Ministry of Health and Welfare (Health Insurance Review and Assessment Agency). This DUR information is available to the general public as well as doctors/pharmacists on the MFDS homepage. Also, through the “System for Supporting Prescription Dispensing of Drug Products” of the Health

Insurance Review and Assessment Agency, some DUR information such as warnings on unsafe drugs for expectant mothers and age brackets are being delivered to doctors/pharmacists in real time.

E) Providing Pharmaceutical Safety Information Customized to Consumers

In 2017, to provide customer-specific pharmaceutical safety information and thereby prevent consumer damage from adverse drug events, the MFDS published a revised DUR information book for patients with renal or liver disease that contains the latest medical information, and distributed a leaflet containing safety guidelines on the use of anti-influenza virus products (eg. oseltamivir). In 2018, the MFDS distributed leaflets on safe use of anti-epileptic products containing valproic acid and iodinated contrast media for injection, and posted safety information on products for treatment of severe acne (eg. isotretinoin), insomnia, and influenza virus (eg. oseltamivir) on-line.

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

The MFDS announced the results of an analysis on 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, the MFDS analyzed severe adverse skin reactions by major medicines, lamotrigine (antiepileptic drug) and DPP-4 inhibitors (hypoglycemic agents). In 2017, a linkage analysis was conducted for the treatment of nicorandil (angina pectoris), fluoroquinolone (broad-spectrum antibiotics), and Proton Pump Inhibitors (peptic ulcer treatment). In 2018, a 5-alpha reductase inhibitor (benign prostatic hyperplasia) underwent linkage analysis.

3) Implementation Plan

In order to utilize and analyze insurance claim data held by the National Health Insurance Corporation and the HIRA, the MFDS is establishing a cooperative system

for linking the medical information held by individual institutions. Also, to overcome the limitations of insurance claim data in providing information such as charges for non-covered drugs and omission of test results, medical information on 6.5 million patients held by five medical institutions nationwide was brought together and constructed as a common data model (CDM), and this move will only expand. If such linkage enables analysis of drug side effects and various medical information, it will be possible to provide better and more accurate safety information based on reliable analysis results and promote proprietary safety measures for released drug products.

C. 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 occur even with proper use depending on individual characteristics. The MFDS introduced a damage relief system for adverse drug reactions, by which the government compensates the victims who die, get injured or hospitalized due to unexpected adverse events despite proper care on their part. The relief system is operated with financial assistance from pharmaceutical companies without any legal proceedings.

2) Achievements

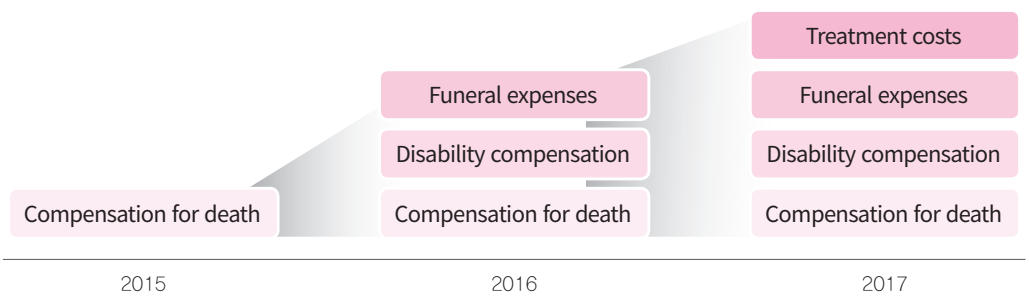
There are prerequisites to stably introduce a damage relief system. This includes establishing a system to assess the cause-and-effect relationship between side effects and pharmaceuticals, manage the financial operation of contributions form social consensus, etc. The MFDS organized the “Industry-Academy-Government Committee for Adverse Drug Reactions” comprising pharmaceutical associations, consumer and

civic groups, and related experts, and formulated a damage relief system suitable for Korean conditions. After discussion with the National Assembly, the revision of the Pharmaceutical Affairs Act to introduce the damage relief system was finally announced on Mar. 18, 2014, and enforced on Dec. 19, 2014.

The damage relief system is expanding its scope gradually to cover deaths in 2015, disability and funeral expenses in 2016 and treatment costs in 2017, completing a social compensation system.

With regard to decisions on the payment of damage relief, 8 out of total 20 applications in 2015, 40 out of total 65 applications in 2016, 80 out of total 126 applications in 2017, and 92 out of total 139 applications in 2018 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, KRW 1.43 billion in 2017 and KRW 1.33 billion in 2018.

Image 3-1 Wider coverage of damage relief



3) Implementation Plan

In 2019, the MFDS plans to expand the scope of treatment costs to non-covered items so that people can receive practical compensation for adverse drug reactions. Additionally, following 2018, in 2019 the MFDS plans to introduce various ways of promoting the system such as specifying provisions on damage relief in the

pharmaceutical instructions for use and providing education programs customized for medical professionals.

The MFDS will make efforts to ensure that the damage relief system serves as a dense and warm social safety net that protects those unexpectedly coming to suffer adverse effects from medicines.

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4. Stable Operation of the Patent and License Linkage System

1) Background

According to the Korea-US Free Trade Agreement (FTA) signed in 2007, the patent-license linkage system, in which the patent is considered during the pharmaceutical license procedure, was introduced to protect patent rights of medical products. The system has been in full swing since March 2015.

2) Achievements

In order to ensure stable implementation of the system, the Pharmacist Affairs Act and its subordinate statute, which addressed the prohibition of sale and the license of priority sales items, were revised in Mar. 2015. After the implementation of the Patent-License Linkage System in March 2015, the MFDS analyzed and evaluated the effects of the system on the domestic pharmaceutical industry and health policy, and reported the results to the National Assembly.

Since the introduction of the Patent-License Linkage System that led to the emergence of patent issues in the development and launch of pharmaceuticals, the MFDS has been investigating and analyzing domestic and foreign patent and license information

related to pharmaceuticals to support the development of pharmaceutical firms.

The MFDS also provided specialized education to support pharmaceutical companies to effectively cope with and utilize the system by understanding the Patent-License Linkage System and improving business capabilities. Six education sessions on the system were provided for the benefit of employees in the pharmaceutical industry.

In order to make effective use of the patent-license linkage system, the MFDS provided consumer-centered administrative services such as electronic payment of applicable patent list entry fees and amendment/publication of a question and answer book for those working on civil complaints.

3) Implementation Plan

The MFDS plans to further strengthen support for the use of the system and help pharmaceutical companies develop drug products and advance into markets making use of the patent-license linkage system.

The MFDS will establish patent information on newly listed drug products and expand provision of overseas information to 16 countries by adding Taiwan, Malaysia, Russia and Kazakhstan to the 12 already included countries of China, Japan, India, four Latin American countries, and investigate and analyze overseas case information. Through these measures, the MFDS will continue to offer more information for product development and export.

Kim Hyo-Jeong, Pharmaceutical License and Patent Management Division ☎ 043-719-2821

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

A. Establishment of an Innovative Monitoring System with a New Dedicated Agency

1) Background

Cases of misuse and illegal leak of narcotic drugs are on a rise worldwide. Worse, some celebrities and children of affluent families recently committed a crime unlawfully using narcotic drugs, and the issue is still in the spotlight. In view of the circumstances, a new system has been introduced to mandate reporting all details on handling narcotic drugs for medical use to the MFDS. However, a new agency is required to innovate the narcotics monitoring system in a scientific and systematic way exploiting collected big data.

2) Achievements

The MFDS appointed a narcotics safety planning director who will be in charge of safety management of drugs (May 3, 2019). The director supervises Narcotics Policy Division and Narcotics Management Division and supports the head of the Pharmaceutical Safety Bureau.

3) Implementation Plan

The narcotics safety planning director will take charge of “preventing abuse and misuse of narcotic drugs and operating the narcotics monitoring system” considering the unique features of narcotic drugs, which are different from general

pharmaceuticals. The major tasks are to: 1) intensify the role of the government as the control tower of narcotics safety management by operating a "Pan-government Enforcement and Inter-ministry Council" and sharing information with related ministries and closely cooperating with each other to manage information registered with the "Integrated Narcotic Drug System" and 2) establish a system to monitor drug users based on big data collected through the Integrated Narcotics Management System and strengthen preliminary action.

Furthermore, the narcotics safety planning director will nurture narcotics specialists such as addiction counselors and educational instructors, develop and oversee projects to support the addicted to return to society, request related ministries to toughen the standards for punishing sale and mediation of narcotic drugs.

Woo Young-Taek, Narcotics Policy Division ☎ 043-719-2808

6. Maintenance of the Narcotic Drugs Management System and Strengthening Safety Management

A. Enforcement of the Reporting System for Handling Narcotic Drugs for Medical Use

1) Background

From May 18, 2018, the MFDS made it mandatory for those handling narcotic drugs for medical use to report details on the whole phases through a computer system. This aims to more strictly manage the safety of narcotic drugs for medical use by means including blocking their illegal leak and abuse and misuse. The electronic report is processed through the "Informatization System for Managing Integrated Information on Narcotic Drugs (the Integrated Narcotic Drug Management System)" constructed by the MFDS.

Accordingly, the MFDS can shift to the future management system, which enables the MFDS to monitor all processes related to narcotic drugs for medical use – from import, production to distribution and use – and constantly monitor the status of nationwide narcotics handling and selectively and intensively manage narcotic drugs by analyzing and deploying big data.

2) Achievements

Before implementing the reporting system for handling narcotic drugs for medical use, the MFDS set up a communication council with nine organizations such as those representing pharmaceutical companies, distributors (wholesalers), doctors/pharmacists (hospitals and clinics, drug stores), etc. The MFDS collected and actively reflected their opinions and improved the system. As a result, 48,000 handlers subscribed to the Integrated Narcotic Drug Management System, and 98.8% of them are reporting their activities on a regular basis (as of March 2019). Therefore, this system is deemed to have successfully settled in the initial stage.

In principle, a person shall report narcotics handling details by logging into the Integrated Narcotic Drug Management System constructed by the MFDS on the web. However, there were opinions that it was hard for hospitals, clinics and drug stores to do so since they dealt with a great deal of narcotics for many patients in need of administration/preparation of medicine. So the MFDS developed a system to be linked with some 350 types of preparation software they were using, and 85% of actual reporters are using the linkage system.

3) Implementation Plan

To ensure moderate use of narcotic drugs for medical use, the MFDS plans to develop an instrument with which doctors and patients can check administration histories in the Integrated Narcotic Drug Management System. The new tool shall be

developed by the end of the year. If doctors check the past histories of patients, it will be helpful to prevent them from engaging in medical shopping and misuse and abuse of narcotics while patients, on their part, can voluntarily restrain misuse and abuse by confirming administration data. Meanwhile, as they can check illegal cases of patient ID theft, the management authorities can also use the data for post-management.

In addition, with the help of the Korea Pharmaceutical Association (Korea Pharmaceutical Information Center), the MFDS will develop a service tool with which patients can check the efficacy/effectiveness and administration/dosage of narcotic drugs for medical use on the mobile phone, using QR codes printed on the drug envelope.

B. Stricter Safety Management Using Big Data

1) Background

After formation of the Integrated Narcotic Drug Management System, it is estimated that an average of 530,000 cases of handling details are daily reported and 100 million cases of information are collected a year. Since a single case of reported information contain 49 types of data such as the name of the nursing home, name of the doctor (license No.), name of the patient (resident registration No.), drug information (including serial No.), etc., policy development and safety management have become possible based on big data.

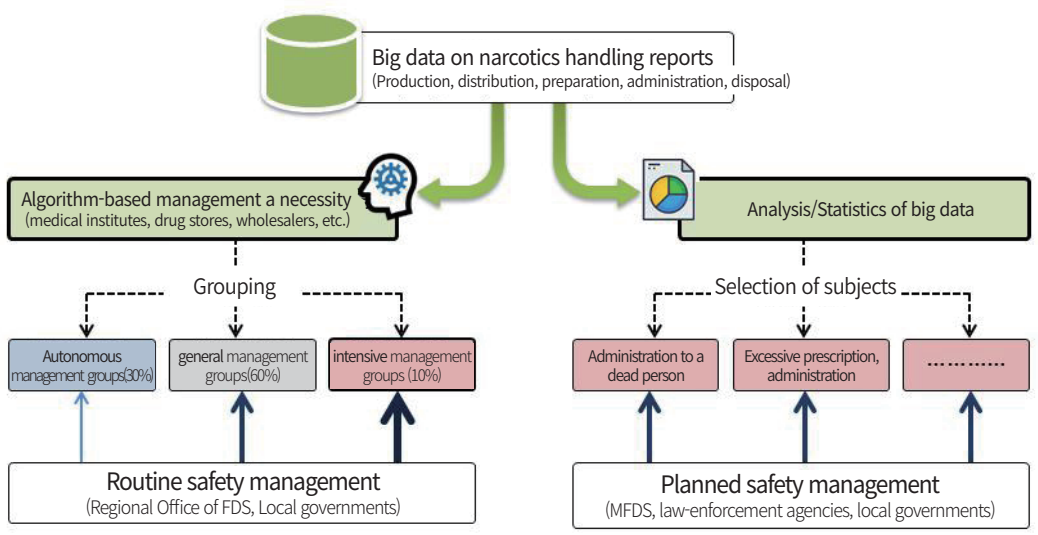
The MFDS decided to implement policies using big data to realize narcotics safety management. Using big data, policy authorities can exploit information from narcotics handlers like doctors and pharmacists and deliver related information to patients and handlers, as well as develop, process, and share statistics.

2) Achievements

From 2019, the MFDS plans to apply a consistent safety management approach that

differentiates narcotics handlers depending on the necessity for control and monitors the intensive management groups year round. To that end, the MFDS provides summarized monitoring statistics on a quarterly basis to each municipality (four times a year) so that they can employ the information for monitoring narcotic handlers in their jurisdiction. The Ministry is also upgrading the integrated narcotic drug management system to help municipality monitoring agents personally check related information starting 2020.

Image 3-2 A consistent safety management system based on big data



After the Mandatory Narcotics Handling Reporting System was introduced, all handling details are reported, making it possible to analyze various information. Data for the latter half of 2018 show that one out of 4.4 Koreans has used narcotics for medical use and those in their 50s were ranked as the largest group to have used narcotics at 21.6%. Such analysis data were offered to the public as press reports (Apr. 11, 2019). Especially, the MFDS analyzed prescription data on Zolpidem, a hypnotic tranquilizer, and provided the findings to individual doctors so that they could study their medical behavior to moderately prescribe narcotic drugs for medical use and

safely manage them.

For post-monitoring of narcotics, the MFDS analyzes big data; identifies hospitals and clinics suspected of administration to a dead person, record of false resident registration numbers, illegal use other than for approved purposes and misuse/abuse of medical narcotics; and cracks down on them in coordination with law-enforcement agencies. By doing so, the MFDS pursues concentration and efficiency of narcotics safety management.

3) Implementation Plan

It has been confirmed that big data gathered through the Integrated Narcotic Drug Management System can heighten efficiency of post-management based on selection and concentration, and enable measures to prevent misuse and abuse of narcotics.

In cooperation with Korean Medical Association, the MFDS is proceeding with research outsourcing in an effort to provide letters of "Helper for Safe Use" to physicians to encourage them safely manage narcotics and present the standards for misuse and abuse of narcotic drugs for medical use by 2021.

Furthermore, the MFDS will organize and run an "On-site Response Team to Narcotics" under the narcotics safety planning director to promptly respond to drug misuse and abuse by operating a channel for reporting illegal use, etc.

Ahn Young-Jin, Narcotics Management Division ☎ 043-719-2893

section 2

Biopharmaceuticals and Cosmetics

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

A. Improvement of Safety Management and Quality Management for Biopharmaceuticals

1) Background

Unlike general synthetic (chemical) pharmaceuticals, biopharmaceuticals originate from living creatures. Therefore, their quality maintenance is difficult, the production process is complex, and securing sterility in the manufacturing process is important given that they cannot be completely sterilized. In that medical products not equipped with reliable quality may do harm to human health, regulatory agencies and pharmaceutical firms across the world are committed to producing safe and effective products based on strict criteria and enhancing mid-to long-term safety management by conducting traceability investigations on cutting-edge biopharmaceuticals after their release.

The MFDS strives to provide good quality of biopharmaceuticals by thoroughly

checking compliance with Good Manufacturing Practice (GMP) in their production process. Presently, the Ministry is proceeding with introduction of the Quality by Design concept, QbD, to produce biopharmaceuticals with high quality and manage their quality at international levels.

2) Achievements

A) GMP Management of Biopharmaceuticals and Reinforcement of GMP Examination

The MFDS enacted the GMP for Biological Products, Etc. (2001) separate from the GMP guidelines applied to synthetic (chemical) pharmaceuticals, and introduced preliminary GMP by item (2003) in order to secure decent quality of biopharmaceuticals, harmonize them internationally and introduce an institution of the type adopted by advanced countries. The MFDS has also been operating GMP guidelines and a separate manual reflecting the characteristics of biopharmaceuticals.

In addition, since 2014 when Korea joined Pharmaceutical Inspection Co-operation Scheme (PIC/S) that has 49 member states including the US, Japan, Europe, etc., the MFDS has been amending related rules to meet PIC/S regulations.

Imported biopharmaceuticals have accounted for about 45% of the domestic biopharmaceutical market in the recent five years and the number of overseas manufacturing facilities has increased from 127 in 2014 to 216 in 2018. Given the dominance of imported biopharmaceuticals, the MFDS inspected 74 overseas manufacturing facilities until 2018 to strengthen the safety management of imported biopharmaceuticals. After inspection, the MFDS provides GMP examination reports to the companies, making the inspection work transparent and improving manufacturing and quality management levels.

B) Improvement of the Lot Release System

In Jun. 2012, the MFDS reformed the national examination system for biological products to form the “Lot Release System” and thus the then prevalent method of

testing finished products was changed to an approach by which the MFDS reviews the overall manufacturing aspects including manufacturing records and summarizes quality management materials of the manufacturers by major manufacturing stage in addition to state examination of finished products.

In 2014, to reasonably improve the Lot Release System, the MFDS also revised the notice on the Regulation for the Procedure and Method to Designate and Approve the Lot Release Pharmaceuticals, from the negative method (exempting some items after examining all according to the results) to a positive one (designating important examination items by risk stage).

In Jul. 2015, the MFDS created detailed standards for risk stage assessment per examination item by differentiating risk stages from the stage of assessing documents alone to the stage examining all items plus documents except release performance of lot release pharmaceuticals.

C) Setup of a Ground to Safely Use Vaccines over the Entire Lifecycle and Provide Technical Support for the WHO's Pre-Qualification (PQ)

For prompt information sharing and consistent response to serious cases of abnormality after vaccination, a cooperation system among related departments (institutions) was established in 2013, and based on the cooperation system, information on abnormal cases is shared every quarter. In 2018, the MFDS published and released guidelines for safe use of vaccines not subject to national vaccination, viz. rotavirus vaccines (Jan. 2018), yellow fever/cholera vaccines (Jul. 2018) and so on. The MFDS formulated the "Roadmap to Integrate and Manage Information on Vaccine-Related Abnormal Cases" (2016) and the "Plan for Establishing a System to Share and Link/Manage Information on Vaccine-Related Abnormal Cases" (2018) to share information on vaccine-related abnormal cases and analyze data. Based on such efforts, the MFDS is trying to set up a ground to safely use vaccines over the entire lifecycle.

To sharpen the competitive edge of domestic biopharmaceutical makers, the MFDS supports them to acquire Pre-Qualification (PQ) of the World Health Organization

(WHO), which can be a stepping stone for domestic vaccines to advance into the global market. To that end, the MFDS organizes a "One-to-One Customized Expert Council" by applicant, and continues to deliver administrative and technical consultation services including quality assessments, clinical tests and manufacturing and quality management standards. In Dec. the MFDS and the WHO signed a PQ cooperation agreement for vaccines, and thereby the Ministry acquired international recognition for its regulatory levels. As of Apr. 2019, 24 products (package unit, accumulated) from six companies obtained PQ.

D) Development of QbD Models for Biopharmaceuticals

To introduce Quality by Design (QbD), a new quality assurance system, the MFDS has implemented internal and external education. As part of the introduction process, the MFDS came up with the "Roadmap to Introduce QbD" (2013) and the "Procedure for Developing QbD Application Models" (2013). As a preliminary process, the MFDS developed a QbD model using genetic recombination medicine between 2015 and 2017 (2015: cultivation and fermentation; 2016: collection and purification; 2017: medicinal products), and published a guidebook for industry application. Besides, the MFDS is developing a QbD application model for vaccine APIs between 2018 and 2019 (2018: cultivation and collection; 2019: purification).

E) Introduction of GMP for Blood Products and Improvement of Their Safety Management

Since the management of raw material plasma used to manufacture plasma derivatives changed from the Korean Red Cross to the MFDS, the Ministry has expanded management subjects to include domestic plasma exporters in addition to existing overseas exporters, and reinforced safety management of plasma by investigating its current status and establishing a Plasma Master File (PMF), Look-back System, and report systems (revising guidelines and instructions, improving system functions, etc.).

For blood (ingredient) products, the MFDS enacted GMP guidelines reflecting their traits (small amount of production, simple process, etc.) in Apr. 2014, and revised them in Jun. 2015 based on the outcome of six GMP pilot evaluation sessions and on-site instruction/training sessions (May – Nov. 2014) for domestic manufacturers that supply blood products to other agencies. This move could consolidate the basis to supply high quality blood products. The adoption of GMP for blood products is expected to construct a safe blood product management system by enhancing the quality assurance mechanisms that manufacturers apply.

3) Implementation Plan

For inspection of domestic and overseas biopharmaceutical manufacturing facilities, the MFDS selects inspection targets based on risk analysis by compiling inspection histories and results, types of manufacturing processes, and domestic and overseas safety information, and evaluating risk grades and checking priority matters. In 2019, the MFDS will select 11 domestic facilities and 12 overseas facilities and perform a regular examination on them considering their inspection records, domestic and overseas quality considerations and impact on the domestic market.

Additionally, the MFDS plans to improve the method of sampling lot release medicine, from sampling and collection by civil servants to direct submission by applicants (firms). To do so, the MFDS will revise regulations and prepare a guidebook on detailed procedures to enable applicants (firms) submit objective and reliable data by reflecting findings of domestic and overseas case studies.

The MFDS will extend its support for introducing WHO Pre-Qualification (PQ) to the field of biosimilars and provide customized services to applicant companies through on-site technical advice on the manufacturing and quality management criteria,, and invite experts from home and abroad through seminars for sharing PQ information and cases.

Meanwhile, to introduce QbD to Korea, the domestic biopharmaceutical companies' lack of technology and experience should be addressed, and to that end, government

support is necessary in sharing and accumulating technologies based on newly developed models. For this, the Ministry will develop a QbD model for vaccine products (APIs) in 2019 following gene recombination medicine (2015 – 2017), and publish its guidelines.

As for blood products, the MFDS plans to develop a "Blood Product GMP Standard Document Model" and provide it to their manufacturers, and continue providing on-site training and pilot evaluation as it did in 2017. The MFDS will build an advanced biopharmaceutical tracking system to manage the history and long-term safety of donors as well as recipients.

B. Safety Management and Advanced Quality Management of Human Tissue

1) Background

Human tissue such as bones and skin taken from living or dead donors have been used as important treatment tools in the medical field in order to restore physical integrity, treat diseases, and prevent disorders.

Thanks to an aging society and rapid development of medical technology, the demand for human tissue has been growing in Korea every year. However, the total demand cannot be met by domestic donors, and therefore, about 80% of the total demand is met by imported tissue.

After the enactment of 「Safety, Management, Etc. of Human Tissue Act」 in 2005, the MFDS has been working to secure the safety of domestic and overseas tissue. In this connection, the Ministry made it mandatory for the Health Insurance Review & Assessment Service to check the donor's medical and medication history especially from 2015. In doing so, the MFDS strengthened the management of the donors' transplant compatibility, preventing donation of tissue of which distribution or transplantation is banned.

In addition, the MFDS established the "Human Tissue Safety Management System (HUTIS)" in Nov. 2015 to enable prompt and efficient traceability management from donation of tissue and collection to transplantation. The MFDS also monitors the usage status of the integrated computer system to understand difficulties, and works on defects to facilitate traceability management and improve users' convenience.

2) Achievements

A) Solid Support and Management for Stable Settlement of Good Tissue Practices (GTP)

In order to strengthen the capability of employees of small NGO-type tissue banks, the MFDS has been providing training sessions from 2014. The MFDS has provided education including advanced courses to tissue bank employees three times a year from 2016. These courses cover the statues on human tissue, GTP, traceability management and reporting of side effects, collection & processing procedures by tissue type, and requirements for quality management. In addition, the MFDS produced educational videos on quality management of human tissue to encourage personnel acquire learning on frequent basis, and continues to provide training sessions to reinforce the human tissue monitoring officers' expertise on relevant laws and GTP, etc.

B) More Exhaustive Survey on Overseas Manufacturers of Imported Human Tissue

In order to enhance the safety management of imported human tissue, the MFDS has conducted surveys on overseas manufacturers since 2011. Also, the Ministry introduced an import approval system in 2015 so that only safety-assured human tissues can be imported through the pre-examination of the appropriateness of the import.

The MFDS is reinforcing the safety management of imported human tissues: performing regular surveys on domestic tissue banks; implementing investigation on overseas manufacturers of imported human tissue from 2011; and adopting the

import approval system in 2015 to examine the appropriateness of the import. Since 2016, the Ministry has also conducted special inspections on overseas manufacturing companies with high risk by comprehensively reviewing examination records of their manufacturing facilities, import approval, amount of money used for import, significant side effects and safety information except for regular surveys on overseas manufacturers of imported human tissue.

3) Implementation Plan

To upgrade the skills of tissue bank employees, the MFDS has been providing training sessions from 2014. The MFDS provided education regarding the statues on human tissue, GTP, etc. three times a year to bolster tissue banks' safety and quality management abilities. In 2019, the MFDS will operate four sessions adding one to allow the employees have more choice of schedule, given that time constraint was an obstacle to their participation in training sessions.

Further, in an attempt to import safer tissue as it represents a large share of distributed human tissue, the MFDS will implement a preliminary registration system for all overseas manufacturers from whom Korea imports human tissue.

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2. Providing Medicinal Herbs and Safety Management of Natural Medicine

1) Background

As the population ages and chronic diseases become rampant, the public's interest in herbal medicine is increasing. Thus, there are growing social demand for quality

control of herbal medicine used for pharmaceuticals (hereafter referred to as "herbal medicine"). In response, the MFDS has made efforts to obtain trust from consumers by strictly managing the quality and safety of herbal medicines.

The MFDS works on building an environment that supports systematic manufacturing ranging from medicinal herbs to final products. To do so, the MFDS introduced the "Good Manufacturing Practice (GMP) for Medicinal Herbs" in 2012, and from 2015, made it mandatory for all manufacturers. The MFDS also carries out customs inspection on medicinal herbs for every import, and from 2008, has been conducting GMP inspection on overseas manufacturers when approving products, for management of the ever-growing volume of imported pharmaceuticals.

2) Achievements

The MFDS strengthened the quality assurance and safety management of herbal medicines by appropriately juggling between support and monitoring/inspection of manufacturing companies.

First, to stabilize the "GMP for Medicinal Herbs" mandated in 2015, the MFDS held policy seminars for the relevant organizations and companies to provide education on manufacturing standards and quality management and promote and share information on GMP policies. Also, to reduce the burden of quality test costs imposed on small manufacturing companies, the MFDS continues to run an open laboratory. This laboratory supported pilot tests for 1,073 cases (8,108 items) in 2017. As a result of implementing policies for stabilizing "GMP for Medicinal Herbs," the number of GMP-verified manufacturing companies increased greatly from 12 in 2012 to 150 in 2018.

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

To enable distribution trusted by consumers and implement advanced standards and specifications for herbal medicines, the MFDS reviewed the existing herbal formulae of the official compendium. Together with this, the Ministry pursued internal and external communication and cooperation by operating a natural medicine industry development council to reasonably resolve pending issues in the natural medicine field.

3) Implementation Plan

In 2019, in keeping with the goal of implementing safe management of oriental medicines, the MFDS will continue to push forward and strengthen the projects that have been carried out since 2015. The MFDS will fortify monitoring and cross-checking of imported medicinal herbs at customs clearance inspection and continue to conduct periodic inspections of overseas manufacturers.

The MFDS is committed to restoring consumer trust in herbal medicine by promoting qualitative growth of herbal medicine manufacturers and developing their competitiveness. In doing so, the Ministry plans to execute education on quality management and induce businesses to use the open lab by bettering its environment and convenience.

Moreover, MFDS will conduct research to scientifically and rationally improve standards and specifications for herbal medicine (crude drugs) and based on the results, keep revising the「Korean Pharmacopoeia」and「Korean Herbal Pharmacopoeia」.

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3. Strengthening of Industrial Competitiveness through Safety Management of Cosmetics

A. Establishing a Safe Environment for Using Safe and Proper Cosmetic Products

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

Since the "Cosmetics Act" was fully revised (on Feb. 5, 2012), the MFDS has strengthened corporate responsibility toward cosmetic safety and quality assurance. The government focuses on follow-up management of products on the market to ensure their rapid market entry. In order to boost the cosmetics industry through development of new raw materials and meet domestic regulations at the international level, the cosmetic ingredient management system has been modified to the "Negative List Method", which notifies the industry of raw materials that cannot be used in cosmetics and allows others to be used.

In keeping with this concept, the MFDS did away with the existing assessment scheme for novel raw materials, and prohibited hazardous cosmetics materials by evaluating raw materials potentially hazardous to national health. The MFDS set the standards for use of potentially hazardous raw materials in cosmetics in need of restrictions such as preservatives and sunscreen, and determined the criteria for safety management of cosmetics on the market to guarantee their quality.

2) Certifying the Companies Complying with the "Cosmetic Good Manufacturing Practices (CGMP)"

According to Article 5 (2) of the "Cosmetics Act" and Article 12 (2) of its enforcement rule, the MFDS encourages cosmetics manufacturers to comply with the "Cosmetics Good Manufacturing Practices (CGMP)" and also releases related notifications.

Hence, since March 2011, the MFDS has been inspecting and evaluating cosmetic manufacturers prior to awarding them with CGMP certification. A total of 147 companies (as of the end of Dec. 2018) are registered as CGMP firms. Products of CGMP companies are contributing to the improvement of the domestic cosmetics market and upgrade of their international prestige.

Furthermore, to disseminate CGMP, manufacturers in charge of some processes can be evaluated in terms of their implementation status, and the method of evaluation was changed from evaluation by product group to evaluation by manufacturer. In order to alleviate the burden on applicants for CGMP evaluation, the evaluation period was shortened from 120 days to 90 days.

B. Strengthening of Industrial Competitiveness through Production Safety Management

Pursuant to Provision 2, Article 5 of the "Cosmetics Act" and Provision 2, Article 12 of its enforcement rule, the MFDS notifies the "Cosmetics Good Manufacturing Practices (CGMP)" and encourages cosmetics manufacturers to comply with it. Now that the cosmetics manufacturers and sellers use the CGMP guidelines to make and supply quality-assured products, the MFDS has been making efforts to disseminate guidelines that can be easily understood. Management and dissemination of these guidelines are also essential to making more manufacturers adopt CGMP since the manufacturers should be able to grasp the guidelines well.

To enhance cosmetics manufacturers' understanding of the CGMP, in Jul. 2013 the MFDS prepared the "Guidelines for the Cosmetics Good Manufacturing Practices (CGMP)" in which the Ministry presented related provisions and delineated its terms in an easy to understand format. According to amendment to the notice on CGMP, the MFDS revised the Guidelines in Dec. 2015 (1st revision) and Dec. 2017 (2nd revision). The MFDS continues its endeavor to help cosmetics manufacturers understand the latest quality control standards and reflect them on manufacturing and quality control processes.

When the "CGMP" are revised, the MFDS applies them to the guidelines and introduces new quality management technologies for the improvement of cosmetics manufacturers' quality control levels.

C. Strengthening Safety Management of the Cosmetics Being Distributed

1) Monitoring Cosmetics

To establish an environment that allows safe manufacturing and distribution of cosmetics, the 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 office and local government for follow-up management of cosmetics. Inspections on cosmetics can be classified as 'frequent inspection' that involves charges, petition, reporting, and monitoring; 'periodic inspection' carried out following the plan of each local government; and 'planned joint inspection' that is implemented on vulnerable or problematic areas by the MFDS, regional offices, and local governments together.

In 2018, the MFDS promoted voluntary inspection of cosmetics manufacturers and sellers. This included a planned joint inspection of products that possibly contained prohibited ingredient mixtures, a sports massage gel promoted by a celebrity, and items subject to false · exaggerative advertising.

To establish a safety management system for cosmetic products that consumers can trust, in 2019, the MFDS will inspect cosmetics on the market through planned joint inspection on violation of cosmetics safety standards (those for mixing limits of raw materials, etc.) and violation of labeling/advertising regulations by "cosmeceuticals" or "dermacosmetics" that promote special efficacy.

2) Collection and Testing of Cosmetics

To secure the safety and quality of cosmetics on the market, the MFDS has been collecting and testing cosmetic products every year according to the "Basic Plan for Quality Inspection", which is part 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 of cosmetics on the market, the need for rapid collection and inspection of cosmetic products has also increased. In order to meet these requirements, the MFDS increased the budget and secured KRW 5.4 million for collection and inspection of cosmetics in 2019. By the present capabilities, over 1,500 items in total can be collected and inspected each year. In addition, for regular quality checks, the 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 recall and dispose of non-conforming products after collection and inspection, the MFDS prepared detailed procedures for recall and disposal in the "Cosmetics Act" and introduced voluntary recall systems for manufacturers and sellers.

In 2019, the MFDS plans to carry out intensive collection and inspection on products of which quality is not appropriately managed. This includes henna coloring agents that are presently in the spotlight. In addition, the MFDS has collected domestic and overseas information on hazards in real time to prevent unsafe cosmetic products from being distributed in the domestic market. The MFDS will continue to inspect and manage ingredients that have safety issues by conducting risk assessments.

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4. Quasi-Drug Safety Management Trusted by the Public

A. Reinforcement of Safety Management for Quasi-Drugs

1) Background

Quasi-drugs are everyday items such as a sanitary pads, toothpaste, mosquito repellents, etc. that are most frequently and widely used and deeply linked to people's lives. Given the frequent use, 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 this regard, the 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. These efforts are focused on strengthening management such as safety verification and introducing reasonable system improvement for quasi-drugs.

2) Achievements

A) Tougher Safety Verification of Feminine Care Products like Sanitary Pads

After consumer anxiety and controversy arose due to detection of volatile organic compounds (VOCs) on sanitary pads in 2017, the MFDS created the grounds for safe use of sanitary pads. The MFDS performed risk assessment and monitoring on hazardous materials that might be contained in feminine care products (sanitary pads, panty-liners and tampons) and confirmed that they were safe to the human body (Dec. 2018). In addition, MFDS organized a voluntary consultative body (Oct. 2017) with the manufacturers occupying 89% of the market in order to reduce VOCs by establishing guidelines for how to cut VOCs, etc. (Dec. 2018). The MFDS is implementing a plan to reduce VOCs by manufacturing stage from supply of raw materials to release of products. As a result, the MFDS was able to lower the maximum detection level to 60%

of that of last year. Further, the MFDS improved the licensing system for sanitary pads by clarifying the standards for safety and effectiveness assessment and mandating description of raw materials through a move that restricted the exemption of toxicity test materials for two member states of the Organization for Economic Cooperation and Development (OECD).

B) Formulation of a Basis for Safe Use of Quasi-Drugs

Against the backdrop of major 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, the MFDS manages the items, which were not subject to control, under the designation of quasi-drugs, and reviews their hazards. For example, "a portable product (portable air · oxygen product) for temporarily supplying air or oxygen through direct or indirect inhalation of air or oxygen" has been managed under the category of quasi-drugs from Nov. 2018. The MFDS manages the safety of such new products under stronger safety standards within the quasi-drug control system. Additionally, the MFDS systematically manages their safety through prior investigation on the usage status, ingredients, and risk considering product features; a related law was enacted in Apr.2018.

The MFDS re-assesses quasi-drugs and evaluates their risk to verify their safety once again even after product approval. With regard to this, the MFDS works to develop an effective management scheme reflecting recent usage trends and safety information. To that end, the MFDS conducted several follow-up measures: changed quality management standards by amending the "Regulation on Quasi-Drugs Product Approval, Report and Assessment" (Mar. 2018); defined the scope of assessment materials for safety and effectiveness (Apr. 2018); and created quasi-drug category numbers for menstrual cup (Mar. 2018).

Meanwhile, the MFDS has been making efforts to safely and efficiently manage quasi-drugs by improving institutions by measures such as repealing unnecessary

regulations. The MFDS deleted “fly or mosquito repellents, prevention agents, and baits and insecticides” from the list of items designated quasi-drugs and changed “humidifier disinfectants” from the category of quasi-drugs to biocides (Nov. 2018). This aimed to ease the burden on manufacturers on account of unnecessary regulations such as their qualifications, etc.

In 2018, the MFDS inspected the suitability of the present methods for raw material management to preemptively secure safety management of quasi-drugs from raw materials to finished products, and monitored hazardous ingredients of 567 items including sanitary pads, masks, and contact lens care articles on the market. Apart from monitoring, the Ministry regularly collected 576 items for quality surveillance, and took administrative action or recalled or disposed of 14 non-compliant items.

As for labeling and advertising, the MFDS planned intensive monitoring of advertising (sale) for commonly used seasonal items for quasi-drug sellers starting the year before last. The MFDS reviewed the market for: regular masks labeled and advertised as quasi-drugs (healthcare masks) in March; bracelets labeled and advertised as quasi-drugs (mosquito repellents) in June; and advertising (sale) of unlicensed humidifier disinfectants in September.

C) Provision of Information on Safe Use of Quasi-Drugs and Public Campaign for Correct Methods for Their Usage

In the aftermath of the incident related to toxic humidifier disinfectants, the public interest in ingredients of household chemical products has grown, raising the necessity for disclosing the entire ingredients of quasi-drugs. In response, the MFDS guided manufacturers to provide information useful for consumers and for those with high risk in the label of items they produced. From Oct. 2018, the MFDS mandated labeling of entire ingredients in paper-based quasi-drugs like sanitary pads and masks, making it obligatory for all items to be labeled for the entirety of substances/ingredients they used. In particular, the MFDS made it mandatory for manufacturers to label cautions for masks considering high risk consumers such as respiratory disease patients

using healthcare masks. Additionally, the Ministry revised the "Rules on Quasi-Drug Labeling" to deliver correct information by indicating expiration dates instead of dates of manufacture (May 2018) for consumers' convenience.

Quasi-drugs are daily necessities and require a promotion method reflecting consumer needs, social issues, and seasonal and environmental factors. Hence, the MFDS makes efforts to efficiently offer information on their safe use considering consumer groups, promotion details, time and media. In spring and winter, the MFDS produced and distributed print materials on healthcare masks in preparation against yellow dust and particulate matters (Apr. to May and Nov. to Dec. 2018), and transmitted related videos online via YouTube and Facebook, etc. (Aug. to Nov. 2018). Moreover, the MFDS made videos on the investigation results on all sanitary pads and the safe use of feminine care products and effectively relayed them through online channels (Aug. to Nov. 2018). The MFDS also provided customized safety information on quasi- drugs used in people's daily lives, such as healthcare masks (Mar. and Nov.), toothpaste and menstrual products [Jun., May (Family Month), Day of menstruation (May 28)], mosquito repellents (summer), and tick repellents [Chuseok (Korean Thanksgiving Day)].

3) Implementation Plan

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

To prevent consumer anxiety, the MFDS will strengthen safety management by controlling hazard levels of substances used in healthcare masks and reinforcing approval and assessment standards for electronic anti-smoking items such as smoking

cessation supplements (Sep. 2018); and analyze hazardous substances that may form during product use and perform their risk assessment.

To assure women of the safety of sanitary pads, the MFDS will: 1) 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; 2) mandate labeling of allergic ingredients present in fragrance agents (Sep. 2019); 3) test-operate GMP for sanitary pads (Oct. 2019); 4) push ahead with a policy for reducing VOCs in sanitary pads; and 5) analyze the presence of dioxins and assess their risk to the human body. Furthermore, the MFDS will change the designation of maternity pads controlled as industrial products to quasi- drugs (Sep. 2019), to ensure better safety for products frequently used by women.

Now that environmental degradation caused by particulate matters has led to a sharp increase in production/consumption of healthcare masks, the MFDS will enhance their gathering and inspection and produce and distribute videos and leaflets on how to properly choose and use healthcare masks. Going further, the MFDS will deliver information on the status of actual distribution and usage, amount of use and reports of abnormal cases, along with guidance on how to correctly choose and use each quasi-drug group based on clues collected by safety verification.

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5. Support for Biopharmaceuticals Penetrating the Global Market and Global Cooperation

A. Support for Korean Biopharmaceuticals Penetrating the Global Market

1) Background

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

In this context, the global growth potential of Korean biopharmaceuticals has increased significantly, and the import and export rates have been rising by 29.8% every year. The market share of the world's first antibody biosimilar 'Remsima Inj. 100mg' has been increasing in the American market as of 2017, since its launch in Sep. 2013 in EMA (Europe), Dec. 2014 in Japan, and Apr. 2016 in FDA (the US) respectively.

As of Dec. 2018, the number of domestic biopharmaceuticals' clinical trials was reported at 26 for vaccines, 37 for biosimilars, 16 for antibody products, 60 for gene therapy products, 153 for cell therapy products and 68 for stem cell therapy products. More diverse Korean products are expected to enter the market soon since there are many pipeline products in vaccines, biosimilars and stem cell therapy, all of which have a global competitiveness edge.

2) Achievements

The MFDS has been developing a close partnership with global regulatory agencies encompassing the WHO and APEC in order to enable domestic biopharmaceuticals to take the lead in the global market. To do so, the Ministry has established safety control

systems for advanced biopharmaceuticals, strengthened tailored support to promote the global competitiveness of domestic vaccines, and provided diverse information as well as professional advice on global and domestic regulations and WHO Pre-qualifications (PQ).

The MFDS also established the "Roadmap to Introduce QbD" in 2013, and delineated the "Procedure for Developing QbD Application Models" in 2014 to advance the quality management system for biopharmaceuticals. Further, from 2015 to 2017, QbD models were developed (2015: cultivation and fermentation; 2016: collection and purification; 2017: medicinal products) and QbD application guidelines published for recombinant DNA products.

The MFDS expanded the number of medicines subject to entrusted manufacturing and improved the institutional framework to allow extra product licenses to rare pharmaceuticals. The MFDS mandated description of preset package units as a condition to apply for a license of biological products, and revised the assessment criteria for influenza vaccines with changed strain so that they are subjected a screening process for their safety, effectiveness, standards and test methods.

The MFDS held the "Global Bio Conference" and connected international workshops operated by the IPRF (International Pharmaceutical Regulations Forum) and AHC (APEC Harmonization Center) with the international event. This is expected to promote the global growth of the biopharmaceutical field designated and nurtured as a future growth engine by providing the opportunity to understand recent global trends and ultimately make Korea a biopharmaceutical powerhouse leading the world.

With a view to supporting Korean vaccines to go global, the MFDS has reinforced the support for distribution of cell banks, development of customized technologies and systems, and WHO PQ to promote export, and also strengthened global cooperation.

In order to increase the domestic vaccine production capabilities of Korea that mostly relies on imported essential vaccines, the MFDS has formed a council of the industry, academia, and government for commercializing vaccines and assisting with construction of production facilities so that the public can be provided with the

vaccines in a timely manner.

Besides, the MFDS established approval/assessment criteria following Europe to expedite approval, and has been cooperating with global institutions and regulatory agencies such as the WHO to help domestic products enter the global market.

Furthermore, since 2014, the MFDS has been promoting the bio-IT platform business, a tailored export support program, to provide regulatory and industrial information on countries that the biopharmaceutical industry is expected to enter. It is a tailored program to support export.

3) Implementation Plan

The MFDS is planning to increase the number of biosimilars, stem-cell therapy products, and gene therapy products to 7, 5, and 1 respectively by 2020, and vaccines to 21 (at self-supply rate of 75%) by 2023 through its global biopharmaceutical support initiative.

By this initiative, the MFDS will provide consulting services and customized information to companies that aspire to penetrate the global market, and publish the "Data Package on Entry Strategy for the Global Market" containing information on domestic and global approval systems and regulations for biopharmaceuticals and related industries. The publication will be provided to relevant agencies to help companies export their products.

Following the development of the QbD model for recombinant DNA products, in 2019, the MFDS is planning to develop the QbD model and make the guidelines, regarding development and quality management for the bulk manufacturing process of vaccine bulk.

The MFDS also plans to start a council comprising public and private sector members, to identify and streamline the regulations to expedite production, to support each product, and establish the relevant guidelines for its commercialization in time.

The MFDS intends to operate this committee from the development of the products, and accelerate commercialization of biopharmaceuticals through mutual discussion, and to provide specific guidelines for commercializing state-of-the-

art biopharmaceuticals so that companies can facilitate rapid commercialization. The MFDS is also pushing to swiftly eliminate unnecessary regulations in commercialization of stem-cell therapy products and streamline implementation of the necessary regulations.

In response to evolving biotechnologies, the Ministry will lay the foundations ranging from research and development to commercialization of the products, and forge a management system, i.e. the Advanced Biopharmaceuticals Act, to systematically and efficiently control the items reflecting the latest technical trends. These include tissue engineering products, cell therapy products and gene therapy products made with cutting edge technology.

In particular, in anticipation of diverse recombination products, combination products and border line products, and to avoid delays in evaluation of a new technology product, the MFDS will establish specific classification standards and procedures. The products MFDS intends to bring under the specific classification standards and procedures include tissue engineered products made from bio material; combined advanced therapy medicinal products made from the combination of cells, scaffold, and growth factors; and 3D printing products using cells.

The MFDS operated a support team for global vaccine production and established a technical support center to commercialize national vaccines, establish and distribute cell lines for vaccines and expand self-supplied vaccines. As a result, the MFDS was able to supply 9 (32%) vaccines as of 2014 and 14 (39%) in 2015, and will be capable of supplying 21 (75%) vaccines by 2023 to expand vaccine self-sufficiency.

The MFDS will provide standards and processes to provide vaccines and other blood products even before their approval in emergency situations such as bioterrorist incidents or epidemics, and also establish a comprehensive plan to provide national medicines by organizing a “Council for a Stable Supply of National Medicines.”

The MFDS will continue operating a “Support Team (Council) for Global Vaccine Production” to expedite vaccine development and provide technical assistance and regulatory information for commercialization of vaccines by securing cell lines and

offering them to the companies. The MFDS will also construct a "Technical Support Center for Global Vaccine Production", run a sample analysis lab for clinical trials and establish an entrusted test lab that can reliably and stably conduct self quality tests.

The MFDS will enhance control of added solvents for biopharmaceuticals by making it a rule to label the ingredients and sizes of the solvents and containers in detail. Additionally, the MFDS will mandate submission of inspection material on gene systems to assure safety, effectiveness and quality of gene therapies and verify safety of the important elements through direct inspection performed by the Ministry.

The Ministry will make necessary policies to support the entire range of activity from R&D to commercialization to facilitate entry into global markets and provide safe and quality products. The MFDS will establish and implement comprehensive and customized support strategies through close cooperation based on information sharing among industry, academia, and the government. By doing so, the MFDS will expand the infrastructure for the biopharmaceutical industry and ceaselessly exert utmost efforts to enable Korean biopharmaceuticals acquire global competitiveness and spearhead the Fourth Industrial Revolution.

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 demand 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 implementing 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, the MFDS was designated as one of the World Health Organization Collaborating Centres for Standardization and Evaluation of Biologicals. Accordingly, the MFDS has been taking part in the following missions: 1) joining development the WHO guideline, 2) participating in a joint study to develop international reference standards and test methods, 3) supporting enhancement of regulatory agencies' capacity including operating education programs and 4) disseminating the WHO's international standards to West Pacific and other areas.

After the designation, the MFDS offered technical advisory for developing 47 WHO international guidelines (2018) on vaccines, etc. as part of the WHO project. Moreover, the MFDS participated in 56 joint study projects to establish international reference standards and develop test methods (2018).

In 2007, the MFDS was designated as an education center for the WHO Global Learning Opportunity (GLO), providing education programs on manufacturing and quality management standards for vaccines. Furthermore, since 2015, the MFDS has been carrying out education on operating test equipment for quality management of vaccines, and 20 trainees from five countries have completed the training held over two sessions until 2016.

In Dec. 2016, the MFDS signed a PQ (prequalification) agreement for domestic vaccines to share regulatory information regarding their quality, safety and effectiveness. This is expected to contribute to streamlining the WHO's on-site inspection required for Korean manufacturers that intend to supply vaccines to international bodies. It will also serve as a remarkable opportunity for them to make inroads into global markets, too.

(2) International Pharmaceutical Regulators' Program (IPRP)

The 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 hosted simultaneously in Osaka, Japan, in November 2013. Since then, the MFDS has taken part in a variety of activities including establishment of criteria for approval · review of biosimilars, 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. In 2018, the MFDS set up the "IPRP Biosimilar Regulatory Information Platform" towards sharing regulatory information and approval experience of each regulatory agency on biosimilars, and creating a communication channel between working group members.

Recognizing the necessity for scientific evaluation of the safety and efficacy of cutting-edge pharmaceuticals and regulatory harmonization, Korea also participates in IPRF as a member of the cell therapy (Mar. 2011) and gene therapy (Oct. 2012) working groups.

(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, the APEC Regulatory Harmonization Operation Committee approved MFDS for running a Center of Excellence (CoE) as a pilot project to provide 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 from Latin America that has a high demand for regulation harmonization education and training.

(4) Reinforcement of International Cooperation among Advanced Regulatory Agencies

The MFDS has worked hard for bilateral cooperation to enable close and direct exchanges with countries around the world. As a result, in October 2013, the 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, the MFDS established cooperative relations with many regulatory authorities: it signed a regulatory cooperation agreement in the Biopharmaceutical field with Health Canada; a cooperation agreement with the Japanese Ministry of Health, Labour and Welfare; and an MOU for cooperation with the Vietnamese Ministry of Health, in 2015.

The MFDS maintains partnerships with multiple regulatory agencies. In 2016, the MFDS concluded a MoU (Memorandum of Understanding) for cooperation with the Ministry of Health of Peru, the Administracion Nacional de Medicamentos, Alimentos y Tecnologia Medica of Argentina and the National Institute of Biological Standard and Control (NIBSC) of the UK respectively.

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

In March 2017, the 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 to hold international forums and workshops in an effort to reinforce professional capabilities in the field of advanced biopharmaceuticals. In every June since 2015, the MFDS has integrally held "Global Bio Conference", which has grown into a representative bio-related event that sees attendance from approximately 3,000 experts from government organizations, industries, academia, and press.

3) Implementation Plan

To become a global top 7 country in the biopharmaceutical field by 2020, the MFDS will intensify 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)

The MFDS, which was designated as WHO Collaborating Centre in January 2011, was reelected to the same position by WHO after evaluating its work performance for the last 4 years. Accordingly, the MFDS will run the WHO Collaborating Centre until January 2019 with an expanded scope of work. In addition, the MFDS has continued the ODA project called "Technical Support for Biopharmaceutical Evaluation and Approval System for Developing Countries in the West Pacific Region." Furthermore, the MFDS has been conducting a joint research project with WHO to develop reference standards and various guidelines.

(2) International Pharmaceutical Regulators' Program (IPRP)

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

(3) Asia-Pacific Economic Cooperation (APEC)

For harmonization of biopharmaceutical regulations in the APEC region, the MFDS designated and operated CoEs for biopharmaceuticals based on an analysis of regulatory differences found during the workshops. In June, the MFDS will hold a workshop, share the outcomes and craft an activity plan for 2020 and beyond.

B) Expansion of Bilateral Cooperation

The 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, the MFDS signed a working agreement with Health Canada and will continue to cooperate with the WHO, National Institute for Biological Standards and Control (NIBSC), and US Pharmacopoeia (USP).

C) Reinforcement of Expertise through Harmonization of Regulations

To support domestic biopharmaceutical companies to make forays into the global market, the MFDS will hold the "2019 Global Bio Conference" from June 24 to 28, 2019, 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 and sharing of knowledge and experience among the participating experts.

Lee Nam-Hee, Biopharmaceutical Policy Division ☎ 043-719-3302

6. Advancement of an Approval & Evaluation System for Biopharmaceuticals

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

Recently, the number of new concept products blended with cutting edge biotechnology has surged in the biopharmaceutical field. Especially, the mechanism of advanced biopharmaceuticals is complex and thus their features are difficult to determine. In addition, there are no criteria for the approval and evaluation of

biopharmaceuticals across the world due to a lack of uniform approval and evaluation standards. Against this backdrop, it is all the more important to establish the standards for their approval and evaluation earlier than other countries, in securing the safety of advanced biopharmaceuticals based on new concepts and quickly approving them. The significance of biopharmaceuticals is increasing in the global pharmaceutical market and more domestically developed medicines like biosimilars, etc. are entering overseas markets. Hence, building an internationally harmonized approval and evaluation system in line with such a growth trend of biopharmaceuticals is the very core of stronger competitiveness in this domain.

The Biopharmaceuticals Review Management Division has endeavored to coordinate civil petitions, and acts as a single channel for them. Moreover, the Division tried to introduce a preliminary approval system; expand subjects of public meetings on civil complaints; introduce new institutions and procedures for biopharmaceuticals such as an electronic history system for consultation on civil complaints over the entire cycle and the biosimilar information room; and develop excellent approval standards and guidelines. Moreover, the Division strengthened evaluators' expertise and skills with education programs by area and invited professionals at major overseas regulatory agencies and academia in the biopharmaceutical field to share current domestic/international development trends, safety management, and regulatory situations and evaluation standards and direction for advanced biopharmaceuticals of each country.

For biosimilars, the Biopharmaceuticals Review Management Division is serving as 1) an international front runner in sharing information on regulatory issues among countries and international discussion on cooperation between regulatory bodies and 2) a leverage for international harmonization in supporting more firms to enter global markets like the US or EU.

For the priming water program, which started in 2014 to develop products as next-generation growth engines and enable them preoccupy the global markets, the Division organized a council with domestic pharmaceutical (development) enterprises to practically assist with their development by agent, monitoring obstacles to their

commercialization efforts and discussing how to overcome them. The Division also provides one-to-one consultation services for the whole process from development to approval.

The Biopharmaceuticals Review Management Division plans to offer education for greater evaluation capacity, keep gathering opinions from the industry, and streamline evaluation standards. The Division will also preemptively come up with evaluation standards for new-concept, sophisticated products by enacting and amending approval and evaluation guidelines by agent.

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B. Advancement of Approval & Evaluation of Herbal Medicinal Products

With the increasing demand for stronger control of herbal (crude) medicinal preparations manufacturing including quality, etc., regulations are getting stricter. For example, the scope of ingredients subject to Drug Master File (DMF) registration was expanded (2015) and submission of chemical profiles and benzopyrene risk assessment became compulsory (Oct. 2016). Meanwhile, due to the rising interest in developing herbal (crude) medicinal preparations, there has been an increase in formulation changes of pharmaceuticals for herbal medicine health insurance. Further, a growing number of Korean medicine hospitals are applying for clinical trials. Therefore, it is necessary to create more reasonable and consistent regulatory conditions for supporting commercialization of herbal medicinal products and to strategically develop them through continued efforts to enhance communication with the industry.

In 2018, the MFDS introduced the amendment (draft) of the official compendium on herbal medicine and six guidebooks for industry. The MFDS also held briefings, public seminars, conferences, meetings, etc. to share regulatory changes and directions for drug product review, and implemented outreach education to boost quality

management levels of companies. The MFDS also provided one-on-one customized consultations for clinical R&D initiatives of the Ministry of Health and Welfare to facilitate clinical trials. These show various efforts of the Ministry toward bettering quality of its regulatory review and approval and supporting commercialization.

The MFDS will forge reasonable regulatory conditions, improve standards and specifications, present evaluation guidelines and update product information to improve predictability and transparency of MFDS review process. The Ministry will also offer consultation services to promote two-way communication with the industry and facilitate clinical trials for successful commercialization.

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

1) Preparation of a Reasonable Evaluation System and Safety Standards for Quasi-Drugs

Recognizing the need for a reasonable and systematic evaluation system that can address a variety of new quasi-drug items, the MFDS has been developing guidelines and amendments of the relevant regulations. In order to support the industry's product development, the MFDS prepared guidelines for an efficacy evaluation system by item; generated a scientific evaluation system for newly designated quasi-drugs and an amendment to evaluation regulations to toughen safety evaluation; and supported quality management of companies through standardized specs by reflecting frequently approved items. In addition, the MFDS will continue to strengthen the quasi-drug review system, develop guidelines for efficacy evaluation and standard specifications and revise the standards and test methods for quasi-drugs to help the industry forge

ahead with product development.

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 advertisements on cosmetics, vitalize the cosmetics industry and support the development of new products, the MFDS came up with a testing method for reviewing substantiation. In order to raise consistency and efficiency of evaluation for newly added functional cosmetics and support development of safe and quality functional cosmetics, the MFDS plans to advance the evaluation system according to the changing environment by developing standards and testing methods for new functional cosmetics, improving the testing method and continuously revising regulations on evaluation of functional cosmetics. Furthermore, the 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. Construction of the Foundation for Innovative Growth of Medical Devices and Establishment of Their Lifecycle Safety Management System

A. Background

With recent developments of advanced technology, the medical devices industry is gaining popularity as a next generation innovative industry leading future growth. However, about 80% of domestic medical devices firms are small and have difficulty in competing with their peers in the global arena.

In addition, the international safety management trend for medical devices is shifting toward integrated control of information by each phase throughout the entire lifecycle. In this vein, in the event of a product proving to be hazardous, it is necessary to have a system in place to minimize damage by spreading safety information quickly, and to trace distribution and inventory information and swiftly recall the item.

B. Achievements

The MFDS proceeded with enacting the "Act on Nurturing the Medical Devices Industry and Supporting Innovative Medical Devices" and established the "In Vitro Diagnostic Device Act" to design an approval & review system reflecting the characteristics of In Vitro Diagnostic Devices (IVDDs).

As a follow-up measure of amendment to the "Medical Devices Act" to attach barcodes to medical devices and construct an integrated information system, the MFDS revised the "Enforcement Rule of the Medical Devices Act" defining information to be registered with the integrated information system and specifying the enforcement date for attaching standard cords to medical equipment. Further, the Ministry enacted the "Rule on Labeling and Managing Standard Cords for Medical Devices" to label their standard cords, etc.; and amended the "Enforcement Rule of the Medical Devices Act" to prescribe procedures and methods to report details on supply of medical devices.

C. Implementation Plan

The "In Vitro Diagnostic Device Act" will allow Korean companies to preoccupy domestic and international markets for innovative medical devices created based on sophisticated technology, and lay the foundations to cultivate and help the presently small industry to become a new future industry with a global competitive edge. The "In Vitro Diagnostic Device Act" will contribute to working out a new approval & review system fit for the features of IVDDs and enhancing their international competitiveness.

In 2019, to strengthen the integrated information system based on standard cords for medical devices, the MFDS will launch the setup of the system and complete it before the enforcement date for registration, and establish a supply information system to facilitate report of details on medical devices supply.

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2. Strengthening a Consumer-Centered Medical Device Safety Management System

A. Background

In Korea given the rise in the aging population and changes in the paradigm with a focus on "quality of life", the medical and medical devices industries are witnessing tremendous growth. Accordingly, the provision of accurate information on medical devices and their safety management in terms such as quality are becoming more crucial than ever. Therefore, the MGDS is working on safety management policies for medical devices through monitoring, quality inspection, advertising management, etc.

B. Achievements

The MFDS modified its strategy, hitherto concentrated on post-monitoring and resolving complaints, to preemptively address risk factors and prevent problems before they occur. Towards this, the Ministry selected, instructed and examined management targets by analyzing hazard data. Especially, given that cases of foreign substances entering medical devices are on the rise, the MFDS recognized the need to control overseas manufacturing facilities, and forged the legal ground (Dec. 2018) through measures like revising the Medical Devices Act regarding "on-site inspection of overseas facilities" and "compulsory reporting of foreign substances." The Ministry also reinforced the infra for post-management of safety by increasing the number of staff (10 persons) and expanded the budget for overseas on-site inspection and control of foreign substances.

In addition, the MFDS conducted quality verification on commonly-consumed, substandard and women-only products, steadily bringing down the rate of non-conforming products (10.3% in 2016 → 7.3% in 2017 → 6.0% in 2018). The MFDS took corrective and preventive measures through technical support for 42 companies that

failed to meet relevant quality standards, thereby preventing damage to consumers. Furthermore, in 2018, the MFDS investigated and disclosed prices of six main products sold at free trial centers and started a related pilot program at the end of the year to protect vulnerable groups including seniors from fraudulent transactions.

The MFDS pushed to amend GMP for medical devices reflecting the latest international GMP standards (ISO13485:2016), and works to develop the foundation for international harmonization and mutual approval among countries in relation to GMP for medical devices. To this end, the Ministry hosted the ISO TC 210 general meeting to enact and revise international standards for quality management of medical devices.

C. Implementation Plan

In 2019, the MFDS will manage medical devices by selecting targets based on data, enable distribution of safe medical devices, control performance of shared medical devices and implement preliminary instruction/inspection on new items, to prevent potential risk factors and preempt problems.

Further, the MFDS will verify the quality of products sold via home shopping platforms, when these products are relevant to abnormal cases or distributed in large volume, and thus improve the use environment and reassure consumers.

To protect the vulnerable classes from fraudulent transactions and prevent damage to consumers, the MFDS will continue the pilot program disclosing prices of the products sold at free trial centers and carry out random and frequent inspections by month and region.

Finally, the MFDS will designate domestic review accreditation agencies specialized in medical devices to join the International Medical Device Regulators Forum's review program exclusive to medical devices, and expand the scope of their review capabilities. The MFDS will also internationally harmonize GMP by introducing a mandatory reviewer education system to strengthen GMP reviewers, and thereby create a basis for mutual approval among countries.

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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 treatment of chronic diseases. These demands are spurred by the aging population and the needs for disease prevention facilitated by enhanced income levels. Accordingly, the 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 reporting on the side effects of medical devices and establish an advanced management system, the MFDS has been running a "Medical Device Safety Information Monitoring Center" since 2011. In 2018, the MFDS reviewed 120 small and medium sized hospitals through safety information monitoring centers for medical devices run by 19 general hospitals. 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 the standards for use of medical devices. The Ministry has also made efforts to ensure that medical device manufacturers take corrective and preventive measures, thereby helping consumers use safe medical devices.

The MFDS has designated human transplant medical devices that may cause fatal injuries to the human body due to side effects or defective use as the object of tracking management, ensuring that the Ministry can track the entire distribution of medical devices, ranging from manufacturing to use. In 2017, the MFDS established guidelines to improve the record system for medical devices used by medical institutions, and made it

mandatory for devices to be registered and managed through a computer system.

In addition, the 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 grades 2 to 4, and applied the information to permissible matters (directions for the use of medical devices, method of use, etc.). It also re-evaluated 903 medical devices with grades 3 and 4 from 2015 to 2018. In addition, the MFDS re-assessed silicon-filled breast implants for which many side effects were reported, to unify the purpose of use and to strengthen the precautions for use.

C. Implementation Plan

In 2019, the MFDS will build an informatization system to safely manage the side effects of medical devices to effectively collect, analyze and evaluate relevant information.

Moreover, the MFDS will link the traceability management system for transplanted medical devices with the preliminary report system for standard clearance, so as to prepare a rapid response system such as blocking import or clearance of medical devices with potential risk, and systematically manage the safety of medical devices by reassessing products subject to public interest including those that cause adverse effects.

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4. Advancement of the Medical Device Approval Review Process

A. Establishment of an Innovative Review System for Medical Devices in the Era of the Fourth Industrial Revolution

1) Construction of an Effective Safety Management System Based on Real World Evidence

The evolution of data analysis technology has enabled generation of significant clinical results through integration and analysis of medical data. Hence, advanced countries such as the US and Europe apply real world evidence, acquired by analyzing real world data used at clinical trial spots, to strengthen safety and effectiveness.

In this context, the MFDS has made efforts to promote the use of real world evidence analyzed based on real world data to determine regulations and make civil petition more convenient and approval and review work more transparent. To that end, the MFDS provided the "Guidelines for Applying Real World Evidence of Medical Devices" including considerations of how to establish the validity and reliability of real world evidence.

2) Measures to Innovatively Alleviate Regulations for In Vitro Diagnostic Devices (IVDDs)

Considering the attributes of IVDDs, the MFDS devised a regulatory measure to classify major and minor changes in terms of approval of changes applied to medical devices. Here, major changes to medical devices shall be approved by reviewing the technical documents considering their impact on product performance and safety. On the other hand, minor changes can be autonomously controlled by the manufacturers (Nov. 2018). The MFDS revised the regulation on approval, report and review of medical devices to continue to operate such measures (MFDS Notice No. 2019-13, Feb.

2019). The MFDS defined "major changes made to IVDDs" to help the manufacturers determine them and prepared a "flow chart to decide subjects of change." To stabilize the institution, the MFDS also published the "Guidelines for Civil Petitioners" (Mar. 2019) so that petitioners can refer to it in determining minor changes and applying for the report. The Ministry has also implemented a scheme by creating an online window through which petitioners can ask questions about major and minor change reports (email: ivdmfds@korea.kr) and receive an answer about their review results. MFDS also amends the Guidelines for Civil Petitioners that reflect additionally reviewed cases on a half-yearly basis. Thanks to eased regulations that factor in the attributes of IVDDs, the MFDS expects to be able to support development of related industries and going further, contribute to better national health.

3) Method and Cases of Applying Cyber Security to Medical Devices

With more and more medical devices adopting communications technology, there are growing concerns about possible threats to patients' safety. In response, the MFDS has generated cyber security requirements for designing medical devices using wired and wireless communications technology. The Ministry also divided safety grades into three steps and presented such a differentiated security framework to the industry.

B. Leading Future Growth of the High Tech Medical Device Industry

1) Supporting Fast Commercialization of New Convergence Medical Devices through Pan-Government Cooperation

From 2015, The MFDS has conducted a project to develop evaluation technology for new convergence medical devices and thereby expedite approval of new convergence medical devices among state-assisted initiatives. The project, based on pan-government cooperation, will help companies develop test methods and a plan to

evaluate the safety and performance of the devices and clinically test them. The MFDS developed 21 guidelines for speedy product approval. Further, the MFDS plans to enable new medical devices enter the market promptly by means of pan-government cooperation and communication with relevant agencies.

2) Nurturing Core Talents to Enable Approval Tailored to the Fourth Industrial Revolution in the Medical Device Area

To quickly commercialize medical devices geared towards the Fourth Industrial Revolution, tailored education is necessary for cultivating professional personnel capable of managing the entire lifecycle of medical devices from development to approval. Therefore, the MFDS separated professional personnel into research developers and licensors, and designed a training program for the research developers and a practice-centered training program for licensors to efficiently nurture capabilities in each functional area. In 2018, to rapidly commercialize medical devices targeted toward the Fourth Industrial Revolution, the MFDS operated training curricula to cultivate professional personnel with skill sets ranging from development to approval. The training program for research developers comprised 11 curricula including "Preparation Process for Approving Products for the Fourth Industrial Revolution" and a total of 23 sessions. The training recorded a high satisfaction level of 91% among 329 people that completed the course. The training program for licensors comprised 11 curricula such as "Preparation Process for Approving Products for the Fourth Industrial Revolution". The course, completed over 22 sessions, had 249 participants who recorded a high satisfaction level of 92%. This year, these training programs will start in May. The MFDS will invite foreign experts associated with medical devices for the Fourth Industrial Revolution, etc. to educate trainees on overseas regulatory trends and application cases, and actively assist with the globalization of new convergence medical devices.

3) Approval and Review Measures for IVDDs Based on Big Data

As advances in Biotechnology (BT) and Information Technology (IT) translate into development of bioinformatics, genomics and proteomics, information on human genes can be analyzed now. In in-vitro diagnosis, accordingly, unlike the past when only a specified biomarker related to a disease was used, more IVDDs for multiple biomarker tests that harness several biomarkers are being developed now. Therefore, the MFDS established a related product group to develop items using various biomarkers. Further, the MFDS published the "IVDD Approval and Review Guidelines for Disease Prognosis & Prediction" (Aug. 2018) including tips for preparing technical documents such as approval and review application forms, matters related to evaluation of analytical and clinical performance, and the requirements for material such as algorithm verification and assessment. The MFDS also held a civil petition briefing session on the guidelines (Sep. 2018) to support businesses in the development process. The IVDD Division plans to reinforce the guidelines for development and approval of IDD software using big data and precision medical technology, and adopt them for domestic products. By doing so, the IVDD Division will support indigenous development of excellent IVDDs.

4) Creation of a Safe Environment to Cope with Infectious Diseases Caused by Climate Change

Owing to climate change and the increasing number of travelers to foreign countries, Korea has seen more patients with high-risk tropical infectious diseases such as dengue or malaria. In this regard, the MFDS came up with an approval and review measure for diagnostic products vital in cutting off mosquito-borne tropical infectious diseases so that the Ministry can support the development of diagnostic products. To do so, the MFDS created guidelines for inspection reagents including tips for filling in approval and review application forms and the requirements for material

on analytical and clinical performance evaluation (Sep. 2018). The MFDS will continue to issue the guidelines for production, import, approval, etc. of IVDDs to actively block infectious diseases from abroad caused by climate change, etc. and respond to changing external environments to protect the people.

C. Leading International Standards and Facilitating Communication and Cooperation

1) Member activities of the International Medical Device Regulators Forum (IMDRF) and Regulatory Harmonization

The IMDRF has the biggest medical device market (86%) and regulatory influence among international institutions related to regulations on medical devices. Hence, the MFDS actively joined international cooperation activities and crafted preemptive medical device regulations to become the 10th member of the IMDRF in Dec. 2017. Since 2018, the MFDS has shared Korean regulations with the world and introduced the guidelines for high-end medical technologies like AI and VR by attending at the 13th and 14th general meetings as a regular member. Moreover, in step with accession to the IMDRF, in Nov. 2018 the MFDS signed an MOU with a major IMDRF member Canada for stronger cooperation for medical devices and future joint activities. This MOU was concluded between the MFDS Medical Device Review Unit and the Medical Device Bureau of Health Canada to share information and promote manpower exchanges. At the 15th general meeting of IMDRF, Korea was selected to hold IMDRF presidency for 2021. Therefore, the MFDS will work harder to lead regulations on medical devices at a global level.

2) Strengthening Promotion of Life-Friendly Medical Devices Targeting Information-Vulnerable Groups

A) Background

Since medical devices have a variety of mechanisms, methods of use, and functions, they have different effects and even become dangerous according to how the consumer uses it. Besides, given individuals can easily use medical devices at home (contact lenses, personal heaters, thermometers, breast pumps, etc.), it is all the more important to properly know how to use them and their precautions for use.

B) Achievements

The 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 2018, the MFDS ran publicity campaigns to share information regarding 20 life-friendly medical devices including intraocular lenses, dental implants, contact lenses, electric wheelchairs, blood glucose meters, personal urine analysis devices, pregnancy testers, etc.

Moreover, to provide safety information to multicultural families, the MFDS produced multilingual leaflets (in Korean, English, Chinese, and Vietnamese) on wound dressing, thermometers, manometers, medical suctions, intraocular lenses, pregnancy testers, contact lenses, and electric wheelchairs, and distributed them to related bodies like support centers for multicultural families.

C) Implementation Plan

This year, the MFDS will continue to promote methods for safe use of medical devices and precautions for to the benefit of information vulnerable groups i.e. the elderly, the disabled and multicultural families.

3) Steady Operation of the Medical Device Communication Forum (MDCF) to Enhance Global Competitiveness

The MFDS has held international medical device communication forums to discuss overseas regulatory trends of the medical devices field in the era of the Fourth Industrial Revolution and explore reasonable regulations for domestic medical devices. Especially, with Korea's accession to the IMDRF (International Medical Device Regulators Forum), the MFDS necessarily works in cooperation with international agencies and pursues continued enhancement of a network with overseas regulatory authorities.

The "Fourth Medical Device Communication Forum" held in 2018 was a meaningful occasion where the government, industry and academia gathered together and sought ways to enhance cooperation under the theme of "In the Era of the Fourth Industrial Revolution, Seeking Global Strategies for Medical Device Regulations." Particularly, it was conducive to building a reasonable regulatory environment for domestic medical devices.

The "Fifth Medical Device Communication Forum" to be held in 2019 aims to review recent developments of regulatory agencies in advanced countries including the US Food and Drug Administration and to proactively counter change in future medical environments. The MFDS will also discuss plans to break down regulatory entry barriers to ensure that domestic manufacturers can expand their global presence.

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chapter 4

Risk Prevention

section 1

Establishment of Foundations for Preemptive Risk Prevention and Crisis Response System Focused on Customers

1. Establishment of a Road Map 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 Nov. 19, 2015. The Act comes with a total of 18 articles, including the mandatory establishment of master plans to promote safety technologies and strengthen the basis for granting research fund contributions (Act No. 13333, 18. May 2015).

In addition, as the Act was enacted and enforced, the MFDS' "First Master Plan for the Promotion of Safety Technologies for Food, Drugs, etc. (2016~2020)" was established and implemented from Apr. 2016. Based on this Master Plan, the MFDS formulates a yearly plan, and thereby determines R&D directions for food and drugs, and sets forth policy initiatives and implementation plans.

Further, the MFDS clarified the legal ground by establishing a provision regarding initiation of the Safety Technology Committee for Food and Drugs according to the

"Act on the Promotion of Technology for Ensuring the Safety of Food, Drugs, Etc." Furthermore, the Ministry worked to enhance the status of the Committee and more methodically set up important policies regarding the development and promotion of technologies for safety of food and drugs, etc. (amended on Dec. 11, 2018, enforced on Jun. 12, 2019)

The MFDS plans to reorganize the "Regulations for the Operation of Research and Development of Safety Technologies for Food, Drugs, etc. (Instructions)" and revamp the composition and operation of the Safety Technology Committee for Food and Drugs (Jun. 2019) in order to efficiently manage and run R&D operations, and forming and managing R&D policies for development and promotion of technologies for safety of food and drugs, etc.

2. Establishment of a Crisis Response Base for the Prevention of Safety Accidents

In order to respond promptly and preemptively to crises that pose 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.

The MFDS 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. The manuals developed so far include: food and pharmaceuticals (2009), medical devices (2011), and cosmetics (2012). In 2018, the MFDS integrated and streamlined food and pharmaceuticals, medical devices, and cosmetics, and revised the measures to be taken, procedures and roles in the event of a crisis.

The MFDS also developed a "Practical Manual for Radioactive Leakage Countermeasures for Neighboring Countries" (2012) and "Crisis Response Practice Manual for the Nuclear Safety Sector (Radiation Leakage Countermeasures)" (2015). In March 2013, following reorganization of the government, safety management of

agriculture, fisheries, and marine products was transferred to the jurisdiction of the MFDS. Accordingly, the MFDS integrated them into the Food Crisis Response Manual at the time of its amendment. 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, the MFDS established a crisis response system based on the "Central Headquarters for Food Safety Accidents" and operates the system in order to strengthen government-wide countermeasure capacity.

Especially, the Manual for Crisis Response integrated in 2018 divided a crisis into two phases: crisis preparation and crisis occurrence. It described how to respond quickly to the occurrence of a crisis; enhanced manual application capacity; created a checklist for early response and crisis communication strategy; and simplified the decision-making approaches and procedures.

In addition, in order to enable field personnel respond quickly to on-site industry-specific safety accidents, the MFDS developed the "Crisis Management Guidelines for Food Companies" (2013) and distributed it to related organizations and businesses. The MFDS provided practical training on a crisis response manual operation system complete with simulations of crisis situations and countermeasures.

Additionally, the MFDS continuously strives to strengthen its ability to respond to crises, by means such as creating an environment where public officials who have difficulty in attending on-site training can access cyber education courses at any time. From 2014, the MFDS has been working on international cooperation: to share domestic and international crisis response systems and knowledge/information, the MFDS holds crisis response international symposiums and forums, reviewing policy trends of industrialized countries like the US and forging an information exchange network.

In 2019, the MFDS will continue to focus on advancing the crisis response system and strengthening the capacity of practitioners. In order to prepare for crises caused by food and drug accidents, the MFDS will continuously improve the crisis response manual so relevant personnel can operate the manual on the ground during a crisis.

As an emergency crisis management organization, MFDS will execute simulation exercises centered on practice and conduct discussions to strengthen early response ability. To promote cooperation among related ministries and agencies, the MFDS will support municipalities to construct a crisis response system. The Ministry will also develop virtual training content to secure realistic training conditions and continue to strengthen the rapid response system to address new types of crises. Through these initiatives to enable a quick response to crises, the MFDS aims to minimize damage to the general public and ensure safety and peace of mind for the people.

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

A. Preventive Risk Management

The MFDS has been carrying out preliminary surveys on potentially hazardous foods since 2006 with a view to preventing food safety issues. To that end, the MFDS collects and inspects samples and prepares safety measures based on hazards-related information collected and analyzed at home and abroad.

After the surveys, the MFDS takes action such as recall, disposal or administrative measures on substandard or nonconforming items. The MFDS also conducts risk assessment on potentially hazardous items with no standard and specification or recommends suspension of manufacturing and sale of such items as part of safety and management measures.

In order to eliminate blind spots in safety management, the MFDS has also conducted preliminary surveys since 2015 focusing on items for which standards have not been set. In 2018, the MFDS carried out 515 cases of collection and inspection for eight food contaminants such as heavy metals and pyrrolizidine alkaloid in pollen products and heavy metals in fish oil. Most of the inspected samples stood at a safe level and the standards and specifications for arsenic in fish oil were newly set.

In 2019, the MFDS will conduct about 550 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 Hazard/Risk Management on Tobacco

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") and announced 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.

The 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 present in regular cigarettes and liquid e-cigarettes was announced. In 2018, the MFDS announced the harmful content of heat-not-burn (HNB) tobacco in response to the great interest shown by the public since their release in 2017.

In addition, given its expertise in toxicity assessment and analysis of harmful components, the MFDS is managing the tasks related to hazard management such as measurement, control and disclosure of tobacco components where amendments to related laws are being pursued.

The MFDS continues to conduct basic studies on hazard management, including establishing systematic methods for measuring tobacco components and toxicity

assessment. The MFDS will design an analysis method for regular cigarettes, HNB, and liquid e-cigarettes in 2019.

In particular, the MFDS plans to cooperate closely with related ministries (Ministry of Economy and Finance, Ministry of Health and Welfare, etc.) in countering new types of tobacco and in revising relevant laws to make submission of data on tobacco ingredients mandatory for tobacco manufacturing/import/sales agents and to enforce disclosure of information to the public.

4. 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. However, the new law regulated only the lodging industry and bath business, not sanitary goods. In accordance with Article 3 of the Addendum to 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 of a new law or amendment of existing law that covered these items. Yet, as there had been no regulatory action for 18 years since then, new items like hand paper towel could not be controlled despite changing circumstances. This, in turn, generated unreasonable cases such as application of rules far from reality.

Therefore, the MFDS made efforts to enact a separate legislation for sanitary goods in order to improve their management system and raise hygiene levels, thereby promoting public health. As the「Cleansing & Hygiene Products Control Act」was enacted and promulgated on Apr. 18, 2017, the legislation of the「Enforcement Ordinance of Cleansing & Hygiene Products Control Act」and the「Enforcement Rules of Cleansing & Hygiene Products Control Act」were established as subordinate regulations. Also, the MFDS instituted「Standards and Specifications 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」 and 「Regulation on the Designation and Operation of Hygiene Education Institutions for Sanitary Goods」, and enforced with effect from Apr. 19, 2018.

According to the 「Cleansing & Hygiene Products Control Act」, the category of hygiene products was expanded, and 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. Further, the import business was reorganized for the safe management of imported hygiene products. The MFDS improved unrealistic facility standards and changed intervals for self-quality inspections reasonably to factor in industrial conditions such as scale of small businesses and to further the efficiency of safety management.

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 reorganized for sanitary goods. As the import business was newly established, the 「Regulation on the Inspection of Imported Sanitary Goods」 was also established in order to facilitate the safety management of sanitary goods.

Besides, pursuant to the 「Regulation on the Designation and Operation of Hygiene Education Institutions for Sanitary Goods」, the MFDS designated institutions that provided education related to sanitary goods to improve sanitary levels, and prepared the 「Regulation on the Operation of Consumer Hygiene Watchdog System for Sanitary Goods」 to facilitate the system.

In 2019, the MFDS will upgrade the 「Standards and Specifications for Sanitary Goods」 for thorough safety management of sanitary goods, and concentrate on control of imported and distributed goods.

Moreover, the 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 types of products that are left unchecked.

5. 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 · med ical 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, the 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 to form 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 products, and carry out joint research and study when necessary. MFDS signed an MOU with Korea Consumer Agency in 2009 and continues to work together 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 release of any inaccurate information and resultant confusion. In 2018, the two organizations provided information on 26 cases through mutual consultation.

MFDS and KCA also announced plans for joint investigation on agendas of interest to consumers, established a communication channel for mutual cooperation, and built a constructive cooperative relationship through regular meetings and joint workshops.

In 2019, 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.

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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

The MFDS has striven to identify, correct, and improve the blind spots in food and drug policies by establishing a two-way communication channel with the public, industry as well as other stakeholders in order to listen to various opinions from all walks of life and encourage them to engage in policy making.

The MFDS established the "National Communication Council" consisting of 1,000 people aged 19 or above, identified consumers' complaints and concerns on the safety of food and drugs and found their needs by analyzing consumer consultation and the media. The MFDS took action on such needs: instruction and inspection, status survey, institutional improvement and provision of life-friendly information.

The MFDS provides prompt feedback on questions regarding the safety of food and pharmaceuticals and offers information on current issues related to food and pharmaceuticals at all times.

Apart from it, the MFDS holds the "Open Forum on Food and Drug Safety" every month to promulgate the idea that "people can make a difference in policy" and to consolidate public trust in the government. This forum is a venue where consumers, civic groups, industry, academia, related agencies and ordinary people participate and present their opinions.

For real-time communication with consumers, the MFDS operated "Consumer Talk Talk" with working-level staff of 11 consumer groups, and gave fast feedback to consumer questions on food and drug safety in consultation with the competent divisions. The MFDS also provided necessary daily information on immediate issues through a consumer hot line (newsletter).

The 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 Based on Communication Tailored to Regions and Classes

The MFDS operates diverse participatory programs so as to communicate with people of various classes from youth to seniors and enable them have firsthand experience of food and drug policy.

The 6 regional office of FDSs and affiliated public organizations collaborated to give youths more opportunities to explore their career. The MFDS ran the experiential "Food · Drugs Junior" program, and is now operating "Food · Drugs Young Leader" for junior and high school students, a food · drugs-related online/offline promotional program. Each team is involved in the production of UCC and logo songs, and carries out SNS publicity and street campaigns.

Furthermore, the MFDS operates "Food · Drugs Avengers", a social communicator initiative for average people including college students, and pursues open

communication reflecting their fresh ideas about food and drug safety policy and life-friendly information. The MFDS also tried to strengthen basic knowledge and capacity of junior and high school students through promotion and communication regarding career experience and food and drug safety topics to nurture future smart consumers.

The MFDS conduct face-to-face education to prevent damage from wrong use of food and drugs and false/exaggerative advertisements, considering the difficulties information vulnerable groups experience in distinguishing and acquiring correct information via broadcast or online channels. In 2018, the MFDS visited welfare centers, senior-citizen centers, public health centers, etc. in seven cities and provinces (Gyeonggi, Gangwon, Gyeongnam/Gyeongbuk, Jeonnam/Jeonbuk), and carried out 153 food · drugs safety educational sessions for a total of 8,717 elderly people.

The MFDS will continue to expand the scope of the "Outreach Consumer Food · Drugs Safety Class" to help vulnerable groups such as elderly people with more food · drugs safety education. Also, the MFDS will continue to operate various youth experiential programs to nurture future smart consumers.

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section 3

Expansion of Sharing · Publicizing · Utilizing Food and Drug Safety Information

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

With free trade agreements and volume of trade with major countries expanding at a rapid pace, stricter management of foods, pharmaceuticals, medical devices and cosmetic safety has become indispensable. The 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, pharmaceuticals, medical devices and cosmetics.

The MFDS has monitored and collected information on hazards in the food sector from 189 websites of 29 countries and in pharmaceuticals, medical devices and cosmetic sector from 156 websites of 20 countries, and has, with the help of Overseas Information Reporters consisting of overseas Koreans , gathered food, pharmaceuticals, medical devices and cosmetic safety information from foreign countries.

The MFDS collected 38,659 cases of risk information in 2018 alone, and took

preemptive safety management actions, such as stricter inspection and temporary suspension of distribution and sales on 550 cases. Among the 986 cases of overseas information collected by Overseas Information Reporters, 341 were used as references for relevant departments of information analysis and business operation.

Also, MFDS also provided 291 cases of risk information to online shopping malls including Auction and Gmarket, and blocked access to 35 websites so as to prevent domestic customers from directly purchasing adulterated foods and medical products overseas through the Internet.

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"to reflect the advantages and characteristics of both organizations. As a result, the forum has made significant contributions to the prevention of food safety-related incidents.

MFDS will continue its efforts to strengthen the "Asia International Food Safety Authority Network" which was established to promote the information collection system globally and thereby enhance cooperation on information exchange to prevent food safety-related incidents at home and abroad. For more rapid and accurate information exchange, MFDS will also strengthen its efforts on establishing hot-lines with top Asian trading partners.

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2. Linkage · Integration of Pan-Governmental Food Safety Information and Advancement of Food Administration

The quality and safety of the food we consume are subjected to an increasing number of potential risk factors at present: climate change, environmental pollution, scale of the food industry, growing trade between countries and others. Consequently, the public is more concerned about health, nutrition and safety associated with food. In addition, there is increasing demand for creative, big data-based innovation to solve food safety problems and issues and make the right decision using science & technology originating from the Fourth Industrial Revolution.

In response to these pressing demands, the MFDS expanded information-linked institutes linked with the Integrated Food Safety Information Network (constructed in Jun. 2015) to 21 agencies, and increased the variety of information to be connected and shared from 159 to 202 types, enhancing the availability of food safety information. Through this, the MFDS aims to link, integrate and use food safety information distributed to several departments including the Ministry of Agriculture, Food, and Rural Affairs, Ministry of Oceans and Fisheries and others, and to disclose this information for the benefit of the public.

The MFDS added, enlarged and linked sanitary information of restaurants through delivery apps that are gaining market share thanks to the changing eating habits of the public. The MFDS addressed vague public anxiety and forged an environment that supports food safety by providing more information on private platforms and enabling people to personally search and check information in everyday life.

Moreover, the MFDS has set up and continues to operate applications named “Food Safety Information in My Hand” and “Food Safety Korea” to help people easily check food safety information with smartphones. The former won the 2018 Grand Prize in the public service category.

The MFDS also contributed to creating food safety services by disclosing public information to the private sector and promoting its use. To this end, the Ministry

developed a healthy lunch box app through a food nutrition ingredient DB and established a laboratory information management system that links standard/specification information with corporate test and inspection systems.

The Integrated Food Safety Information Network enabled real-time usage of nationwide food administration information. However, as it was limited to food safety information, the MFDS decided to converge, analyze and exploit additional areas of food safety-related information like environment and space, and to construct a food incident prevention and response system. In doing so, the MFDS established the Informatization Strategy Plan and a three-year implementation plan for setting up a Next-Generation Integrated Food Safety Information Network to develop intelligent services supported by the latest IT technology.

The MFDS plans to develop capabilities to predict and prevent food incidents by converging food safety information with information on external elements affecting food safety (weather, soil, underground water, etc.). The Ministry will also reinforce functions for efficiently supporting food administration such as AI consultation for civil complaints and mobile civil petitions.

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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

The MFDS has promoted the efficient management of testing and inspection agencies and the convenience of handling civil complaints by enacting 「Act on Testing and Inspection in the Food and Drug Industry」 in 2013(enforced since 31st July 2014) and the enforcement ordinance, the enforcement regulation of the same act, and launched the 「Regulation on the Evaluation of Testing and Inspection Agencies in the Food and Drug Industry」 in 2014.

In the area of testing·inspection activity, Korea recognizes activity of public testing and inspection agencies that are designated according to the ordinance of the Prime Minister, private testing and inspection agencies that are designated by the Minister of the Food and Drug Safety, as well as foreign testing·inspection laboratories located in overseas countries. These agencies are also classified by categories: food, livestock, pharmaceuticals, cosmetics, medical devices and hygiene products.

In the area of testing · inspection activity, Korea recognizes activity of 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, as well as overseas testing · inspection agencies located in foreign countries. Inspection agencies can also be classified by category: food, livestock, pharmaceuticals, cosmetics, medical devices and sanitary goods.

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 other relevant regulations and apply for the designation. The applicant shall be evaluated through the submitted documents 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 the MFDS as of the end of December 2018.

Table 4-1 **The current status of testing·inspection agencies by categories**

(As of 31, Dec 2018, Unit: case, Source: Laboratory Audit and Policy Division)

Category	Total	Domestic Institutions		No. of Foreign Testing Laboratories
		No. of Public Agencies	No. of Private Agencies	
Food	161	25	76 (P 14, C 62)	60
Livestock	74	26	47 (Import 4, C 43)	0
Pharmaceuticals	39	23	16 (pharmaceuticals 11, medicinal herbs 4, pharmaceutical · medicinal herb 1)	0
Cosmetics	38	23	18	0
Medical devices	16	1	15	0
Sanitary goods	32	23	9	

※ P: Professional Food Testing and Inspection Agency
C: Commissioned Self-Quality Testing and Inspection Agency

The 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, the 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 prevent and promptly respond to food · pharmaceutical-related accidents.

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chapter 5

Research & Development for Food & 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.

A. Safety Technologies for Food, Drugs, etc. that Assures the Public

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, the 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.

To protect public safety and health through scientific safety technologies for foods and pharmaceuticals, the MFDS conducts six specific R&D projects in the following areas: safety management of food, etc.: safety management of drugs, etc.; safety management of medical devices, etc.; safety evaluation technology; advancement of safety technology; and safety management for agro-livestock and fishery products. The Ministry has steadily increased the budget for these R&D projects (annual average growth rate of 2.5%), reaching 85.8 billion won in 2019; details are shown in [Table 5-1].

Table 5-1 **Financial Operation of Major R&D Projects for the Last Five Years**

(As of Dec 31, 2018, Unit: 100 million won, Source: Research Planning and Management Division)

Classification	Budget for 2015	Budget for 2016	Budget for 2017	Budget for 2018	Budget for 2019	Average Growth Rate (%)
Total	776.1	792.7	818.6	830.7	858.1	2.5%
Safety management of food, etc.	292.3	269.8	280.8	298.0	310.2	1.5%
Safety management of drugs	200.0	224.0	240.9	232.2	237.6	4.4%
Safety management of medical devices	79.4	73.0	85.2	77.5	80.7	0.4%
R&D for safety evaluation technology	134.0	145.5	125.3	133.4	135.8	0.3%
Advancement of safety technology	38.4	38.4	34.4	32.4	31.4	-4.9%
Safety management for agro-livestock and fisheryproducts	32.0	42.0	52.0	57.2	62.4	18.2%

As regards the 2018 R&D outcomes, under the category of safety management of food, etc., MFDS invested KRW 29.8 billion and implemented 103 R&D tasks 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. Further, the MFDS invested KRW 23.22 billion won and carried out 98 tasks to improve the pharmaceutical safety system by preparing a scientific basis for safety management policies for pharmaceuticals, etc. MFDS also developed technologies for screening and evaluation to help rapid commercialization of pharmaceuticals. Within safety management of medical devices, etc., the MFDS invested KRW 77.5 billion and performed 37 tasks that focused on enabling safe medical devices and developing scientific evaluation technologies in preparation for changes in future medical environments.

In the area of R&D for safety evaluation technologies, the MFDS invested KRW 13.34 billion and carried out 54 tasks. The tasks were directed towards the establishment of base technologies for safety prediction and evaluation covering toxicity, pharmacology,

clinical testing and advanced analysis, laboratory animals, and alternative tests in order to establish a scientific foundation for safety management policy of food, drugs, etc. For the advancement of safety technology, the MFDS invested KRW 3.24 billion and conducted 10 tasks. The tasks were to promote superior private-led technical development for food and drug safety. Since this development was not to be led by the government, the MFDS planned to build a base and a support system for such development connecting technical development, assistance for commercialization and reinforcement of professional capability. For safety management of agro-livestock and fishery products, the MFDS invested KRW 5.72 billion and carried out 19 tasks, to develop scientific inspection technologies, map out safety management measures on hazardous elements and set up a preventive safety management system.

The MFDS plans to expand investment on safety technologies with focus on industries with future prospects. To do so, the Ministry will develop new prediction & prevention technologies against potentially hazardous substances among the products closely linked to people's daily lives.; advance approval · review policies to reinforce international competitiveness of industries such as pharmaceuticals and cosmetics; and implement R&D with a view to pioneering technologies and preoccupying markets for leading the 4th Industrial Revolution.

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2. Impartial Research Management and Provision of Services for Researchers

To establish transparency and impartiality in research project management, the MFDS carries out the planning, notification, selection and final evaluation of research projects and manages their performance through a research management system. The MFDS also provides various services such as briefing sessions and brochures (Q&A)

in order to help researchers with administrative work related to their projects and provide a proper understanding of various types of research funds managed by the MFDS, including general accounts such as research funds, outsourced R&D funds and contributions according to the "Act on the Promotion of Technology for Ensuring the Safety of Food, Drugs, etc."

In 2018, a total of 215 new R&D projects were selected through 9 sessions of selection evaluation. These included 69 self-R&D projects, 140 outsourced R&D projects, and 6 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 "Contract Agreement Standards by Negotiation", a contract regulation of the Ministry of Strategy and Finance. Through this system it was possible to make a proper estimate of research funds to be allotted to substantive R&D projects and researchers. Final evaluations or interim (annual) evaluations were performed for 331 projects over 16 sessions.

To ensure transparency and impartiality in R&D funding, the MFDS entrusted account settlement to an external professional accounting corporation. Since 2018, the MFDS has operated a preliminary consulting system for the use of research fund by designating an accounting corporation, so that the outsourced R&D institutions can observe rules on research funds from the start of their tasks. The also MFDS published and disseminated the "Guidelines for Standard Account Settlement for R&D Projects" along with the accounting corporation (Aug. 2018).

In addition, the MFDS is committed to facilitating smooth research activities by notifying changes every year. For this, the MFDS published the R&D Guide (Mar. 2018) to provide appropriate guidance to researchers of MFDS projects on how to use, manage and settle the expenses.

The MFDS held a briefing session (funded: May 2018, outsourced: June 2018) on use of R&D cost (settlement) for research directors and related researchers in charge of MFDS R&D projects. The MFDS issued an easy guide (two volumes) on how to properly allocate R&D fund for researchers (Aug. 2018) by organizing frequently asked

questions and answers according to categories and divisions of outsourced R&D costs (costs for personnel, expenses, and general management costs).

The MFDS will pursue fair and transparent evaluation of R&D projects and strive to yield targeted outcomes. In doing so, the Ministry will revise and upgrade evaluation standards with a focus on project selection/final (interim) evaluation based on generation of results. The MFDS is presently preparing the ground for operation of the pan-government integrated research management system and pan-government integrated R&D cost management system in the making as part of the national integrated R&D management project led by the Ministry of Science and ICT. Through this, the MFDS will link MFDS-funded research with the pan-government integrated research management system and integrated R&D cost management system (Ezbaro).

In addition, the MFDS will update the "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, the MFDS is slated to hold "Visiting Briefing Sessions for the Use of R&D Costs by the MFDS" for research directors and research institutions, and carry out on-site inspections for commissioned settlement and execution management of R&D expenditures. These measures will encourage researchers to appropriately execute the research funds, and create a transparent and reliable environment for management of research funds.

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3. Outcome Management for Research and Development Projects

A. Efforts to Generate, Promote and Disseminate Excellent Research Outcomes

The MFDS utilizes R&D results from proposal of standards and specifications, formulation of guidelines, and development of test methods as a scientific basis to establish food and pharmaceuticals policy. The MFDS also manages R&D outcomes throughout the entire cycle from planning of projects to their performance assessment after completion. To do so, the Ministry sets project performance goals and indicators suitable for specific projects under the "Act on the Performance Evaluation and Management of National Research and Development Projects, Etc." and collects, verifies, and analyzes project performance according to the MFDS standard performance indicators.

A crucial R&D performance indicator of the MFDS is the "rate of connection between food · drug safety and policies" and the R&D performance indicators for unit projects in areas such as food and pharmaceuticals are "elicitation of food and pharmaceutical safety standards (the number of developed test methods, number of suggested guidelines, and number of manufactured reference standards)" and the "SCI thesis index." The results for each of the indicators exceeded the targets by more than 100% and such outcome has improved for the recent three years (2016 – 2018).

In 2018, the MFDS conducted a mid-term (self/higher-level) evaluation on two projects, "Safety Management of Food, Etc." and "Safety Management of Medical Devices, Etc. (MSIT)" The former was rated "Excellent" and the latter "Normal" by the Ministry of Science, ICT and Future Planning, and the evaluation was reflected in the budget and business plan for the following year. In addition, researchers of "Safety Management of Medical Devices, Etc." who received an "excellent" rating won prizes and the "Prime Minister Award", etc. The MFDS also submits candidates for 100

selections for best performance of the MSIT; in 2018, performance of "Construction of the Infrastructure for the World's First Multilevel Integrated Evaluation Technology to Promote Development of Next Generation Stem Cell Therapy" was selected as one of the winners in the infrastructure area.

The projects subject to mid-term R&D evaluation in 2019 are "Safety Management of Pharmaceuticals" and "Safety Management of Livestock and Fishery Products" and absolute evaluation on their performance over the last 3 years will be carried out. The subject projects will undergo stronger self-evaluation on their qualitative excellence by an expert group and an evaluation committee, and further the suitability of the result will be subjected to higher-level evaluation by the MSIT.

The MFDS improved "R&D Standard Performance Indicators" from quantity to quality-based ones to create qualitatively superb performance, and is presently revising related rules and guidelines to reflect it.

The detailed projects subject to performance evaluation in 2020 are "R&D for Safety Evaluation Technology" and "Advancement of Safety Technology." The MFDS plans to execute self-evaluation on the extent to which they have achieved performance indicators and how excellent their performance over their three-year outcome (2017-2019) has been. Furthermore, the MFDS will comprehensively analyze those projects and determine/ improve performance goals and indicators to make sure that they match project characteristics. The Ministry will also strive to provide opportunities through which the MFDS, related agencies and food and pharmaceuticals researchers can share information and promote performance by holding the "2019 MFDS Performance Contest for R&D Projects", etc.

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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 controversies over the safety of chemical substances has made it vital to establish a system for conducting integrated risk assessment on them, which comprehensively considers their impacts on human life, likely caused by exposed media such as various foods, cosmetics, environment and through paths such as mouth · skin · breathing.

In the next five years from 2018, integrated risk assessments will be carried on 60 substances simultaneously which have been exposed to the human body through various products or whose impact on body health was newly reported. As a part of this drive, the MFDS has evaluated 19 substances including bisphenols, in 2018. Besides, the MFDS added the functions of analyzing food consumption according to year and thereby developing exposure evaluation models to add to the Monitoring Information Management System/Monitoring database and Assessment Program (MIMS/MAP). The Ministry also has set human exposure safety standards for three

harmful substances and nine food additives. The MFDS laid down the foundation for rapid calculation of internal & external exposure amount by developing the specialized Physiology Based Pharmacokinetic Core Model (PBPK Core Model) for calculating the amount of external exposure from human biomonitoring results on harmful substances. To efficiently assess integrated risks, the MFDS established a working-level collaboration system with relevant ministries and departments including the Ministry of Environment, Ministry of Trade, Industry and Energy, Ministry of Oceans and Fisheries and the Rural Development Administration. Additionally, to systematically review risk assessment results, the MFDS organized the "Comprehensive Management Unit for Human Body Risk Assessment" comprising of MFDS experts from various fields and a working-level TF. The MFDS set up a private expert committee for obtaining professional review and advice on the risk assessment results. Furthermore, to realize practical risk assessment cooperation with the European Food Safety Authority (EFSA), MFDS will conclude a business agreement. This is expected to largely contribute to the elevation of Korea's expertise, as a nation, 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. 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 an 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 the export and import of agricultural · marine · livestock products internationally, MFDS plans to propose reasonable standards and specifications in an ongoing and uniform manner.

B. Establishment of International Level Residual Substance Testing Method

As the types and amounts of imported products increase over time, introduction of scientific testing methods is required. Besides, to efficiently implement the Positive List System (PLS), 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, in accordance with the verification process suggested by the CODEX Alimentarius Commission (CAC), the MFDS has been developing testing methods to detect and measure residual pesticides and animal drugs in agricultural, marine, and livestock products. The MFDS will also continue to work on strengthening the system's residual substance safety management.

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

To properly manage the extent of human exposure to harmful contaminants through food, the MFDS is carrying out surveys and risk assessment on the state of exposure to harmful contaminants. The MFDS will accordingly establish a reduction plan for substances that need to be reduced on a priority basis.

In 2018, the MFDS set up a principle and a standardized system for evaluating

exposure amounts and assessed the risk of harmful contaminants such as dioxins, PCB, mold, natural toxins and heavy metals. The MFDS prepared a ground for risk assessment by establishing testing methods on new contaminants (deca-BDE, SCCP, PCNs, ciguatoxin, etc.) and contaminants with no criteria (ergot alkaloids, inorganic arsenic, etc.) and by then investigating their status. The MFDS developed the program "Guide for Safe Food Consumption" using the accumulated and consolidated data on contamination levels and uploaded it onto "Food Safety Korea", creating an environment where people could practice reduction of exposure to harmful contaminants. To safely manage radioactivity which might result from the Fukushima nuclear disaster in Japan, the MFDS made radioactivity surveys on livestock and marine products necessary. The Ministry introduced inspection equipment for additional nuclides (α and β) to three regional offices and improved the γ nuclide testing methods to raise the test's credibility.

In 2019, the MFDS will continue to establish a standardization system of risk assessment methods for building a higher reliability of the assessment results and to support the management of dietary life customized to one's daily life, by conducting various studies to reduce the exposure to harmful contaminants such as developing websites tailored towards product processes or individuals. Besides, the MFDS plans to devise and improve testing methods for mold toxins, natural toxins and heavy metals considering the effects of climate change and industrialization, and create a baseline/foundation for risk assessment by surveying harmful contaminants (PBBs and harmful metals) whose testing methods were set up in 2018. Meanwhile, to counter domestic and international radioactivity accidents, the MFDS will set up inspection equipment in four cities and provinces as well as three regional offices, and solidify a constant inspection mechanism by exchanging information regarding one another. Furthermore, the MFDS will improve upon their radioactivity testing methods (plutonium and strontium) and thereby contribute to reliable radioactivity analysis.

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4. Microbiological Risk Assessment and Development of Microbial Testing Methods in Foods

Microbiological risk assessment is required as a scientific basis for establishing standards and plans for national food safety management. Nowadays, foodborne illness associated with the climate change arouses social anxiety. Other environmental factors are also changing: growing international trade, increasing overseas tourism, and movement of ballast water of ships, etc. Hence, to preemptively respond to such dynamic elements, there is a need to study microbiological risk assessment and to disclose the research findings to the public. In addition, the development of detection methods for pathogens in foods is necessary for safety management of microorganisms in food. Technologies to reduce foodborne illness and stronger prevention measures are also important to fundamentally control these issues.

In 2018, the MFDS conducted risk assessment on 1) the entire stages from production to consumption, i.e. *Salmonella* in meat, E.coli in processed vegetables and *Vibrio* spp. in fishery products and also 2) high-risk hazardous microbes. The MFDS prepared a scientific basis for logically setting criteria for low-risk foodborne pathogens. The MFDS released the risk assessment results including that on *Clostridium perfringens* in ice-cream in reports and abstracts, available in English on the MFDS website. The MFDS recognizes that a simple and reliable risk assessment system is needed to strengthen a preventive microbial risk management.

Therefore, the MFDS promises to develop a web-based one-stop system for microbiological risk assessment integrating the risk information DB, growth/death prediction DB and the dose-response model DB. To promptly cope with a crisis based on overseas risk information, the MFDS established test methods for norovirus in frozen raspberry and *Cyclospora cayetanensis* in leaf and stem vegetables. The Ministry also presented an amendment of the test methods for microorganisms like *Listeria monocytogenes*, through systematic verification procedures such as an analytical comparison of the national system with the internationally used test

methods, and food application tests. The MFDS secured a management technology for fermented products by developing a genome-based analysis program. Going further, the MFDS will improve 1) the pre-treatment method for rapid detection of nine foodborne pathogens for upgrading their detection capacity; along with 2) the detection method of relavant genes to harmonize it with relative organizations. Test methods to examine foodborne viruses including norovirus, astrovirus, adenovirus and rotavirus on environmental surfaces will be devised.

During the Pyeongchang Olympic Games held in Feb. 2018, the MFDS supported the big international event by inspecting noroviruses in 740 samples, including feces of the cooking staff working at olympic village canteen, etc. and excluding the infected people with no symptoms from cooking. The Ministry also contributed to block the spread of foodborne illness in September, when a nationwide foodborne outbreak took place due to chocolate cakes. At the time, the MFDS determined egg white liquid as its causative food in five days.

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5. Strengthening the Safety Management of Food Additives, Utensils, Containers, Packaging, and Hygiene Products

Now that new processed foods are being developed and an increasing number of one-person households bring about thriving markets for instant foods and Home Meal Replacement (HMR), it is necessary to safely manage transferable substances derived from food additives, utensils, containers, and packaging and hygiene products. In this regard, their test methods should be continuously developed and their strict monitoring and safety assessment has to be implemented.

The MFDS disclosed risk assessment reports on food additives in food (23 food colors). The Ministry also analyzed the content of food additives in food (16 tar

colors and 3 dopper chlorophyll) and their content by food type, and evaluated their daily consumption levels against an Acceptable Daily Intake by applying to food consumption. To assess transferable substances derived from utensils, containers, and packaging, the MFDS investigated their transferred amounts and evaluated the risk levels compared to safety standards for the human body such as a Tolerable Daily Intake (TDI). For hygiene products, the MFDS examined residues after use or transferred amounts to food, and created an evaluation method through human body exposure. The MFDS will work to scientifically manage the safety of the food people eat in their daily lives and of hygiene products.

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6. Establishing a Basis for Safety Management of Food Nutrition, Dietary Life, and Functional Health Foods

A. Construction of a Base System for Nutrition and Dietary Life Safety Policy

Changing dietary patterns stemming from the increasing number of one-person and dual-income households has led to a nutritional imbalance. Thus, a basic DB including nutrients and their contents is necessary for drawing up a risk assessment system on the excess or lack of nutrition.

In response, the MFDS built a nutritional risk assessment platform to quickly figure out national health problems and analyze specific nutrient cases. The MFDS also made an in-depth analysis of the 2016 national sodium and sugar intake to prepare scientific base materials to push for a sodium and sugar reduction policy. Meanwhile, the MFDS continued to set up a national food nutrient DB and provided nutrient information on the food types actually consumed by Koreans, including the ones eaten while dining-out.

The MFDS will keep analyzing sodium and sugar consumption for forging a scientific base of its policy to cut down the use of potentially hazardous nutrients; and improve a nutritional risk assessment platform for the rapid analysis of sodium and sugar consumption. On the other hand, the MFDS plans to expand a national food nutrient DB and thus identify and offer nutrient information on food types desired by Koreans.

B. Advancement of Test Methods for Nutrients and Index Components of Functional Health Foods

As diverse types of foods and functional health foods are developed, active improvement of their test methods through comparative reviews with the latest overseas methods is to be demanded for food safety management. Additionally, a national standard lab that meets international criteria should be constructed to secure the reliability of test analysis outcomes.

Therefore, the MFDS improved its nutrient test methods to apply to more foods, and participated in the international proficiency evaluation to lay down the foundation for building a national standard lab and also earned a satisfactory rating. Besides, the MFDS also improved its test methods for index components of officially notified functional health foods and designed the mass analysis method for a higher test reliability. The Ministry also examined the suitability of index components of 68 functional health foods and made a list (draft) of components to be reset.

The MFDS plans to continue to upgrade nutrient test methods for functional health foods and consequently come up with index component specifications (draft) and test methods (draft) for the index component list to be reset in relation to the officially notified functional health foods.

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7. Strengthening the Scientific Surveillance System for Adulterated Foods

A. Eradication of Defective and Adulterated Food Using the Latest Gene Technology

Because of an imbalance in the demand and supply of marine products, cheap living items have been imported and there have occurred multiple cases of deceiving and taking unfair advantage of consumers by sellers who are manufacturing and distributing red pepper powder mixed with seasoned red pepper sauce, etc. So, the MFDS intends to set up a gene type DB on food raw materials and establish an inspection system to examine and compare a food sample on the spot with the gene information. To this end, the MFDS laid out a barcode sequence search method (Blast Search) and an identification program to determine the authenticity of fishery products, and a standard test method for barcode determination through the fish identification method, which is based on gene sequence. Besides these initiatives, the MFDS has crafted genome-specific primers and genetic analysis methods for three agro-products (codonopsis lanceolata, balloon flower roots and adenophora triphylla). The MFDS will soon establish a DNA information bank to determine the authenticity of food materials made from Korean fishery products, by identifying species-specific DNA barcodes of domestic marine products and using Next Generation Sequencing (NGS). The Ministry will also develop scientific discrimination methods for food materials difficult to distinguish visually, due to similar shapes or simple processing proccesses (cutting, grinding, etc.).

B. Development of Scientific Site Surveillance Technology to Fight Defective and Adulterated Foods

On account of better living standards and people's interest in health, foreign

functional health foods are directly purchased by consumers, even though they are not approved in Korea due to failure of safety evidence. Those products may cause harm to them, so a scientific analysis method determining these defective materials is required along with the safety management of directly purchased overseas foods. Therefore, the MFDS completed defective materials surveys mainly on directly purchased overseas food products for self-consumption (claiming better sexual functionality, diet efficacy and effectiveness, etc.) and requested suspension of online sale of foods with defective materials. On top of this, the MFDS will study more than 400 cases of foods and functional health foods every year to survey and probe the presence of illegal food materials. The 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 defective substances cannot be mixed into food products for human consumption.

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section 3

Research for Safety Management and Supporting Commercialization of Medical Products

1. Advanced Research to improve 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, the MFDS presents a modification based on its research projects and has developed a pharmacopoeia of international level by gathering a host of internal and external opinions through mediums such as the "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. The MFDS has steadily secured and distributed this reference standard for medical products, starting with the reference standards for chemical pharmaceuticals since 1991. The MFDS now provides a total of 577 reference standards, including 223 items of chemical pharmaceuticals, 31 items of bio-pharmaceuticals, 290 items of herbal medicines, 32 items of IVD medical devices, and 1 item of quasi-drugs. In addition, to secure the reliability of quality, the MFDS periodically conducts stability tests on the reference standards it stores. It also published and distributed the "2018 MFDS Comprehensive Guide for Reference Standards." The MFDS will continue to expand and provide reference standards for medical products in the future, by reflecting on the demand surveys done in the field.

Also, to secure the quality of the distributed pharmaceuticals, the MFDS conducted testing and inspection of 25 items used by chemical pharmaceuticals, 18 items of bio-pharmaceuticals, 448 items of Chinese (herbal) medicines, 18 items of cosmetics and quasi-drugs and finally, 21 items of medical devices. In particular, it conducted rapid testing, inspection and risk assessment of 84 items, containing volatile organic compounds (VOCs) among distributed sanitary pads (666 items) in light of the recent controversy. Since obtaining ISO 17025 certificate from an internationally-accredited testing organization in 2004, the MFDS expanded its accreditation field and acquired accreditation for 24 test items in three areas. in order to ensure the objectivity and reliability of the testing and inspection results. The Ministry will also continue to expand the pool of accreditation test items and enhance the reliability and capability of testing and inspection through a designated National Standardized Laboratory in the future.

2. Research on Safety Management of Pharmaceuticals

The MFDS prepared 419 cases to be included in the revised version of the Korean Pharmacopoeia, for establishing the foundations of quality management in the pharmaceutical industry. Further, the MFDS enhanced scientific validity and

reliability of the revised pharmacopoeia through two meetings led by the Central Pharmaceutical Affairs Council. It actively reflects on external opinions about the revision of industrial settings and gathers internal and external opinions through the publication of the "Korean Pharmacopoeial Forum" twice a year. Also, the MFDS held a briefing session for working-level people in the industry to share the direction of improving their testing methods and to listen to the 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 new reference standards. MFDS also safely managed the quality of the reference standards by carrying out stability tests for items out of the reference standards that are 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 an international level.

Since 2010, the MFDS has been publishing braille books, sign language videos, and information booklets translated into multiple languages on the safe use of pharmaceuticals, for the visually/hearing impaired and multicultural families who are unable to access this pharmaceutical usage information easily.

In addition, the MFDS developed the drafts of Korean LCD (Linguistic Convention Document) and training materials to support the implementation 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 the equivalency evaluation of injectable liposome formulation. These studies would be further used for policy-making. The MFDS will continue its research efforts on safety management by focusing on unmet demands, such as medicines for chronic diseases and orphan drugs; preemptive development and research on the screening and evaluation techniques supporting the development of new technology

and product commercialization; and research on consistency and scientific evidence for the approval and evaluation of pharmaceuticals.

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3. Research on Prevention and Safety Control of Infectious Diseases

The MFDS conducted multiple lines of research on the development of methods for testing the quality and effects of vaccines against new infectious diseases; the research also included the development of reference standards for clinical evaluation and testing methods. Based on this, the MFDS developed testing methods for vaccines against MERS, Zika, and Chikungunya and also designed a method to test the immune-adjuvant to be used for MERS vaccine. The MFDS conducted research and development of testing methods for the quality evaluation of vaccines against diphtheria, tetanus toxoid titer to ensure self-sufficiency in major domestic vaccines. The MFDS also performed research and development of immunogenicity testing methods and a standard serum for vaccines against HPV (Human Papillomavirus), B-type streptococci, meningococcus, herpes zoster, and pertussis to develop immunogenicity assays for each vaccine and standard serum panels to assess their immunogenicity. The MFDS also manufactured and established the candidate substance of national reference standards for the intradermal BCG vaccine. Besides these, the MFDS also developed "Material Collection (Draft) on Surrogate Markers for Vaccine Efficacy Evaluation" and "Information Collection on the Vaccine Immunogenicity Evaluation/Test Method" for domestic vaccine developers and licensors. Through these achievements, the MFDS tries to contribute to the support of vaccine self-sufficiency and preemptive safety management against new and infectious diseases.

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4. Research on Biopharmaceutical Safety Management

According to a mid-to-long-term roadmap for advancements in biopharmaceuticals earlier stated in the Korean Pharmacopoeia (KP), the MFDS registered four cases, such as isoelectric focusing with the KP, and the "Registry of the Test Method for Recombinant Monoclonal Antibody Medicine" to advance high-tech biopharmaceuticals. Additionally, the MFDS planned to forge a preemptive regulatory basis for the safe supply of new biopharmaceuticals using innovative technology. For this, the MFDS formulated has two guidelines for the approval/review of biopharmaceuticals such as "considerations (draft) in the Case of design and analysis of clinical trials to acquire the conditional license for cell therapies." The MFDS has also developed five standard test methods to evaluate the quality of biopharmaceuticals, including in-vitro potency assay of antibody drugs.

In addition, the MFDS bettered the reliability of inspection capabilities of sophisticated biopharmaceuticals by improving the ISO 17025 system and expanding its educational range; hosted "2019 Regulatory Affairs Conference on High-Tech Biopharmaceuticals" and "R&D Planning Workshop" attended by all the experts from the industry, academia and research institutes to strengthen the regulatory affairs capacity; and implemented regulatory affairs with R&D teams of high-tech biopharmaceuticals, by exploring their research results and regulatory trends and gathering opinions on the necessary research tasks.

As part of efforts to enhance the quality analysis capabilities of the domestic biopharmaceutical industry and to provide support in the commercialization of products, the MFDS shares the latest internal and external regulatory information such as "2017 Overseas Regulatory Trends of Advanced Cell Tissue Engineering Agents" and the "Report on Development Trends of High-Tech Evaluation Models for Biopharmaceuticals." As an educational program, the MFDS held a "Workshop on the Development and Analysis of the High-Tech Biopharmaceuticals" for domestic development enterprises, offering the development trends of latest analysis

technology and implementing analysis training for the participants.

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5. Research on Safety Management of Herbal Medicine

The MFDS has developed the test methods and expanded standards and specifications for herbal medicines, to strengthen its quality and safety management, and secured herbal medicine resources and thus solidified a ground for leading international standards to actively respond to global changes like the Nagoya Protocol.

To improve the quality of herbal medicines, the MFDS implemented pre- and post- safety management. To this end, the MFDS conducted its cross-validation at the import stage, benzopyran testing and risk assessment at the Drug Master File (DMF) stage, and a quality inspection at the distribution stage. The Ministry also developed advanced analysis methods such as DNA barcodes and chemical profiles for a total of 49 cases (until 2018) including herbal medicines that cannot be verified with sensory tests (Cynanchum Wilfordii and Cynanchum Auriculatum). The MFDS produced and distributed promotional videos and animation films to ensure that consumers can easily understand how to safely manage herbal medicine.

The MFDS held a national conference (Apr. 2018) and there elicited cooperation methods from each ministry by organizing and operating the "Council on Herbal Medicine Resources." The MFDS also launched "Research to Collect and Examine National Herbal Medicine Resources." All this was part of an effort to preserve and harness national resources, such as in response to the Nagoya Protocol. After opening the "Okcheon National Herbal Medicine Resource Management Center" to preserve and manage temperate herbal medicine, the MFDS is proceeding with the "Jeju National Herbal Medicine Resource Center" to establish the basis for the management of subtropical herbal medicine. For the center, the MFDS has already crafted its basic

plan (September) and design.

The MFDS embarked on "Research on the Development of International Standards for Herbal Medicine" (February) in order to identify and propose international standards in the standardization area of herbal medicine (ISO/TC249) led by China. The MFDS thus proposed new initiatives like "measurement of benzopyran in herbal medicine" (June) and continued to participate in the Forum for the Harmonization of Herbal Medicine (FHH). In addition, the MFDS signed an ODA agreement with the WHO WPRO and offered three-month training programs for civil servants from Vietnam.

In 2019, the MFDS will establish a foundation for the safety management policy of herbal medicines, by developing hazardous material test methods and upgrading all the related standards and specifications. Further, the Ministry will construct a base to enlarge National Herbal Medicine Resource Management Centers and propose new tasks to lead international standards for controlling the quality and safety of herbal medicine.

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6. Research on Safety Management of Cosmetics and Quasi-Drugs

Cosmetics, quasi-drugs, and sanitary goods are widely used by all age groups, ranging from children to the elderly and applied directly in contact 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 harmful substances. In order to support safety management policies for living supplies like cosmetics, etc., the MFDS conducted contamination surveys and human health risk assessment on the ingredients and products likely to have safety concerns. The MFDS proposed safety standards and also relieved consumer anxiety by using these results. The MFDS announced the outcomes of contamination analysis and the human health risk assessment of sanitary pads and pantyliners, regarding 16 substances such as

phthalates, and checked and disclosed the emission amounts and risk levels of Volatile Organic Compounds (VOCs) regarding 39 diapers for infants. To immediately respond to hazard-detection information from foreign countries, including Europe, the MFDS assessed the risk of three substances like atranol, a spice ingredient, and methylene glycol and proposed to no longer use them as cosmetics ingredients, based on the results. Reflecting on the risk assessment results of preservatives, the MFDS presented new limitations in their use for cosmetics, regarding four substances, including 4, 4-Dimethyl-1, 3-Oxazolidine (Dimethyl Oxazolidine).

For the safe use of cosmetics and quasi-drugs, the MFDS regularly provides safety information by developing promotional content and employing news reports. The MFDS also disclosed the "Cosmetics Risk Assessment Report" to boost the transparency and reliability in setting safety standards. The Ministry posted on its website the whole blurb regarding the risk assessment report on the exposure amounts of 24 toxins e.g. nickel, a prohibited ingredient in cosmetics manufacturing, and atranol, a limited ingredient in it. In the spring and fall seasons before, when Korea was plagued by fine particulates, the MFDS interviewed with the press to help the public properly understand how to use healthcare masks as quasi-drugs and delivered information on the subject: "The higher the figures, the better the masks?"

Studies should be continued to improve/develop standards and specifications and develop/disseminate guidelines, and thereby to enhance the efficiency of approval work and the autonomous quality control capacity of the industry. The MFDS developed an alternative to the typical test method, using a harmful reagent and an analysis method not yet established, which involved limited and prohibited ingredients recorded in the "Standards and Test Methods for Functional Cosmetics" and reflected them on the amendment to the guidelines. In addition, the MFDS instituted the "Guidelines for the Limit of Microorganisms in Cosmetics" to support the testing business conducted by workers at quality inspection agencies by laying out test methods and the result analyses cases related to the limit of microorganisms was so soft depending on cosmetics formulations. The MFDS drew up 1) an amendment

(draft) to the notice on the "Standards and Test Methods for Quasi-Drugs" by changing test item standards for two substances including silicone resin used as an additive to quasi-drugs and by improving test methods; 2) an amendment (draft) to the guidelines for the standard efficacy evaluation method of sterilization and disinfection of quasi-drug denture washers; and 3) an amendment (draft) to the guidelines for the test methods used to demonstrate the antibacterial effect and anti-aging of cosmetics promoted through labeling/advertising. To gather more opinions from the public and the field, the MFDS steadily operated the "Network Council of the Industry, Academic, Research Institutes and the Government" and a "Research Group", understanding the status of test/inspection institutes and collecting opinions in preparation for the implementation of "Hygiene Products Control Act."

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7. Research on Medical Devices Safety Management

As the development of the advanced medical devices where new technologies like AI and big data are being applied is recently accelerating, the medical device industry is in the spotlight as a core area of the 4th Industrial Revolution. In this vein, the rapid commercialization of medical devices and the development of preliminary evaluation technology is urgently needed to pre-occupy the global market. To that end, the MFDS studied about how to support the advancement of the safety management regulations for medical devices, so that the MFDS could prepare policies and institutions for their safety management during the drug's entire lifecycle encompassing initial development, commercialization and prior/post release stages. Besides, the MFDS also develops globally harmonized safety evaluation technologies and evaluation indicators for approval review. In doing so, the MFDS does research on advanced regulations to quickly introduce medical devices based on new technologies such as digital health,

and enacts and amends current standards and specifications, and develops guidelines in response to calls for scientific review/evaluation technologies. As a golden-time assistance strategy for prompt evaluation of medical devices, it is crucial to develop focused evaluation technologies for medical devices based on AI for the 4th Industrial Revolution and info-communication technologies also be converged because the products have now moved from development stage to the commercialization stage. As part of government policy, MFDS supports for the countering paradigm shifts in the future medical environment e.g. enacting a high-tech medical device support act or an IVDD act, the MFDS will establish a related review/evaluation directives for sophisticated medical devices, and accordingly facilitate their development and promote their commercialization. Apart from this, the MFDS also plans to conduct relevant education and publicity, and develop technical instruction programs to raise medical device manufacturers' awareness of standards and encourage their use and make a mid-to long-term roadmap for standardization targets, according to main item/product. Through this, the Ministry will develop Korean Industrial Standards (KS) and make them international standards in the smart healthcare field for the era of the Fourth Industrial Revolution. With such efforts, the MFDS intends to contribute to the development of the medical device industry as the country's future growth engine and to national safety.

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section 4

Development of Safety Evaluation Technologies for Food and Drugs

1. Korea National Toxicology Toxicity Program 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 the recent incidents, involving detection of pesticides in eggs and VOCs in sanitary pads, the need for preventive research has increasingly 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 in the public mind. Therefore, it is necessary to provide toxicity test data and toxicity information based on reliable methods, and strengthen preemptive safety management areas, in order to reassure the public about food and drug safety-related social issues.

The MFDS has continuously carried out toxicity tests for food ingredients and herbal medicine. The MFDS has also been operating Tox-info, a system that provides toxicity information to the public. MFDS collects additional toxicity information on chemical substances related to food and pharmaceuticals every year, and 2,777 pieces

of information on toxicity and 570 more on recent count, have been collected and provided to the public and emergency medical workers so far.

In 2019, the MFDS plans to expand the test subjects into hygiene products, including sterilizer preservatives in order to carry out governmental tasks (No. 57-4. Strengthening the Integrated Risk and Safety Evaluation of Substances and Products Hazardous to Human Health).

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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, just as the European Union has banned animal testing. In response to this move, Korea revised the "Cosmetics Act (No. 14027, amended in Feb. 2016, and effective from Feb. 2017)" in 2017, prohibiting the distribution and sale of animal-tested cosmetic products and mandating them for alternative test methods. The MFDS founded Korean Center for the Validation of Alternative Methods (KoCVAM) in 2009. The MFDS concluded the evening in the International Cooperation on Alternative Test Methods (ICATM) in 2011 with the EU, the US, Japan and Canada, and has actively been engaged in developing the guidelines for alternative test methods. In 2018, "Local Lymph Node Assay Using Flow Cytometry (LLNA: BrdU-FCM)", which is an in-vitro skin sensitization test proposed by the MFDS, was approved for the first time in Korea as the OECD test guideline. In addition, the "Short Time Exposure Tests Using the Reconstructed Human Cornea-like Epithelium (RhCE) Model" was selected as a project to develop the OECD guidelines and its approval process will be implemented through an international expert evaluation conducted in 2019. Besides, the MFDS is working on the development of alternative test methods such as an "In Vitro Inhalation Toxicity

Test" and an "In Vitro Skin Sensitization Test Using Human Keratinocytes" and conducting validation studies on the "Developmental Toxicity Test Using Embryonic Stem Cells" and "Skin Sensitization Test Using Artificial Skin Models."

The MFDS has formulated 18 guidelines pertaining to the alternative test methods for cosmetics toxicity tests and will continue such efforts.

The global advancement of domestic pharmaceutical companies requires the production of reliable non-clinical trial datasets 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 2018, it held a total of 6 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.

Yun Hye-Seong, Toxicological Screening and Testing Division ☎ 043-719-5151

3. Research on Safety Management of Drugs and Construction of the Next Generation Safety Evaluation Basis

Now that drug-related incidents are increasing recently, the Pharmacological Research Division provided data on the work of 17 temporary narcotics on the central nervous system, and dependency and toxicity impact on the heart caused by them, as basis materials for designating a substance as a drug. The division also established 20 reference substances for new drugs and distributed them to relevant institutions to enhance analysis skills of narcotics, and launched a government-wide council involving related agencies such as the Supreme Prosecutor's Office or National

Forensic Service to promote national capacity of drug testing/analysis. The division is strengthening the collaboration system with relevant institutions by participating in international drug conferences and operating research groups, and sharing domestic and foreign information. The division plans to focus on national safety evaluation work on narcotics. So, it will prepare a technical review report of the international level by adding evaluation items for temporary narcotics, and share more information among related agencies by setting up an integrated DB on drug information.

In addition, the division will study 1) a test method to evaluate cardiovascular pharmacology safety to improve predictability and accuracy of pharmaceutical safety evaluation of the medicine using hiPSC-aCMS based on clinical big data and 2) interaction between the pharmaceutical and pharmaceutical, and between the pharmaceutical and food, using big data and machine learning. This is conducted as part of an effort to develop next generation safety assessment technologies. The division intends to keep providing safety information through research on safe use of pharmaceuticals and their safety assessment.

Seo Soo-Kyeong, Pharmacological Research Division ☎ 043-719-5201

4. Securing Public Safety through Advancement of Clinical Evaluation and Reduction of Side Effects

With the arrival of the 4th Industrial Revolution era, more efforts have been put into the personalized treatment for patients and the prediction of drug reaction. Also, it is becoming imperative to create an environment to prevent side effects and promote proper use of medicines based on big data. Therefore, it is time to reinforce the safe use of medicines and form consensus on the necessity of safe drug use and scientific safety management through prediction and patient-oriented evaluation of pharmaceutical side effects. To this end, the MFDS is making efforts to establish a

policy foundation to use medicines safely: offering a scientific basis of patient-oriented medicine information and optimal uses and doses; constructing a ground for clinical trials, providing Safety information for drug use to seniors and women; developing technologies to assess clinical trials; and proposing institutions on clinical trials.

The MFDS standardized PRO (Patient-Related Outcomes) through which patients could report their symptoms, and accumulated information on appropriate doses of metoprolol, and on the impact analysis and pharmacokinetics of Zolpidem (hypnotic sedative medication) medicinal reactions by sex. Also, the MFDS is reinforcing a cooperation network among the industry, academic, research institutes and the government by holding a symposium on fertility evaluation technologies using AI and big data, etc. The Ministry identified the genes that are related to the adverse effect of pediatric leukemia treatments such as Busulfan and the resistance markers of anticancer drugs using a personalized medicinal genome technique. Moreover, the MFDS strives to establish a basis for precision medical care by developing technologies for making gastric cancer gene panels unique to Koreans and predicting reactions to cancer immunotherapy.

To provide personalized medical services for patients, the MFDS has plans as follows: 1) develop guidelines to operate the PRO system and support technologies related to designation of sample analysis agencies for clinical trials; 2) support a scientific infrastructure to safely use medicines based on regulatory affairs, by preparing the guidelines for drug use/doses by medicine depending on its genotypes and providing pharmaceutical genetic information; and 3) reduce side effects by developing clinical prediction technologies using big data.

Chung Je-Hyek, Clinical Research Division ☎ 043-719-5251

5. Enhancement of an International-Level Advanced System For Analyzing Adulterated Substances

To prevent the illegal manufacturing of food and pharmaceuticals, the Advanced Analysis Team presented analysis results on 672 samples upon the request of the Criminal Investigation Office of the MFDS and relevant institutions (Korea Customs Service, National Police Agency, and Public Prosecutors' Office. The MFDS identified three ingredients of new synthetic cannabinoids among the products introduced by international mail, and published 8 papers in the renowned foreign scientific journal (SCI, Science Citation Index). In addition, in order to ensure the reliability of test results, the MFDS acquired ISO/IEC 17025 from the Korea Laboratory Accreditation Scheme (KOLAS) and has operated the certifications of 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 June 2018, the MFDS disclosed information on ingredient contents of 11 harmful components from three Heat-not-burn (HNB) e-cigarettes consumers were greatly interested in. The MFDS participates in the ACS (Asia Collaborative Study) on harmful components in tobacco and joins TobLabNet activities as an analytical member, thereby enhancing the system's ability to analyze tobacco components.

Kang Ho-Il, Advanced Analysis Team ☎ 043-719-5301

6. Advancement of Development, Preservation, and Utilization of Laboratory Animal Resources

Laboratory animals are essential bio resources for the development and evaluation of food and drugs' safety and efficacy. However, most of them are imported due to the weak infrastructure for development and use of disease model animals. In this context, laboratory animal resources are to be prepared. Furthermore, since biological samples such as organs and tissue of the laboratory animals can be utilized as research resources, it is necessary to establish a system to share them. For the five years starting 2015, the MFDS has developed 53 species of disease modelling in animal resources including those for cancer, dementia, and metabolic disease through the "Center for Mouse Models of Human Diseases". In addition, the MFDS has newly constructed the "Laboratory Animal Resource Bank", in the Daegu-Gyeongbuk Medical Cluster and operates with regional agencies to build the infrastructure required for securing and utilizing laboratory animal resources, and enacted the "Regulation on the Operation · Management of Laboratory Animal Resource Bank", thereby securing 42,631 resources e.g. tissue, serum, cells and so on.

As regards the national dementia R&D project, the MFDS will run an infra to use 20 disease-modelled mice concerning their nervous system, and prove the scientific traits of Korean laboratory animal resources, Korl: ICR and C57BL/6NKorl to support Korean researchers. Moreover, the MFDS intends to collect useful biological samples of laboratory animals through the Laboratory Animal Resource Bank, thereby enhancing the infrastructure to share with them, among associated agencies and researchers.

Kim Jun-Gyou, 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 (NLRS) and the National Institute of Food and Drug Safety Evaluation under the MFDS rule, and it examines the quality of biological products such as vaccines and blood products one more time.

As of Dec. 31, 2018, a total of 217 products are subject to a national lot release. A total of 2,528 lots were approved for shipment in 2018, which accounts for 61 additional lots as compared to the last year (see table 5-1) It is expected that applications for shipment approval will steadily increase based on the uptake in the share of domestically manufactured vaccines and the expansion of production facilities for blood products.

Table 5-2 **National Lot Release Statistics in the Last 8 Years**

(As of Dec. 31, 2018, Unit: lot, Source: 2018 Annual Report on National Lot Releases)

Category \ Year	2011	2012	2013	2014	2015	2016	2017	2018
Total	1,772	2,007	2,255	2,369	2,334	2,375	2,467	2,528
Vaccine products	941	900	995	922	856	885	919	865
Botulinum products	92	152	242	471	536	597	521	545
Blood products	739	955	1,018	976	942	893	1,027	1,118

The MFDS has been operating the 'Biological Drug Delivery System' based on hazard analysis since Apr. 1, 2016. The MFDS will set the risk stage for 217 items in 2019, then conduct a certification test and review the manufacturing and quality control data according to the detected risk stages.

In 2018, to forge an infrastructure to build a leading NLRS, the MFDS created a comprehensive plan (draft) including a mid-to long-term roadmap to improve the National Lot Release System. In addition, the Ministry added detailed action plans and annual schedules for each agenda to improve institutions like risk assessment, regular certification and semi-product certification. Furthermore, the MFDS established and revised 49 standard work guidelines to upgrade the quality assurance system and has operated 11 business manuals by enacting/amending the five major manuals like the "Procedure for Operating Proficiency Programs for Biological Products at Multiple Institutions." From 2015 to 2018, the MFDS enacted and revised 141 test records and until 2018, enacted 106 checklists to examine the Summary Protocol (SP) for the approval of national lot release. The Ministry turned test records, test reports and checklists in DBs and drew up standard control measures by form. In 2019, according to the roadmap for improving the NLRS, the MFDS will formulate an item-specific certification test plan, to amend the detailed instructions on the risk level evaluation of medicine approved by the national lot release and to set up a basis for a regular certification system.

2. Strengthening Cooperation and Communication through the Operation of a Public-Private Consultative Group

The MFDS has operated a Public-Private consultation body to promote quality control efficiency and international harmony through an exchange of information and technologies between laboratories.

As of now, there are 14 manufacturers and two quality inspection agencies participating in the "Vaccine Quality Control Laboratory Network (Lab-Net)." In 2018, the MFDS carried out joint research on three topics related to the establishment of national reference products. Through these activities, the MFDS has established national reference products and upgraded its proficiency in the endotoxin content tests. The MFDS also held a workshop on the "2018 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, the MFDS is operating/conducting the "Civil-governmental Association for a Blood Product Quality Study" with domestic manufacturers and importers and three blood centers. In 2018, the MFDS organized a council comprising 35 internal and external experts and hosted ISS forum in April to share the annual operation plan and policy action plans of the MFDS divisions related to blood products.

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 along with the inspection of proficiency between institutions on the human antithrombin potency assay. The MFDS also carried out 4 site visits for manufacturers and importers. Additionally, the MFDS ran the "Network Sub-Unit for Quality Control Labs", establishing a national reference standard of an antibody (antitoxin) to neutralize mamushi toxin, and visited the manufacturing facilities to listen to field opinions, and in this way, support quality control information and technology. In 2019, the MFDS will continue its communicative and cooperative activities by producing and establishing national reference standards, conducting trainings for quality control testers, operating proficiency programs, and visiting

manufacturing sites, through regular public-private consultations with manufacturers and importers, quality inspection agencies, and blood centers.

Kang Ho-Il, Advanced Analysis Team ☎ 043-719-5301

3. International Cooperation Activities

In order to strengthen its capabilities for the safety management of biological products and discuss and exchange information on regulatory issues, the 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, the MFDS has signed a contract to carry out WHO's Technical Service Agreement (TSA) and has accordingly been tested for the vaccine supplied to the WHO. In 2018, the MFDS signed an additional contract test for 4 lots of Japanese encephalitis live vaccines, 8 lots of BCG vaccines, 9 lots of pertussis vaccine and 4 lots of cholera vaccine for two years to be completed by the end of 2019. The MFDS implemented potency assays for 6 lots of vaccines including BCG vaccines under the contract and the results were sent to the WHO offices to conduct the entrusted testing work.

Designated in 2011 as a cooperation center in the field of standardization under the auspices of the World Health Organization, the 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 second training program held in 2017, the MFDS implemented the 2018 International National Lot Release/Test Certification Training for 9 days from

Oct. 16 to 24, 2018. A total of 56 officials in charge of vaccine quality control from 19 countries in Asia, the Middle East, and Africa attended the training.

In addition, the "Western Pacific Lab-Net International Workshop" was held in June 2018 in order to strengthen the cooperation between national regulation laboratories in the Western Pacific region. Quality control experts from Korea, Austria, Japan, India, Vietnam, and experts from the WHO Regional Office participated in the workshop, and shared the status of the NLRS and quality control of blood products. Especially, The participating experts presented and discussed studies on quality assessment and clinical cases.

In 2018, the MFDS joined in two international collaborative studies organized by Britain's National Institute for Biological Standards and Control (NIBSC) to establish international reference standards for blood coagulation factor V and PKA activators. In addition, the MFDS participated in joint studies organized by the National Institute of Infectious Diseases. The research was on standardizing the tests for freedom from aggregated immunoglobulin G and establishing reference standards for the test for freedom from anti-complementary effect.

The major international cooperation activities planned in 2019 include an operation of the WHO International Training Center for national shipment approval/test certification for 10 days (in October) for developing countries around the world. Further, the 4th Western Pacific Lab-Net International Workshop will be held in June along with the Global Bio Conference (GBC). In addition, the MFDS will actively push ahead with international joint studies as well as participate in international collaborative research projects at the request of foreign regulatory institutes.

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.

In 2018, the MFDS received an internal review and on-site KOLAS evaluation to expand the scope of its accreditation, and finally won additional accreditation for one vaccine item and 9 test items. As a result, the Ministry is now operating ISO/IEC 17025 for 19 test items. In addition, the MFDS took part in the International Proficiency Program organized by the European Directorate for the Quality of Medicines & Healthcare, and received accreditation for its quality inspection capability at the international level regarding the potency tests of MMR vaccines, fibrinogen of fibrin sealant, and thrombin. The MFDS also came up with an endotoxin test as a domestic proficiency program in order to verify the testing ability of testing agencies and securely trust them in those tests.

The MFDS will provide testing personnel in-charge of national shipment approval professional education on ISO/IEC 17025 operation, measurement uncertainty, internal auditor courses and clinical statistics. Moreover, to examine the international quality test capability of the Ministry, the MFDS plans to participate in the international proficiency program hosted by the European Directorate for the Quality of Medicines & Healthcare as a content test for immunoglobulin G and the test for freedom from aggregated immunoglobulin G; and the polysaccharide content test for protein-conjugated hemophilus influenza vaccines organized by the WHO. The MFDS will also operate the Bradford protein assay as a domestic proficiency program. The MFDS will be equipped with the aspect of a reliable test analysis and the research facility by developing its international testing and analysis capabilities in vaccine and blood product sectors.

Kim Jae-Ok, Blood Products Division ☎ 043-719-5451

chapter 6

Appendix

1. Ministers · Commissioners · Vice Ministers in MFDS

1) Ministers

Name	Terms of Office
Lee Eui-Kyung	Mar. 9, 2019 ~
Ryu Young-Jin	Jul. 12, 2017 ~ Mar. 8, 2019
Sohn Mun-Gi	Mar. 28, 2016 ~ Jul. 11, 2017
Kim Seung-Hee	Apr. 7, 2015 ~ Mar. 12, 2016
Jeong Seung	Mar. 23, 2013 ~ Mar. 12, 2015

2) Commissioners

Name	Terms of Office
Jeong Seung	Mar. 15, 2013 ~ Mar. 22, 2013
Lee Hee-Seong	Dec. 30, 2011 ~ Mar. 14, 2013
No Yeon-Hong	Apr. 2, 2010 ~ Dec. 11, 2011
Yun Yeo-Pyo	Mar. 8, 2008 ~ Apr. 1, 2010
Kim Myeong-Hyeon	Jun. 21, 2007 ~ Mar. 7, 2008
Mun Chang-Jin	Feb. 1, 2006 ~ Jun. 20, 2007
Kim Jeong-Sook	Sep. 3, 2004 ~ Jan. 31, 2006
Sim Chang-Gu	Mar. 3, 2003 ~ Sep. 2, 2004
Lee Young-Sook	Mar. 20, 2002 ~ Mar. 2, 2003
Yang Gyu-Whan	Aug. 11, 2000 ~ Mar. 19, 2002
Heo Geun	Jan. 29, 1999 ~ Aug. 10, 2000
Park Jong-Sei	Mar. 9, 1998 ~ Jan. 28, 1999

3) Vice Ministers

Name	Terms of Office
Choi Sung-Rak	Aug. 20, 2017 ~
Yoo Moo-Young	May. 11, 2016 ~ Aug. 6, 2017
Sohn Mun-Gi	Oct. 21, 2015 ~ Mar. 27, 2016
Jang Gi-Yun	Dec. 8, 2014 ~ Oct. 20, 2015
Jang Byeong-Won	Apr. 19, 2013 ~ Nov. 20, 2014
Kim Seung-Hee	Dec. 30, 2011 ~ Apr. 18, 2013
Lee Hee-Seong	May. 20, 2010 ~ Dec. 29, 2011
Lee Sang-Yong	Mar. 31, 2008 ~ Apr. 18, 2010
Mun Byeong-Woo	Jul. 24, 2007 ~ Feb. 25, 2008
Kim Myeong-Hyeon	Sep. 7, 2005 ~ Jun. 20, 2007
Byeon Cheol-Sik	Oct. 19, 2004 ~ Sep. 6, 2005
Jeong Yeon-Chan	May. 1, 2003 ~ Sep. 30, 2004
Lee Hyeong-ju	Apr. 18, 2002 ~ Apr. 10, 2003
Park Jeong-Gu	Jun. 26, 1999 ~ Apr. 7, 2002
Kim Hee-Seong	Mar. 25, 1998 ~ Jun. 25, 1999

2. Changes in the Number of Staff

<table>
<tr><td>May. 7, 2019</td><td>○ Established the Narcotics Safety Planning Directorate: +1 officer (high-level official)
○ Changed the operational managerial positions to administrative ones: ±5 officers
- Headquarters (1) One grade-9 officer for business operations → One grade-8 officer for administration
- Regional offices (4) Four grade-9 officers for business operation → Four grade-8 officers for administration</td></tr>
<tr><td>Mar. 4, 2019</td><td>○ Reflected on the required number of personnel for 2019 (31 officers)
- 31 officers (two grade-5 officers, two grade-5 officers (temporary), nine grade-7 officers, 10 grade-8 officers, five grade-9 officers, three researchers)
* Headquarters (5 officers): Labeling/advertising for food, etc. (1), Introduction of the agricultural product PLS (1), public data (1), agro-livestock and fishery products (2, temporary)
* National Institute of Food and Drug Safety Evaluation (NIFDS) (1 officer): Introduction of the agricultural product PLS (1)
* Regional offices (25 officers): on-site inspection of medical devices (10), safety management of imported foods (15)
○ Reflected on the performance evaluation of new departments
- Narcotics Management Division → Extended the evaluation period by one year (~2020.2.28.)
- Biopharmaceuticals Review Management Division → Changed to a regular organization</td></tr>
<tr><td>Dec. 11, 2018</td><td>○ Reshuffled the arrangement of 2018: ±10 officers
- Transferred the ‘renewal of medical products’ to regional offices: HQ Pharmaceutical Management Division → Medical Product Safety Division of the Daejeon Regional Office (one grade-7 officer)
- Integrated the special judicial police affairs of each division to the management support divisions of regional offices
: Regional office investigation TF → Regional office management support divisions (15 officers)
* Seoul 3, Busan 3, Gyeonggi-do/Incheon 3, Daegu 2, Gwangju 2, Daejeon 2
○ Duty allocation for the food area
<table><tr><th>Classification</th><th>Present</th><th></th><th>Changed</th></tr><tr><td>Operation and management of corporations</td><td rowspan="2">Food Safety Labelling and Certification Division</td><td rowspan="2">→</td><td rowspan="2">Food Safety Policy Division</td></tr><tr><td>Operation of the self-quality inspection system</td></tr><tr><td>Emergency response to GMO</td><td>Imported Food Policy Division</td><td>→</td><td>Import and Distribution Safety Division</td></tr><tr><td>Management of inedible agricultural/fishery products</td><td>Food Safety Management Division</td><td>→</td><td>Import and Distribution Safety Division</td></tr><tr><td>Setting nutrient standards for processed foods</td><td>Food Safety Labelling and Certification Division</td><td>→</td><td>Dietary and Nutritional Safety Division</td></tr></table>○ Established new duties according to the amendment of the「Laboratory Animal Act」
○ Designated the “Innovative Administration Office” as the “Public-Private Cooperation Division”
○ Changed singular administrative occupational series to plural ones according to the HQ’s plan to expand plural series (singular series: 3 persons → plural series)
* Inspection System Division (grade 5 - 1 person, grade 6 – 1 person), agro-livestock and fishery products (grade 9 – 1 person), Agro-Livestock and Fishery Products Safety Division (grade 9 – 1 person)</td></tr>
</table>

<table>
<tr><td>Mar. 30, 2018</td><td>○ Reflected the required number of persons for 2018 (61 persons)
- 1 Inspection Center established (Gimpo Imported Food Inspection Center)
- Added 61 persons (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 persons), Strengthen imported food safety management (1 person), Supply national essential drugs (1 persons), Strengthen safety management of cosmetics (2 persons), Enhance life-cycle safety management for medical devices (1 person), Operate Laboratory Animal Resources Bank (2 persons), Information Security and Control Center (3 persons), Imported food inspection (40 persons)
○ Reshuffle of persons in 2018: ±10 persons
- (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 persons) Division of Imported Food Inspection Management → Inspection Center Busan2, Gyeongin3</td></tr>
<tr><td>Jan. 1, 2018</td><td>○ Deployed 8 persons 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 person to the employment quota of term-based public officers
* (Current) 1 person for promotion → (Amended) 1 person 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
- Reshuffle relevant bureaus and divisions to strengthen safety management of imported food and to ensure efficiency of food safety management
* Reshuffle Food Nutrition and Dietary Safety Bureau to Food and Consumer Safety Bureau
* Reshuffle Agro-Livestock and Fishery Products Safety Bureau to Imported Food Safety Policy Bureau
<table><tr><th rowspan="2">Classification</th><th colspan="2">Description</th></tr><tr><th>Bureau</th><th>Division</th></tr><tr><td>Food Nutrition and Dietary Safety Bureau</td><td>Food Safety Policy Bureau</td><td>Food Policy Coordination Division → Food Safety Policy Division (Changed Name)
General Food Management Division → Food Safety Management Division(Changed Name)
Food Consumption Safety Division → Food Safety Labelling and Certification Division (Changed Name)
Health and Functional Food Policy Division (Transferred from Food Nutrition and Dietary Safety Bureau)
Livestock Products Standard Division → Residues and Contaminants Standard Division (Changed Name)</td></tr></table></td></tr>
</table>

Mar. 21, 2017

Classification	Description	
	Bureau	Division
Food Nutrition and Dietary Safety Bureau	Food and Consumer Safety Bureau	Dietary and Nutritional Safety Policy Division (Dietary Life Safety Division and Nutrition Safety Policy Division were merged) Agro-Livestock and Fishery Products Policy 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)
Agro-Livestock and Fishery Products Safety Bureau	Imported Food Safety Policy Bureau	· 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 merge of divisions)

○ 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.

Feb. 28, 2017

- Reflected the required number for 2017 (38 persons)
  • Three divisions were established (Alcoholic Beverages Safety Policy Division, narcotics Management Division, Biopharmaceuticals Review Management Division)
  • 38 persons increased: (one class-4 officer, four class-5 officers, eleven class-6 officers, nine class-7 officers, two senior officers and eleven researchers)
  * expanded scope of responsibility of special judicial police (3 persons), expand food traceability system gradually (2 persons), strengthen imported food safety management (4 persons), strengthen safety management of alcoholic beverage (1 person), Implement restaurant sanitation grade system (1 person), strengthen safety management of livestock-fishery products (2 persons), drug approval update, etc. (5 persons), Narcotics Management Division (6 persons), strengthen approval of health functional food (2 persons), Biopharmaceutical Review Management Division (9 persons), strengthen international cooperation (2 persons), document controller (2 persons)

Jan. 26, 2017

- 15 persons decreased: (one class-5 officer, three class-6 officers, three class-7 officers, one class-8 officer, one class-9 officer, two senior officers and four researchers

HQ(△5)	Affiliated institutions (△10)	
	NIFDS(△4)	Regional Offices(△6)
one class-5 officer, one class-6 officer, one class-7 officer, one class-9 officer, one senior officer and one researcher	two senior officers and 2 researchers	two class-6 officers, two class-7 officers, one class-8 officer and one researcher

Jul. 29, 2016	○ Adjusted open type position for Director General level - Director General of Pharmaceutical Safety Bureau was newly designated as an open position. Post of Deputy Director General for Food Standard Planning is no longer subject to open position ○ Change in scope of work for Customer Risk Prevention Bureau - The function of consumer organization support and cooperation was transferred from Customer Risk Prevention Policy Division to Communication and Cooperation Division
May. 19, 2016	○ Reflected the required number for 2016 (12 persons) ○ 1 Division established (Integrated Food Information Service Division)<Apr. 26, 2018 temporarily> ○ Increased 12 persons * HQ: Integrated Food Information Service Division (2 persons), Cyber security (1 person), Strengthening safety management of imported food (2 persons), Safety and traceability of drug (1 person), Traceability of medical device (1 person) * NIFDS: R&D management(1 person), Biosimilar approval process (1 person) * Regional Office of FDS: Food traceability (1 person), Archives management (2 persons)
Feb. 5, 2016	○ Adjustment in positions in 2016: ±15 persons (two grade-3 · 4 officers, six grade-4 · 5 officers, two grade-5 officers, 5 senior officers)
Dec. 30, 2015	○ Reduced total number of personnel: 16 persons (5 persons from the Headquarters, 3 persons from the National Institute of Food and Drug Safety Evaluation, 8 persons from regional offices of food and drug safety) ○ Management Operations Personnel switched to General Staff: ±5 (±4 from the Headquarters, ±1 from a regional office of food and drug safety) ○ Open Position: Director General of Food Nutrition and Dietary Safety Bureau was newly designated as an open position. Post of Director General of Medical Device Evaluation Department is no longer subject to open position
Dec. 4, 2015	○ Increased the number of personnel for cyber security: 1 person (Headquarters) ○ Import Food Analysis Division in Gwangju Regional Office of Food and Drug Safety abolished (△ 4)→ Import Food Analysis Division newly established in Seoul Regional Office of Food and Drug Safety (+4) ○ 'Open Position' newly established: Chief of Consumer Risk Prevention Bureau ○ National Institute of Food and Drug Safety's internal personnel adjustment: Orthopedic and Restorative Devices Division (△2) → Advanced Medical Devices Division (+2)
May. 29, 2015	○ Reflected the required number for 2015 (14 persons) • Newly established 1 division (Pharmaceutical Safety Evaluation Division) <17. 5. 31. temporarily> * Increased 14 persons * HQ: Food Radiation (2 persons), Archives/Personal Information (1 person) * NIFDS: Food Radiation (1 person) * Regional FDA: Pharmaceutical Safety Evaluation Division (3 persons), human tissue (2 persons), Integrated network (1 person), Food Traceability (2 persons), Archives/Personal Information (2 persons) * Adjusted ranks: ±22 persons(class 3 · 4-2, class 4 · 5-5, class 5-15) ○ Follow-up measures for audit on prescribed number for 204 * National Qualification Center of NIFDS → Vaccine Division, Blood Products Division * Inspection analysis center of Busan · Gyeonggin regional FDA → 2nd affiliated agency

Jan. 09, 2015	○ Reflected organization diagnosis of 2014: +9 persons(class 5-2, class 6-3, class 7-3, class 8-1) • HQ: △ 21 person * (transfer · abolition) Health Functional Food Standard Division abolished, New Material Food Division → transferred to NIFDS, abolished Medical Device Quality Division, (created) Health Functional Food Policy Division, Medical Device Safety Evaluation Division • NIFDS: +14 persons * (transfer · abolition) Radiation Safety Division → abolished, (created) New Material Food Division(transfer from HQ), external diagnosis division, (renamed) Medicine Specification Research Division → Medicine Research Division • Regional FDA: +16 persons * (established) Incheon port/Yongin Imported Food Inspection Center (temporary inspection center, normal organization) - Transferred management operation position to general position: ±28 (HQ ±3, NIFDS ±21, Regional Office of FDS ±4) - Reduced total number: △16 persons (HQ 5, NIFDS 4, Regional FDA 7)
Aug. 27, 2014	- Reflected required number for 2014 (12 persons) • 1 division established (Quasi-drug Policy Division) • 12 persons increased * safety management of quasi-drug reinforced (3 persons HQ, 1 person NIFDS), test inspection quality management reinforced (2 persons), integrated food safety information network constructed and operated (3 persons), plasma safety management reinforced (2 persons HQ, 1 person NIFDS) - Resolve disagreement between job and ranks (1 person): public health operation assistant secretary → office operation secretary
Feb. 20, 2014	○ Vice minister in special service, transferred to general position according to revision of 「National Government Organization Act(Dec. 24, 2013)」 - Adjusted number of employee to transfer the successful candidate of administration position test to other job type (3 persons)
Dec. 18, 2013	○ Adjusted the number of employee according to reorganization of job type (Dec. 12, 2013) • Technical post(94 persons) → General post(94 persons) • Contract post(11 open type positions*) → transferred to term-based public officials * Director level: Director of Food Standard Planning Office, Biophamaceutical Inspection Office, Medical Device Inspection * Manager level: Spokesperson, managers of International Cooperation Office, Information Management and Statistics Office, Audit and Inspection Office, Herbal Medicine Policy, Bioequivalence Evaluation Division of NIFDS, Radiation Safety Division, Clinical Research Division • Special post(2persons)* → general post(term-based secretary, administrative official) * Emergency and Security Office, facility · equipment class 5 ○ Reduced 17 persons according to operation plan of integrated number of officials of Ministry of Public Administration and Security (June 2013)* * HQ(△6 persons), NIFDS(△3 persons), Regional FDA(△8 persons)
Nov. 5, 2013	○ Established Gamcheon port import food inspection center for stable performance of Japanese imported fishery product inspection ○ Adjusted disagreement between current number and prescribed number and other function posts: ±17 persons

Oct. 4, 2013	○ Reflected required number for 2013 and increased personnel for national policy project ○ 2 division established: Alcoholic Beverages Safety Management and Planning Division (temporary), Pharmaceutical Approval and Patent Management Division ○ Increased 15 persons • Required numebr for 2013: 12 persons • Dedicated for eradiation of adulterated food: 5 persons • Transfer radiation safety control personnel (radiation safety division) to ministry of welfare (△ 3 persons) ○ Others • Adjusted open type position (3 director level, 8 manager level) • Changed name and location of Gyeongin FDA* * Incheon metropolitan city → Gyeonggido, Gwangyang import inspection center (Yeosu → Gwangyang)
Mar. 23, 2013	Established Ministry of Food and Drug Safety ○ Transferred safety policy function of food and drugs of Ministry of Health and Welfare, and agro-livestock fishery product sanitation and safety of Ministry of Ministry for Food, Agriculture, Forestry and Fisheries to MFDS according to revision of「National Government Organization Act (Mar. 23, 2013)」 ○ Personnel: 1483 persons → 1760 persons (+277 persons) • Transfer of Ministry of Agriculture and Forestry*: 260 persons * livestock area (1 bureau, 8 divisions, 171 person), fishery area (1 bureau, 87 persons), area of agriculture (1 person) • Transfer of Ministry of Welfare*: 10 persons * food area (1 division, 6 persons), medicine area (2 persons), common area (2 persons) • Increase (+12 persons), decrease (△5 persons)
Nov. 18, 2012	○ Established separate quota for filling up vacancy due to maternity leave for MFDS and agencies (a total of 64 persons) ○ Added open type position of bioequivalence manager ○ Changed competent department of Medical Device Inspection Division (advanced Medical Device Division) ○ Established regulation for job division of imported foods of Regional FDA
Jul. 30, 2012	○ Increased persons due to reinforcement of safety management of raw materials and introduction of national lot release approval system • 19 persons (class 5-3, class 6-2, class 7-3, senior officers-3, researchers-8) ○ Rearranged jurisdiction with Uiwang inspection center through creation of Gwangju imported food inspection center in Gyeonggin office ○ Abolished function class 10 according to revision of Government Officials Act • Changed 33 persons of functional class 10 → functional class 9 in lump sum
Feb. 03, 2012	○ Established biopharmaceutical and medical device approval inspection division and created personnel • Established Advanced Medical Device Division and Cell Gene Medicine Division ○ Discarded manufacturing quality research team of NIFDS and established Biopharmaceutical Quality Management Division in charge of quality management function of biopharmaceuticals ○ Renamed the division and reorganized review division for each clinical trial area of medical device • Biopharmaceutical inspection division: advanced product division → gene recombination medicine division • Medical Device Inspection Division: Diagnosis Device Division → Cardiovascular Device Division, Treatment Device Division → Orthopedics and Rehabilitation Device Division, Material Product Division → Oral Digestion Device Division
Jul. 29, 2011	○ Installed emergency planning office at Director General for Planning and Coordination

Dec. 31, 2010	○ Discarded side effects monitoring team of NIFDS and established medicine safety information team in charge of collection and evaluation of side effect information of medicine at Administration
Apr. 30, 2009	○ Reorganized organization (reduced 6 divisions with application of project system) - Administration 1 office 5 bureau (1 team · 4 bureau) 65 divisions → 1 office 5 bureau (1 team · 4 bureau) 48 divisions • Established Criminal Investigation Office, Overseas Investigation Office • Reorganized harmful substance management office to risk prevention policy bureau • Reorganized Biopharmaceutical Bureau to Biopharmaceuticals and Herbal Medicine Bureau • Reorganized nutrition functional food bureau to nutrition policy office • Reorganize 4 evaluation bureau to 4 inspection bureau (food standard bureau, medicine inspection bureau, biopharmaceutical inspection bureau, medical device inspection bureau) - National Toxicity Science Institute → National Institute of Food and Drug Safety Evaluation (3 bureau 18 divisions → 3 bureaus 29 divisions) • Reinforced the function of food and medical device safety support, organize connection with Administration, food risk evaluation bureau, medical device research bureau, and toxicity evaluation research bureau ○ 6 Regional FDA • Reorganized General Services Division to customer support division, medicine division to medical product safety division, test analysis division to harmful substance analysis division, food and drug analysis division to imported foo analysis • Transfers 101 persons and simple tasks of instruction and guidance according to arrangement plan of special provincial administrative agency of food and drug to cities and provinces
Feb. 29, 2008	○ Reorganized to bureau and division (office) system - Create Spokesperson under administrator, Regulatory Reform and Legal Affairs Office in Director General for Planning and Coordination, respectively - Reorganized performance management team under vice minister to performance management team under Director General for Planning and Coordination, inspection and examination management team to inspection management team of harmful substance management center of food and safety bureau ○ Abolished innovation planning office, policy promotion team ○ Adjusted name of some division creatively and transferred the team based system to division based system according to government reorganization policy
Sep. 14, 2007	○ Create performance management team under vice minister team, food poisoning prevention management team under Food HQ, medicine quality team under Medicine HQ, medicine quality bureau under Medicine HQ, quality equivalence evaluation team under medicine quality bureau, medical device approval inspection team under medical device HQ, and research support team in National Toxicity Science Institute, respectively ○ Reorganized medicine equivalence team of Medicine HQ to bioequivalence evaluation team ○ Reorganized National Toxicity Science Institute to National Toxicity Science Institute, biotechnology support team to the team under pharmaceutical research bureau, endocrine disorder substance team under toxicity study bureau to endocrine disorder evaluation team of risk evaluation research bureau, respectively
Aug. 25, 2006	○ Create inspection and examination management team under vice minister, information support team and total counseling center under Policy promotion management HQ, new material food team under nutrition functional food HQ, clinical management team and herbal medicine team under Medicine HQ, cosmetic evaluation team under medicine evaluation division of medicine HQ, herbal medicine evaluation team under medicinal herb evaluation division of medicine HQ, biopharmaceutical management team under biopharmaceutical HQ, medical device quality team under medical device HQ, respectively ○ Abolished inspection management team of harmful substance management center of Food HQ ○ Reorganized biopharmaceutical team of Biopharmaceutical HQ to biopharmaceutical safety team, medicine evaluation division of Medicine HQ to medicine evaluation bureau to quasi-drug team, respectively

Jun. 30, 2006	- Introduced position of high-ranking officials (22 positions)
Dec. 30, 2005	○ 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 • 6HQ: policy promotion management HQ, food HQ, nutrition function food HQ, medicine HQ, biopharmaceutical HQ, medical device HQ • 4 evaluation bureau: food evaluation, medicine evaluation, medicinal herb evaluation, medical device evaluation bureau - Reorganized effectiveness research division - risk research division of Toxicology Institute to Pharmaceutical bureau · Risk evaluation bureau - Reorganized food monitoring division of 6 Regional FDAs to food safety management team - Create food safety standard team and risk information management team under food HQ, gene medicine team and tissue engineering team under Biological Medicine HQ, separated legal trade officer to administrative legal affair team and trade cooperation team - established exposure evaluation team, applied application team under National Institute of Toxicological Research - established operation support team at Daegu, Gwangju, Daejeon Regional FDA, respectively
Apr. 15, 2005	○ Changed Planning Office to Policy Promotion Office, Planning Budget Office to Finance Planning Office, Promotion Office to Policy Promotion Office
Dec. 31, 2004	○ Changed renovation officer to renovation planning officer, abolished test analysis officer of safety evaluation office, established research and planning coordinator
May. 24, 2004	○ Separated medical device division of Pharmaceutical Safety Bureau to medical device safety division and Medical Device Management Division ○ Established biotechnology support division under Effectiveness Research Bureau of National Institute of Toxicological Research
Jan. 09, 2004	○ Reorganized food evaluation division and food additive evaluation division under safety evaluation office to food specification evaluation division and food safety division ○ Transfer function and personnel for medicine safety, effectiveness and equivalence evaluation tasks performed by National Institute of Toxicological Research, to Medicine Evaluation Division of Administration ○ Reorganized general toxicity, special toxicity and pharmacology division of National Institute of Toxicological Research to toxicity research division, efficiency research division and risk division
Jul. 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 in National Toxicity Laboratory
Feb. 28, 1998	Opened Food and Drug Administration - Transferred the tasks of food policy division, chemical division and medical device division of Transferred the execution asks of food policy bureau, and medical device of Ministry of Health and Welfare • Some tasks such as enactment and revision of laws and determination of policy remained at Ministry of Health and Welfare - Installed National Toxicity Laboratory and 6 Regional FDAs
Apr. 6, 1996	Established food and drug safety administration and 6 Regional FDA as affiliated agencies of Ministry of Public Health and Welfare - Carried out some tasks of food division Ministry of Health and Welfare → Transfer safety administration to Regional FDA • Safety HQ: 2 bureaus (6 divisions) 5 offices (22 divisions) - 4 divisions of National Institute of Health (sanitation, chemical, herbal medicine, radiation standard division) → reorganized as 5 safety evaluation division (food, food additive, cosmetics, biological products, medical device) - National Institute of Health and Safety → Toxicity Laboratory reorganized

3. Roles and Responsibilities (HQ)

Department		Main Functions
Spokesperson		Promote the policies and achievements of the MFDS
Planning and Coordination Bureau	Planning and Finance Office	Direct and coordinate mid-to long-term policies and plans; direct and coordinate responses to the National Assembly; coordinate budget organization, execution and settlement; and accordingly coordinate and direct R&D projects
	Innovative Administration Office	Manage the organization and quotas; establish and inspect performance management plans; direct employment policies; and improve the administration system, and direct and coordinate the improvement of organizational culture.
	Regulatory Reforms and Legal Affairs Office	Formulate and review the drafts for statutes · administrative rules, direct regulatory reforms; support cabinet · vice-minister meetings; support the legislation work of the National Assembly; and direct administrative appeals and litigation affairs
	International Cooperation Office	Direct and coordinate international trading and international cooperation projects pertaining to food and drugs; manage resident officers of overseas diplomatic offices
	ICT Management and Statistics Office	Establish and evaluate a mid-to long-term informatization plan for food and drugs; operate, maintain and repair the information systems; and direct policy-based statistics
	Customer Support Office	Establish and execute comprehensive plans for better customer satisfaction; develop a customer support policy; direct and coordinate civil complaints and operate counseling centers
	Emergency Planning and Safety Office	Control and coordinate the overall plan and training schedule to cope with national emergencies; manage resources adequately for responding to emergencies (supplies, companies, etc.)
Audit and Inspections Office		Audit the MFDS, its agencies and groups and handle and analyse the 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, and facility work
Consumer Risk Prevention Bureau	Customer Risk Prevention Bureau	Develop consumer policies to protect consumer rights and interests in the area of food and drugs; and develop policies to prevent risks related to food and drugs
	Communication and Cooperation Division	Establish and execute total communication plans for food and drugs Communicate with people to ensure that they are more aware of food and drug safety
	Risk Information Division	Collect all the risk information related to food and drugs from home and abroad; and construct a risk information collection and analysis system and develop related techniques
	Integrated Food Information Service Division	Establish and coordinate policies for central government agencies to link/integrate and judiciously use food safety information; and supervise and support the operation of the Integrated Food Safety Information Network.
	Laboratory Audit and Policy Division	Direct and coordinate system improvement, and enact and revise laws and regulations related to the inspection and examination of food and drugs; and establish plans for the enhancement of quality of inspection and examination agencies and for their comprehensive development

Department			Main Functions
Food Safety Policy Bureau	Food Safety Policy Division		Establish sanitation and safety management policies for food, health functional foods, food additives, utensils, containers, and packaging; and coordinate the improvement of relevant regulations.
	Food Safety Management Division		Establish a comprehensive plan for guidance and crackdown on the operation of food businesses; and formulate and manage a food collection and inspection plan.
	Food Safety Labelling and Certification Division		Operate labeling standards for food, etc., and labeling and advertisement review standards for infant/baby foods and weight control foods; set up and coordinate a comprehensive plan regarding HACCP; and run the Food Traceability System
	Health and Functional Food Policy Division		Develop policies regarding health and functional foods and improve relevant regulations; establish and supervise a comprehensive safety management plan; and supervise processes regarding approval and reports of health functional foods
	Alcoholic Beverages Safety Management and Planning Division		Establish and coordinate a comprehensive plan on the policies regarding safety management of alcoholic beverages and, improve and amend relevant laws and regulations; and promote safety management and provide educational programs; impose administrative penalty
	Food Standards Planning Office	Food Standards Division	Establish and execute a total plan for improving food standards and specifications
		Residues and Contaminants Standards Division	Establish and implement a comprehensive plan to improve standards and specifications for the presence of hazardous materials in food.
		Food Additives Standards Division	Establish and execute a total plan for the operation and establishment of standards and specifications for sterilizers and disinfectants, etc., of food additives, utensils, containers and packages, etc.
Pharma-ceutical Safety Bureau Pharma-ceutical Safety Bureau	Pharmaceutical Policy Division		Develop a policy for the safety management of medicine; enact and revise notices and laws on medicine; and operate the medicine approval system and develop relevant policies
	Pharmaceutical Management Division		Establish and coordinate a plan for monitoring pharmacists; operate the labeling and advertisement system for medicine; and designate and manage medicines likely to be abused or misused
	Pharmaceutical Quality Division		Establish a plan related to manufacturing and quality management standards of medicine; and operate systems; establish education plans; and promote international cooperation
	Clinical Trials Management Division		Direct coordination and establishment of the policies related to clinical trials; approve and manage clinical trial plans for medicine
	Pharmaceutical Approval and Patent Management Division		Operate registration, management and related systems of medical patents; and enact and revise regulations
	Pharmaceutical Safety Evaluation Division		Collect, manage and evaluate information on the side effects of medicines and quasi-drugs; and operate a medicine damage relief system

Department			Main Functions
Pharmaceutical Safety Bureau Pharmaceutical Safety Bureau	Narcotics Safety Planning Office	Narcotics Policy Division	Develop policies for narcotics and raw materials, and establish and coordinate their total plan; enact and revise related laws and notices
		Narcotics Management Division	Establish and implement a comprehensive narcotics safety management plan; support and oversee the Integrated Narcotics Information Management Center; establish and coordinate a basic plan for the distribution and surveillance of narcotics and raw materials of narcotics, etc.
Bio pharmaceuticals and Herbal Medicine Bureau	Biopharmaceutical Policy Division		Establish and coordinate policies related to the safety of biological products, gene recombination medicine, gene therapy, cell therapy, tissue-engineering medicine, and human tissue and plasma
	Biopharmaceutical Quality Management Division		Establish the manufacturing and quality management standards for biopharmaceuticals; manage and operate changes; and establish and coordinate a plan for monitoring biopharmaceuticals and human tissue transplants
	Herbal Medicine Policy		Establish and coordinate the policies related to the safety of herbal medicine and medicinal herb products; and enact and revise related laws and regulations
	Cosmetics Policy Division		Establish and coordinate cosmetics-related policies; enact and revise related laws and regulations; and establish a consolidated 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 a plan for monitoring quasi-drugs
Medical Device Safety Bureau	Medical Device Policy Division		Establish and coordinate the policies related to the distribution of medical devices; smoothly operate the system for the approval, classification, and designation of medical devices and develop related policies
	Medical Device Management Division		Establish and coordinate a plan for monitoring medical devices, establish and coordinate an instruction and enforcement plan for medical device handlers; and preliminary deliberations on the advertisement of medical devices
	Medical Device Safety Evaluation Division		Manage the side effects of medical devices; manage the safety information of medical devices; address matters on the re-evaluation and reassessment of medical devices

4. Number of Staff

1) Prescribed Number

As of Apr 30, 2019 (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	1,890	1	24	12	49	31	214	314	330	159	71	158	497	9	2	19
HQ	603	1	11	10	35	20	126	128	113	9	7	36	88	7	2	10
Agency	1,287	-	13	2	14	11	88	186	217	150	64	122	409	2	-	9
NIFDS	424	-	7	-	6	1	28	13	11	19	5	107	224	2	-	1
Regional Office of FDA	863	-	6	2	8	10	60	173	206	131	59	15	185	-	-	8
Seoul Regional Office of FDA	134	-	1	1	1	2	9	28	35	15	9	5	25	-	-	3
Busan Regional Office of FDA	221	-	1	1	4	-	17	44	53	46	11	2	40	-	-	2
Gyeongin Regional Office of FDA	303	-	1	-	3	2	18	58	60	40	24	5	90	-	-	2
Daegu Regional Office of FDA	53	-	1	-	-	2	4	11	14	9	4	1	7	-	-	-
Gwangju Regional Office of FDA	74	-	1	-	-	2	7	14	21	11	6	1	10	-	-	1
Daejeon Regional Office of FDA	78	-	1	-	-	2	5	18	23	10	5	1	13	-	-	-

2) History of Change in Prescribed Numbers

May. 7, 2019	1,890 persons (1 persons increased) - Established Deputy Director General for Narcotics Safety Planning
Feb. 26, 2019	1,889 persons (31 persons increased) - Required person for 2019: 31 persons • Labeling and advertising of food and other products: 1 person • Implementation of PLS system for agricultural products: 2 persons • Public data: 1 person • Manage collaboration between departments and divisions: 2 persons • On-site inspection for medical devices: 10 persons • Oversight on import declarations for imported food: 15 persons
Mar. 30, 2018	1,858 persons (61 persons increased) - required personnel for 2018: 61 persons • Deal with safety management of sanitary goods: 11 persons • Strengthen safety management for imported foods: 1 person • Supply national essential drugs: 1 person • Strengthen safety management of cosmetics: 2 persons • Enhance life-cycle safety management for medical devices: 1 person • Operate the Laboratory Animal Resource Bank: 2 persons • Information Security and Control Center: 3 persons • Imported food inspection: 40 persons
Feb. 28, 2017	1,797 persons (38 persons increased) - required person for 2017: 38 persons • Expanded scope of responsibility of special judicial police: 3 persons • Expand food traceability system gradually: 2 persons • Strengthen imported food safety management: 4 persons • Enhance alcoholic beverage safety management: ±1 person • Implement restaurant sanitation grade system: 1 person • Strengthen safety management of livestock-fishery products: 2 persons • In charge of pharmaceutical approval update, etc 5 persons • Enhance safety management of narcotics: 6 persons • Enhance approval capability of health functional food: 2 persons • Medical product approval and review: 9 persons • Enhance international cooperation: 2 persons • Document controller: 2 persons
Jan. 26, 2017	1,759 persons (15 persons decreased) - reduced 17 persons according to integrated operation plan of MOPAS (13 June) • HQ: △5, NIFDS: △4, Regional offices: △6
May. 19, 2016	1,744 persons (12 persons increased) • Required person for 2016: 12 persons • Personal for Integrated Food Information Service Division: 2 persons • Personal for cyber security: 1 person • Personal for strengthening safety management of imported food: 2 persons • Personal for safety and traceability of drug and medical device management: 2 persons • Personal for R&D management and biosimilar approval process: 2 persons • Personal for food traceability and archive management: 3 persons

Dec. 30, 2015	1,762 persons (16 persons decreased) - Cutback 16 people according the Integrated Personnel Management Plan (June 2013) of the Ministry of Security and Public Administration ('13.6) • Headquarters: △5 • National Institute of Food and Drug Safety Evaluation: △3 • Regional Offices of Food and Drug Safety: △8
Dec. 4, 2015	1,778 persons (1 person increased) Added a new staff for cyber security (1)
May. 29, 2015	1,777 persons(14 persons increased) - Required person for 2015: 14 persons • Personnel for Pharmaceutical Safety Evaluation Division: 3 persons • Personnel for human tissue: 2 persons • Personnel for operation of integrated food safety information network: 1 person • Personnel for food traceability: 2 persons • Personnel for management of food radiation: 3 persons • Personnel in charge of records and personal information: 3 persons
Jan. 09, 2015	1,763 persons(7 persons decreased) - Frequent position of 2014: 9 persons -16 persons reduced according to integrated operation plan of MOPAS (June 203) • HQ: △5 persons, NIFDS: △4 persons, Regional Office of FDS: △7 persons
Aug. 27, 2014	1,770 person s(12 persons increased) - Required person for 2014: 12 persons • Personnel for quasi-drug safety management: 4 persons • Personnel for test and inspection quality management: 2 persons • Personnel for operation and construction of integrated food safety information network: 3 persons • Personnel for plasma safety management: 3 persons
Dec. 18, 2013	1,758 persons(17 persons decreased) - reduced 17 persons according to integrated operation plan of MOPAS(June 13) • HQ: △6 persons, NIFDS: △3 persons, Regional Office of FDS: △8 persons
Oct. 4, 2013	1,775 persons(15 persons increased) - Frequent position of 2013: 6 persons - Increase persons in charge of eradication of adulterated food: 5 persons increase persons of Government 3.0: 1 person - required number for 2013: 12 persons • Personnel for management of alcoholic beverage 2 persons • Personnel for medicine approval and patent 4 persons • Personnel for follow-up management of cosmetics 3 persons • Personnel for local inspection of medical device GMP 2 persons • Personnel for protection of personal information 1 person - Transfer of persons of radiation safety management from Ministry of Welfare: △3 persons
Mar. 23, 2013	MFDS established, 1,760 persons (277 persons increased) - Personnel transferred from Ministry of Agriculture and Forestry: 260 persons - Personnel transferred from the Ministry of Welfare: 10 persons - Increased imported food inspection staff: 12 persons - Common division: △5 persons

5. Laws and Regulations under the Ministry of Food and Drug Safety

Name of Law (18)	Enforcement Ordinance (21)	Enforcement Rule (Ordinance of Prime Minister) (24)
Framework Act on Food Safety	Enforcement Decree of Framework Act on Food Safety	
Food Sanitation Act	Enforcement Decree of Food Sanitation Act	Enforcement Rule of Food Sanitation Act
		Rule on Health Examination of Employee in Food and Sanitation Area
Special Act on Imported Food Safety Management	Enforcement Decree of the Special Act on Safety Management of Imported Foods	Enforcement Regulations of the Special Act on Safety Management of Imported Foods
Act on the Establishment and Operation of the Korea Institute For Food Safety Management Accreditation	Enforcement Decree of the Act on the Establishment and Operation of the Korea Institute For Food Safety Management Accreditation	
Health Functional Foods Act	Enforcement Decree of Health Functional Foods Act	Enforcement Rule of Health Functional Foods Act
Special Act on Safety Control of Children's Dietary Life	Enforcement Decree of Special Act on Safety Control of Children's Dietary Life	Enforcement Rule of Special Act on Safety Control of Children's Dietary Life
Livestock Products Sanitary Control Act	Enforcement Decree of Livestock Products Sanitary Control Act	Enforcement Rule of Livestock Products Sanitary Control Act
Agricultural and Fishery Products Quality Control Act	Enforcement Decree of Agricultural and Fishery Products Quality Control Act	Rule on Labeling of Genetically Modified Agro-Fishery Products and Safety Examination of Agro-Fishery Products
Pharmaceutical Affairs Act	Enforcement Decree of Pharmaceutical Affairs Act	Rule on Safety of Medicine, etc
	Regulation on Damage Relief of Side-Effect of Medicine	Enforcement Rule of Regulation on Damage Relief of Side-Effect of Medicine
	Decree on Facility of Manufacturer and Importer of Medicine, etc.	Enforcement Rule of Decree on Facility of Manufacturer and Importer of Medicine, etc.
		Rule on Manufacturing, Sales Management of Biological Products
Act on the Control of Narcotics, ETC.	Enforcement Decree of Act on the Control of Narcotics, ETC.	Enforcement Rule of Act on the Control of Narcotics, ETC.
Cosmetics Act	Enforcement Decree of Cosmetics Act	Enforcement Rule of Cosmetics Act

Name of Law (18)	Enforcement Ordinance (21)	Enforcement Rule (Ordinance of Prime Minister) (24)
Medical Devices Act	Enforcement Decree of Medical Devices Act	Enforcement Rule of Medical Devices Act
Laboratory Animal Act	Enforcement Decree of Laboratory Animal Act	Enforcement Rule of Laboratory Animal Act
Safety, Management, etc. of Human Tissue Act	Enforcement Decree of Safety, Management, etc. of Human Tissue Act	Rule on Safety of Human Tissue
Food and Drug Examination and Inspection Act	Enforcement Decree of Food and Drug Examination and Inspection Act	Enforcement Rule of Food and Drug Examination and Inspection Act
		Rule on Inspection and Examination Request of MFDS and its Organizations
Food and Drugs Safety Technology Promotion Act	Enforcement Decree of the Act on Promotion of Safety Technology for Food and Drugs	Enforcement Regulations of the Act on Promotion of Safety Technology for Food and Drugs
Cleasing and Hygiene Products Act	Enforcement Decree Cleasing and Hygiene Products Act	Enforcement Rule of Cleasing and Hygiene Products
Act on Labelling and Advertising of Food, ETC.	Enforcement Decree of Act on Labelling and Advertising of Food, ETC.	Enforcement Rule of Act on Labelling and Advertising of Food, ETC.
	Ministry of Food and Drug Safety and its Organizations	Enforcement Rule of Ministry of Food and Drug Safety and its Organizations
		Rule on Establishment and Supervision of Non-Profit Corporation under MFDS
		Enforcement Rule of Emergency Resource Management Act under MFDS

■ Contributors

(As of 31, May 2019)

No.	Contents	Division and Director	Contributors
	Foreword, Contents	Director for ICT Management Na In-mook	Kim Jong-Wook
			Lee Woo-Sun
			Kim Bo-Hyeong
I. Outline	1. Vision, Objectives, and Core Strategies	Director for Planning and Finance Jang Min-Su	Park Seon-Yeong
			Namkung Jong-Hwan
	2. Organization · Affiliated Organizations	Director for Organization and Management Innovation Ju Seon-Tae	Kim Jin-Hwi
	3. History		Jeong Won Kyun
II. Food	Section 1. Strengthening of the Food Safety Management System		
	1. Securing of Safety in Online Distribution of Food and Drugs	Cyber Investigation Bureau Kim Myeong-Ho	Im Chang-Geun
			Hwang Soon-Im
	2. Strengthening of Food Production · Manufacturing Safety		
	A. Establish Safe Food Manufacturing Infrastructure	Food Safety Management Division Kim Yong-jae	Jung Jung-soon
			Choi Soo-Jin
		Food Safety Labelling and Certification Division Oh Jeong-wan	Kim Hong-tae
			Hwang Su-jin
	B. Safety Management of the Production and Distribution of Agricultural, Livestock and Fishery Products	Agro-Livestock and Fishery Products Safety Division Rhee Seong-Do	Kim Cheol-Hee
			Shin Hyang Suk
			Lee Younghee
			Kim Seong-hee
	3. Enhancing the Safety Management of Foods Being Distributed · Consumed		
	A. Nationwide Joint Crackdown	Food Safety Management Division Kim Yong-jae	Park Dong-Hee
			Hong Jeong-Uk
	B. Reinforcing Collection · Inspection of Foods Being Distributed		Cho Seong-Hun
			Ahn Jin-Young
	C. Operation of the Food Traceability Management System	Food Safety Labelling and Certification Division Oh Jeong-wan	Ryu Chang-Hi
			Cho Yoon-Hee
	D. Establishment of Hazardous Food Recalling System and Reinforcement of Information Sharing with Consumers	Food Safety Management Division Kim Yong-jae	Cho Seong-Hun
			Yoo Sun-Young
	E. Improvement of the Food Labeling System to Provide More Information to Consumers	Food Safety Labelling and Certification Division Oh Jeong-wan	Shin Young-Hui
			Lee Kyoung-Min

No.	Contents	Division and Director	Contributors
II. Food	F. Establishment of a Private and Public Joint Monitoring System	Food Safety Management Division Kim Yong-jae	Jeong Jeong-Soon
			Kim Yang-Su
			Jang Soo-Jin
	4. Reinforcement of Safety Management System for Imported Foods		
	A. Bolstering the Foundations for the Safety Management of Imported Foods and Countering the WTO Dispute on Japanese Foods	Imported Food Policy Division Kim Hyun-Seon	Oh Jae-Jun
			Son Sung-Yeol
	B. Reinforcement of On-Site Inspection at Exporting Countries for Precautionary Safety Management	On-site Inspection Division Han Un-Sub	Choi Gye-Sun
			Lee Chung-Heon
	C. Reinforcement of Safety Management of Imported Food at the Customs Clearance Stage	Imported Food Inspection Division Kim IL	Jang Hwa-Jong
			Park Chul-Yun
	D. Reinforcement of Safety Management at the Distribution Stage of Imported Foods	Imported Food Distribution Safety Division Choi Hyun-Cheol	Na Geum-Dong
			Noh Ji-Young
	E. Reinforcement of Safety Management for Novel Foods including Genetically Modified Foods	Novel Food Division Park Jong-Seok	Joo In-Sun
			Jang Mi-Ran
			Shin Ji-Eun
		Imported Food Inspection Division Kim IL	Jang Hwa-Jong
			Park Chul-Yun
		Imported Food Distribution Safety Division Choi Hyun-Cheol	Park Jin-Ah
			Lee Khe-jhae
		Imported Food Policy Division Kim Hyun-Seon	Kim Ki-Eun
		Food Safety Labelling and Certification Division Oh Jeong-wan	Nam Hye-Seon
			Ahn Hyun-Joo
	5. Reinforcement of Safety Management for Alcoholic Beverages	Alcoholic Beverages Safety Policy Division Nah Ahn-Hee	Cho Kang-Shin
			Jung Yeong-hun
	Section 2. Internationalization of Scientific Food Standards and Specifications		
	1. Improving Food Safety Standards and Specifications	Food Standard Division Lee Kang-Bong	Choi Youn-Ju
			Park Mi-Sun
		Residues and Contaminants Standard Division Lee Dong-Ho	Jeong Ji-Yoon
			Cho Min-Ja
	2. Improving and Reinforcing Standards and Specifications on Food Additives, Equipment, Containers, and Packaging	Food Additives Standard Division Oh Keum-Soon	Cho Tae-Yong
			Ahn Jong-Hoon

No.	Contents	Division and Director	Contributors
II. Food	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	Dietary and Nutritional Safety Policy Division Lee Soo-Doo	Choi Gyu-Ho
			Choi Woo-Jeong
	B. Strengthening the Safety of Children's Diet		Kim Sang-Rok
			Bahn Kyeong-Nyeo
	2. Prevention of Food Poisoning through Building up Favorable Hygienic Surroundings of the Restaurant and Meal Service	Foodborne Diseases Prevention and Surveillance Division Sin Young-Min	Yoon Tae-Hyung
			Jo Jung-Ok
	3. Strengthening Safety Supervision on Health Functional Foods and Resonable Regulation Improvement	Health Functional Food Policy Division Kang Dae-Jin	Choi Eun-Jin
	4. Strengthening of Safety Management of Nation's Nutrition		
	A. Leading Koreans to Moderately Consume Potentially Hazardous in Moderate	Dietary and Nutritional Safety Policy Division Lee Soo-Doo	Yoon Eun-Gyeong
			Bahn Kyeong-Nyeo
	B. Expansion of Nutrition Labeling and Provision of National Nutrition Service	Dietary and Nutritional Safety Policy Division Lee Soo-Doo	Yoon Eun-Gyeong
			Do Jung-Ah
		Food Safety Labelling and Certification Division Oh Jeong-wan	You You-soon
			Mun Ji-hye
III. Medical products	Section 1. Medicines		
	1. Introduction and Stabilization of GMP in Conformance with International Standards	Pharmaceutical Quality Division	Kim Eun-Kyung
			Choi Hee-Jung
	2. International Harmonization and Advancement of Pharmaceutical Regulation		
	A. Establishment of a Globally Competent Medicine Approval and Evaluation System	Drug Review Management Division Lee Yoon-sook	Ko Yong-seok
			Kim Ja-Young
	B. Vitalization of Cooperative Projects with Foreign Regulatory Authorities	Pharmaceutical Policy Division Kim Sang-Bong	Kim Pan-Soon
			Lee Cheol-Seung
	C. Advancement of Pre-and Post-Management System of Clinical Trials	Clinical Trials Management Division Kim Jeong-Mi	Lee So-Hyang
			Kim Byoung-Sam
			Seo Jin-Ju
	3. Strengthening the Safety Management of Approved Pharmaceuticals		

No.	Contents	Division and Director	Contributors
III. Medical products	A. From manufacturing · import to distribution · consumption, Strengthening the Safety Management of Life-Cycle Pharmaceuticals	Pharmaceutical Management Division Kim Myeng-Ho	Jung Young-Sook
			Jang Tae-Ho
	B. Collection, Evaluation, Production, and Supply of Safety Information on Released Drug Products	Pharmaceutical Safety Evaluation Division Moon Eun-Hee	Cho A-Rah
			Bae Byeong-Hun
	C. Adverse Drug Reaction Relief System [Damage Relief System for Adverse Drug Reactions]		Lee Yu-Bin
			Moon Seong-Eun
	4. Strengthening the Competitiveness of the Pharmaceutical Industry by Stable Operation of the Patent-Regulator Approval Linkage System	Pharmaceutical Approval and Patent Management Division Kim Hyo-Jung	Jung Hyun-Ho
			Lee Kyung
			Kim Hyun-Ji
	5. Establishment of a Management System for Preventing Abuse and Misuse of Narcotic Drugs	Narcotics Policy Division Woo Young-Taek	Lim Rock-Joug
			Lee Hye-Sun
	6. Establishment of a Pre-emptive Narcotic Drugs Prevention System for Reassuring the People Management	Narcotics Management Division Ahn Young-Jin	Kwon Dae-Kun
			Oh Seung-Min
	Section 2. Biopharmaceuticals and Cosmetics		
	1. Improvement of Safety Management and Quality Management of Biopharmaceuticals and Human Tissues	Biopharmaceutical Quality Management Division Choi Seung-Jin	Kim Ji-ae
			Son Yeoung-gi
	2. Providing Medicinal Herbs and Safety Management of Natural Medicine	Herbal Medicine Policy Division Kim Young-woo	Kang In-ho
			Kim Ji-yu
	3. Strengthening of Industrial Competitiveness through Safety Management of Cosmetics	Cosmetic Policy Division Choi Mi-Ra	Kim Min-jeong
			Kim Se-gyeong
	4. Quasi-Drug Safety Management Trusted by the Public	Quasi-drug Policy Division Kim Chun-Rae	Lee Seung-cheol
			Kim Young-jun
	5. Support for biopharmaceuticals penetrating the global market and global cooperation		
	A. Support for Korean Biopharmaceuticals Penetrating the Global Market	Biopharmaceutical Policy Division Lee Nam-hui	Park Ji-hye
			Park Dong-hyeon
	B. Securing of Global Competitiveness of Biopharmaceuticals through International Cooperation		Lee Yu-gyeong
			Lee Yeon-hui
	6. Advancement of Approval & Evaluation System for Biopharmaceuticals		
	A. Advancement of Approval & Evaluation System for Biopharmaceuticals and Initiation of International Standards	BioPharmaceuticals Review Management Division Choi Young-Ju	Oh Il-Ung
			Oh Sang Yeon
	B. Quality Improvement of Herbal Medicine Approval & Evaluation and Commercialization Support	Herbal Medicinal Products Division Park Ju-Young	Moon Hyeon-Ju
			Hwang In Sun

No.	Contents	Division and Director	Contributors
III. Medical products	C. Efficient Improvement of Evaluation System for Quasi-Drugs and Cosmetics	Cosmetic Evaluation Division Yoon Mi-Ok	Lee Jeong-Pyo Chung Sung-Hee
	Section 3. Medical Devices		
	1. Construction of the Foundation for Innovative Growth of Medical Devices and Establishment of Their Lifecycle Safety Management System	Medical Device Policy Division Jung Jin-Ee	Seo Yun-geuk Yeo Sung-gu Yun Jeong
	2. Strengthening Consumer-Centered Medical Device Safety Management System	Medical Device Management Division Choi Ji-Woon	Seong Dong-Cheon Jung Sang-O
	3. Establishment of a Safety Evaluation System for Medical Devices	Medical Device Safety Evaluation Division Yu Hee-Sang	Park Yeon-Sim Lee Hye-Hyun
	4. Advancement of Medical Device Approval Review Process	High-tech Medical Devices Division	Kang Youn-Gkyu Son Seung-Ho
IV. Risk Prevention	Section 1. Establishment of Foundations for Preemptive Risk Prevention and Crisis Response System Focused on Customers		
	1. Establish a Road Map for R&D on Safety Technologies for Food and Pharmaceuticals	Customer Risk Prevention Policy Division Kim Sung–Gon	Sung Hyun-I
	2. Establishment of Crisis Response Base for the Prevention of Safety Accidents		Park Jin-Gook Kim Jae-Hyun
	3. Advanced Prevention by Preliminary Investigation of Hazards/ Risk Factors of Food and Pharmaceuticals		Jung Hyun-Jung
	4. Establishment of a Safety Management System for Sanitary Goods		Park Sung-Kwan Kim Jung-Han Jeon Hye-Jin
	5. Strengthening the Cooperative System on Food and Drug Safety Issues between MFDS and Korea Consumer Agency		Park Jin-Gook Kim Jae-Hyun
	Section 2. Building Consumer Trust through Reinforced Communication on Food and Drugs with the Public		
	1. Enhancing Two-way Communication by Identifying Consumer Needs	Communication and Cooperation Division Shin In-Soo	Baek Nam-i Lee Je-myung So Dam-yi Chang Seok-kee
	2. Disseminating a Food · Drugs Safety Culture Based on Communication Tailored to Regions and Classes		Ko Min-ji Jung Hwi-kwan Im Seon-Mee

No.	Contents	Division and Director	Contributors
IV. Risk Prevention	Section 3. Expansion of Sharing · Publicizing · Utilizing Food and Drug Safety Information		
	1. Collecting · Analyzing · Utilizing Food and Medical Product Safety Information	Risk Information Division Lee Ym-Shik	Park Sung-Kug Woo Dae-Gon
	2. Linkage · Integration of Pan-Governmental Food Safety Information and Advancement of Food Administration	Integrated Food Information Service Division Yang Chang-Suk	You Mi-Suk Hwang Jong-Seon
	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	Laboratory Audit and Policy Division Song Seong-Ok	Lee Hyeon-hee Choi Hyun-sung
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.	Research Planning & Management Division Park In-Suk	Kim Ho-Jeong Choi Si-Weon
	2. Impartial Research Management and Provision of Services for Researchers	Research Management TF Kim Hee-Sung	Seo Ji-Woo Cho Young-Min
	3. Outcome Management for Research and Development Projects	Research Planning & Management Division Park In-Suk	Lee Seon-hwa Kim Mi-ra
	Section 2. Expanding Risk Assessment for Scientific Food Safety Management		
	1. Improvement of Integrated Risk Assessment System with Expanded National and International Cooperation	Food Safety Risk Assessment Division Koo Yong-eui	Kim Soon-han Kim Yong-hoon
	2. Advancement of the Risk Assessment System for Residual Substances in Agricultural, Livestock and Marine Products	Pesticide and Verterinary Drug Residues Division Oh Jae-ho	Cho Byung-hun Lee Jeong-mi
	3. Strengthening the Scientific Basis for Reducing Hazardous Contaminants in Food	Food Contaminants Division Kang Gil-jin	Choi Jang-deok Shin Min-soo
	4. Microbiological Risk Assessment and Development of Microbial Testing Methods in Foods	Food Microbiology Division Kwak Hyo-sun	Kim Mi-gyeong Cheung Chi-yeun
	5. Strengthening Safety Management of Food Additives, Utensils, Containers and Packaging	Food Additives and Packages Division Kang Yun-sook	Kim Seung-hwan Lim Ho-soo
	6. Establishing a Basis for Managing the Safety of Food Nutrition, Dietary Life and Functional Health Foods	Nutrition and Functional Food Research Team Lee Hye-young	Heo Soo-jung Bang Soo-jin
	7. Strengthening Scientific Surveillance of Food Alteration and Food Fraud	New Hazardous Substances Team Lee Dong-ho	Seo Jeong-hyeuk

No.	Contents	Division and Director	Contributors
V. Research and Development for Food and Drug Safety	Section 3. Research for Safety Management and Supporting Commercialization of Medical Products		
	1. Advanced Research to improve Quality Management of Medical Products	Drug Research Division Lee Hyo-min	Kim Joo-hwan Shim Hyun-jun
	2. Research on Safety Management of Pharmaceuticals		Kim Yeon-hee Shim Hyun-jun
	3. Research on Prevention and Safety Control of Infectious Diseases	Biologics Research Division Lee Kwang-moon	Chun Hyung-ok Kim Il-hwan
	4. Research on Biopharmaceutical Safety Management	Advanced Therapy Products Research Division Ahn Chi-young	Eom Joon-ho Kim Min-jung
	5. Research on Safety Management of Herbal Medicine	Herbal Medicine Research Division Kang Ju-hye	Kim Jong-hwan Hyeon Seong-ye
	6. Research on Safety Management of Cosmetics and Quasi-Drugs	Cosmetics Research Team Son Kyeong-hun	Min Chung-sik Kim Sang-seop
	7. Research on Medical Devices Safety Management	Medical Device Research Division Park Ki-sook	Lee Seung-ro
	Section 4. Development of Safety Evaluation Technologies for Food and Drugs		
	1. Korea National Toxicology Program and International Cooperation in Toxicity Testing Methods	Toxicological Research Division Lee Jong-kwon	Jung Ki-kyung Yang Jun-young
	2. Development of Alternatives to Animal Testing and Advancement of Non-Clinical Tests	Toxicological Screening and Testing Division Yoon Hae-seong	Kim Kwang-jin Yi Jung-sun
	3. Research Laying the Groundwork for the Safety Management of Narcotics and the Next Generation Safety Evaluation	Pharmacological Research Division Seo Soo-kyeong	Kim Young Hoon Cha Hye-Jin
	4. Securing Public Health and Safety through Advancement of Clinical Evaluation and Reduction of Adverse Events	Clinical Research Division Chung Je-hyuk	Oh Woo-yong Yi Jung-Yeon
	5. Strengthening Analytical System of Illegal Substance as International Leading Group	Advanced Analysis Team Kang Ho-il	Park Seong-soo Park Hyoung-joon
	6. Advancement of Development, Preservation and Utilization of Laboratory Animal Resources	Laboratory Animal Resources Division Kim Jun-Gyou	Lee Su-hae Cho Hyun-Young
	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	Vaccines Division Ban Sang-Ja	Lee Chul-hyun
	2. Strengthening Cooperation and Communication through the Operation of a Public-Private Consultative Group		Ahn Joon-Ik

No.	Contents	Division and Director	Contributors
	3. International Cooperation Activities	Blood Products Division Kim Jae-Ok	Baek Dae-Hyun
	4. Strengthening the Quality Management Function in National Testing and Operation of the Proficiency Program		Choi Chan-Woong
VI. Appendix	1. Ministers/Commissioners/Vice Ministers in MFDS	General Affairs Division Kim Hyeon-jung	Go Ji-hun
			Choi Ki-hwan
	2. Changes in the Number of Staff	Director for Organization and Management Innovation Ju Seon-Tae	Kim Jin-Hwi
	3. Roles and Responsibilities (HQ)		
	4. Number of Staff		Jeong Won Kyun
	5. Laws and Regulations under the Ministry of Food and Drug Safety	Director for Regulatory Reform and Legal Affairs Oh Young-jin	Hong Jeong-Mi
			Sim Yeon

2019

Ministry of Food and Drug Safety White Paper

Published by	Ministry of Food and Drug Safety, Minister Lee Eui-Kyung
Printed	June, 2019.
Editor-in-chief	Vice Minister Choi Sung-Rak
Editorial board member	Director for ICT Management
Address	Osong Health Technology Administration Complex, 187, Osongsaengmyeong 2-ro, Osong-eup, Heungdeok-gu, Cheongju-si, Chungcheongbuk-do, 28159, Republic of Korea
Tel	+82-43-719-1601~39
Fax	+82-43-719-1600
Design	Stanly Qbrick +82-2-599-6075
Registration Number	11-1471000-000211-10
ISSN	1975-4841