Government Innovation for a better [healthy]life
Better MFDS

2021
Ministry of Food and Drug Safety
White Paper

Ministry of Food and Drug Safety

Foreword

With the whole nation plagued by COVID-19, people have paid greater attention than ever to safety and health. In response, the Ministry of Food and Drug Safety (MFDS) is striving to make them enjoy a better life under the goal of "Safe Food and Drug, Healthy People."

In 2020, as part of an effort to fight against COVID-19, the MFDS stabilized supply and demand of face masks by publicly distributing them, operating the Five-Day Rotation Face Mask Distribution System, and fully supporting mask production. Our ministry has prevented the epidemic spread by quickly finding confirmed cases through the emergency use approval of diagnostic reagents and contributed to the response to the global public health crisis, as evidenced by the designation of the infectious disease diagnostic test method as an international standard. In addition, the MFDS is playing a crucial role in helping people return to daily lives by supporting the prompt approval of COVID-19 vaccines and treatments.

To enhance preliminary safety management at food production sites, the MFDS required HACCP to apply to imported kimchi manufactured in overseas factories as well as commonly consumed types of food such as lunch boxes and instant foods. To more thoroughly control hygiene safety for vulnerable groups such as children, our ministry required small children's meal service facilities to be registered at the Children's Food Service Management Centers so that there is no more blind spot in hygiene and nutrition management. The MFDS strengthened the safety management of drugs by only allowing the import of foreign medicines whose manufacturer can be confirmed by fully implementing the overseas drug manufacturer registration system. We also created a safe environment for using narcotic drugs by establishing a system to prevent misuse and abuse of narcotics based on big data and thus uncovering their illegal use.

Amid the ongoing national public health crisis, the MFDS arranged a legal basis to facilitate the development of crisis response medical products and build a supply base for emergency use. On the ground, our ministry is dramatically increasing treatment opportunities for patients by designating No. 1 innovative medical device based on artificial intelligence and supporting the marketing of products that utilize new technologies. Further, we are coming up with new regulations for high-tech medical products, including the guidelines for approving and evaluating digital therapy devices.

The 2021 Food and Drug Safety White Paper contains food and drug safety policies and activities of the Korean government. We promise to lead the safety of food and medical products with regulatory capabilities on par with international levels and take responsibility for the healthy lives of our people. We hope this white paper will help you understand food and drug safety policies.

August 2021

Minister of Food and Drug Safety

Kim Gangrip

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chapter 1

Outline

1. Vision · Objective · Core Strategies

Safe **Food and Drug,** Healthy **People**

Concentrating capabilities on overcoming COVID-19
and strengthening food and drug safety -
"The MFDS will return a healthy daily life to the public"

1 "Safety first" Introduction of Vaccines and Treatments

① Focus on preventing and diagnosing COVID-19 and supplying its therapies
② Manage the entire life cycle of new vaccines and treatments
③ Switch to a constant crisis response system for public health

2 Securing Food Safety for People to Feel Safe

① Manage safety to meet changed distribution settings such as online transactions
② Bolster nutritional safety of restaurant and meal service foods
③ Provide information to match the level of consumer understanding

3 Leading Safety of Medical Products with International-Level Regulations

① Enhance product safety based on actual patient information
② Create an environment to use quality-assured medical products
③ Reform the approval and evaluation system to be more internationally competitive

4 Preemptive Creation of a Safety Environment for the Future

① Reduce blind spots of food and drug safety using science
② Support innovative growth of food and drug industries through international regulatory harmonization

2. Organization · Affiliated Organization

Minister

- Spokesperson
- Vice Minister
  - Criminal Investigation Division
  - Director for Audit and Inspection
  - Director for Approval Management
  - Director for Novel Products Approval
  - **Director General for Planning and Coordination**
    - Director for Planning and Finance
    - Director for Organization and Management Innovation
    - Director for Regulatory Reform and Legal Affairs
    - Director for International Cooperation
    - Director for ICT Management
    - Director for Customer Support
    - Director for Emergency Planning and Safety
    - Big Data-based Policy Analysis Team
  - General Affairs Division
  - **Customer Risk Prevention Bureau**
    - Risk Prevention Policy Division
    - Risk Information Division
    - Integrated Food Data Planning Division
    - Laboratory Audit and Policy Division
    - Hygiene Products Policy Division
  - **Food Safety Policy Bureau**
    - Food Safety Policy Division
    - General Audit and Policy Division
    - Food Safety Certification Division
    - Health Functional Food Policy Division
    - Food Policy of Labeling and Advertising Division
    - Food Standard Division
    - Residues and Contaminants Standard Division
    - Food Additives Standard Division
    - Deputy Director General for Food Standard Planning
  - **Imported Food Safety Policy Bureau**
    - Import Food Policy Division
    - On-site Inspection Division
    - Imported Food Inspection Division
    - Imported Food Distribution Safety Division
  - **Food and Consumer Safety Bureau**
    - Dietary and Nutritional Safety Policy Division
    - Livestock Products Safety Policy Division
    - Agro-Fishery Products Safety Policy Division
    - Foodborne Diseases Prevention and Surveillance Division
  - **Pharmaceutical Safety Bureau**
    - Pharmaceutical Policy Division
    - Pharmaceutical Management Division
    - Pharmaceutical Quality Division
    - Clinical Trials Policy Division
    - Pharmaceutical Safety Evaluation Division
    - Narcotics Policy Division
    - Narcotics Management Division
    - Deputy Director General for Narcotics Safety Planning
  - **Biopharmaceuticals and Herbal Medicine Bureau**
    - Biopharmaceutical Policy Division
    - Biopharmaceutical Quality Management Division
    - Herbal Medicine Policy Division
    - Cosmetics Policy Division
    - Quasi-drug Policy Division
  - **Medical Device Safety Bureau**
    - Medical Device Policy Division
    - Innovative and Diagnostic Medical Device Policy Division
    - Medical Device Management Division
    - Medical Device Safety Evaluation Division

National Institute of Food and Drug Safety Evaluation

- General Affairs Division
- Planning & Coordination Division
- Pre-Submission Consultation Division
- Expedited review division
- Center for Advanced Analysis
- **Food Safety Evaluation Department**
  - Food Safety Risk Assessment Division
  - Pesticide and Verterinary Drug Residues Division
  - Food Contaminants Division
  - Food Microbiology Division
  - Food Additives and Packages Division
  - Nutrition and Functional Food Research Division
  - New Hazardous Substances Division
  - Novel Food Division
- **Drug Evaluation Department**
  - Pharmaceutical Standardization Division
  - Cardiovascular and Neurology Products Division
  - Oncology and Antimicorbial Products Division
  - Advanced Drug Quality Division
  - Bioequivalence Evaluation Division
- **Biopharmaceuticals and Herbal Medicine Evaluation Department**
  - Biologics Division
  - Recombinant Protein Products Division
  - Cell and Gene Therapy Products Division
  - Herbal Medicinal Products Division
  - Cosmetics Evaluation Division
  - Vaccines Division
  - Emerging Infectious Disease Vaccines Division
  - Blood Products Division
- **Medical Device Evaluation Department**
  - High-tech Medical Devices Division
  - In-vitro Diagnostic Device Division
  - Cardiovascular and imaging Devices Division
  - Orthopedic and Restorative Devices Division
  - Dental and Gastroenterology Devices Division
- **Pharmaceutical and Medical Device Research Department**
  - Drug Research Division
  - Biologics Research Division
  - Advanced Bioconvergence Therapy Research Division
  - Herbal Medicine Research Division
  - Cosmetics Research Division
  - Medical Device Research Division
- **Toxicological Evaluation and Research Department**
  - Toxicological Research Division
  - Toxicological Screening and Testing Division
  - Pharmacological Research Division
  - Clinical Research Division
  - Laboratory Animal Resources Division

Regional Office of Food and Drug Safety

- **Seoul Regional Office of Food and Drug Safety**
  - General Affairs Division
  - Food Safety Management Division
  - Agro-Livestock and Fishery Products Safety Division
  - Pharmaceutical Safety Management Division
  - Medical Device Safety Management Division
  - Import Management Division
  - Hazardous Substances Analysis Division
  - Food Standard Analysis Division
  - Imported Food Inspection Center
    - Gangneung
- **Busan Regional Office of Food and Drug Safety**
  - General Affairs Division
  - Food Safety Management Division
  - Agro-Livestock and Fishery Products Safety Division
  - Medical Products Safety Division
  - Import Management Division
  - Center for Food & Drug Analysis
    - Hazardous Substances Analysis Team
    - Food Standard Analysis Division
  - Imported Food Inspection Center
    - Jaseongdae
    - Shinseondae
    - Yangsan
    - New Port
    - Tongyeong
    - Gamcheon
- **Gyeongin Regional Office of Food and Drug Safety**
  - General Affairs Division
  - Food Safety Management Division
  - Agro-Livestock and Fishery Products Safety Division
  - Medical Products Safety Division
  - Medical Products Inspection Division
  - Import Management Division
  - Center for Food & Drug Analysis
    - Hazardous Substances Analysis Team
    - Food Standard Analysis Division
  - Imported Food Inspection Center
    - Uiwang
    - Gwangju
    - Incheon
    - Pyeongtaek
    - Incheon Port
    - Yongin
    - Gimpo
- **Daegu Regional Office of Food and Drug Safety**
  - General Affairs Division
  - Food Safety Management Division
  - Medical Products Safety Division
  - Hazardous Substances Analysis Division
- **Gwangju Regional Office of Food and Drug Safety**
  - General Affairs Division
  - Food Safety Management Division
  - Agro-Livestock and Fishery Products Safety Division
  - Medical Products Safety Division
  - Hazardous Substances Analysis Division
  - Imported Food Inspection Center
    - Gwangyang
    - Gunsan
- **Daejeon Regional Office of Food and Drug Safety**
  - General Affairs Division
  - Food Safety Management Division
  - Medical Products Safety Division
  - Medical Products Inspection Division
  - Hazardous Substances Analysis Division
  - Imported Food Inspection Center
    - Cheonan

3. History

2021.02
Establishment of the Innovative Diagnosis Device Policy Division (Headquarters) and the Vaccine Testing for New Infectious Diseases Division (NFDS)

2020.08
Establishment of the Chief Approval Office, Chief High-Tech Product Approval Office, and Big Data Policy Analysis Team/ Removal of the Communication and Cooperation Division, Pharmaceutical Approval and Patent Management Division (Headquarters) Establishment of the Preliminary Consultation Division and Fast Evaluation Division/ Removal of Medicine Review Management Division and Biopharmaceuticals Review Management Division (NFDS)

2020.02
Establishment of the Sanitary Products Policy Division (Headquarters) and Cheonan Imported Food Inspection Center (regional FDS)

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)

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

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

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

2014.08
Establishment of Quasi Drug Policy (Headquarters)

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

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

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

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

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

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

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

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

2003.08
Establishment of Yangsan Imported Food Inspection Center (Busan 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

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)

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

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

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

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

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

2011.01
Establishment of the Pharmaceutical Safety Information Team (Headquarters)

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

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

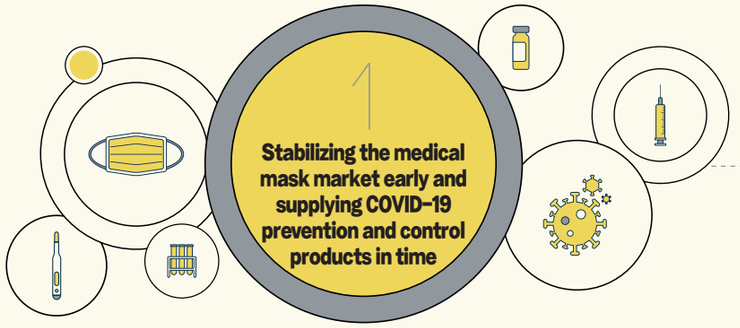
4. 2020 Achievements and 2021 Plan

I

Four-Year Achievements and Assessments Seen at a Glance

Four-Year Achievements and Assessments Seen at a Glance

1. Stabilizing the medical mask market early and supplying COVID-19 prevention and control products in time
2. Securing food safety systematically from production to consumption
3. Creating an environment for patients to safely use medical products
4. Supporting innovative growth of food and drug through reasonable regulations



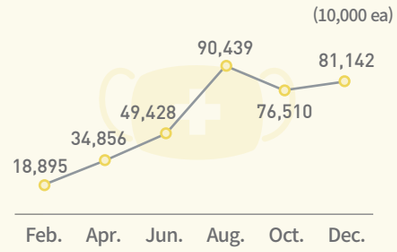
❶ Medical mask

Stabilized the supply through increased production and public supply— five-day rotation purchase system (Mar. 9- Jul. 12)

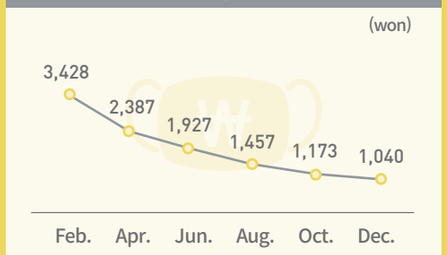
❷ Diagnosis reagent

Implemented emergency use approval (Feb. 4) and fast approval from an early stage of COVID-19

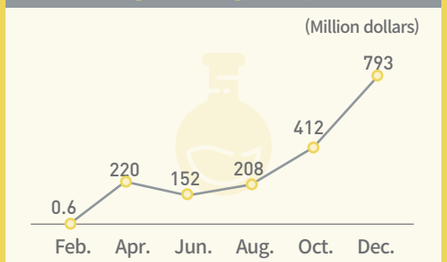
Mask production amount



Mask prices



Diagnosis reagent export



❶ Safe food environment

Improved Hazard Analysis and Critical Control Points (HACCP) management ('18.9)
Continued to inspect the sanitation of delivery food stores and meal service facilities, and stabilized the restaurant sanitation grade system

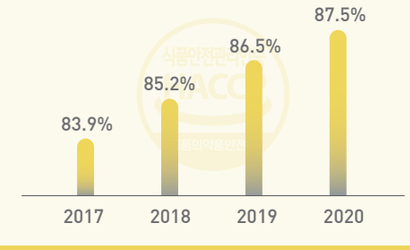
❷ Strengthening of agricultural and livestock product safety

Carried out on-site inspection before distribution and sale
Won the WTO dispute over the import restriction on Japanese food ('19.5)
Conducted the Positive List System (PLS) ('19.1-)

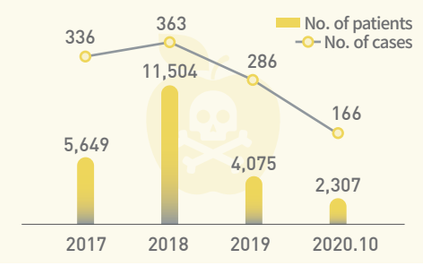
❸ Enhanced control of children's meal

More widely supported management such as hygiene and nutrition of children's meals and education on their eating habits, and built infrastructure to manage dietary life of kids

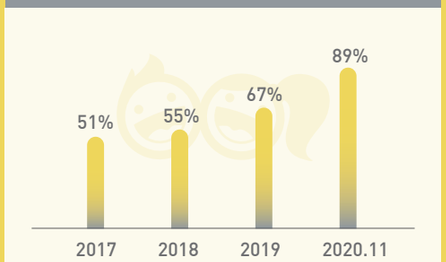
Production rate of HACCP-applied goods



Food poison trend



Ratio of children who receive meal assistance



❶ Management of side effects

Broadened the scope of compensation for side effects of medicine Made it mandatory for clinical trial participants to buy insurance policy (’18.12)
Arranged a long-term follow-up system including implantable products (’20.12)

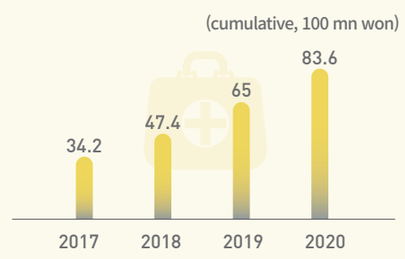
❷ Supply of essential medical products

Nationally supplied rare and emergency medical devices (’19.6)
Permitted the import of medicines which contain hemp ingredients for treatment and designated more national essential medical products

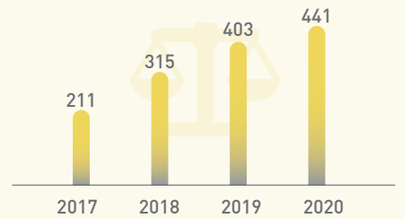
❸ Stronger safety management system

Reinforced safety from manufacture to prescription and use by registering overseas pharmaceutical plants (’19.12), requiring prevention of foreign substances to be verified in advance (’20.9), performing evaluation of sanitary pads and reducing their harmful ingredients(’18-), and reporting on medical narcotics usage (’18.5)

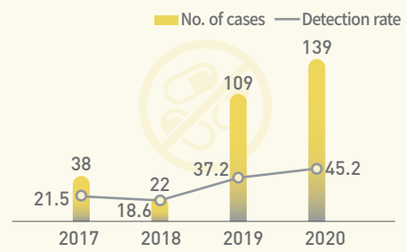
Compensation amount for adverse effects of medicine

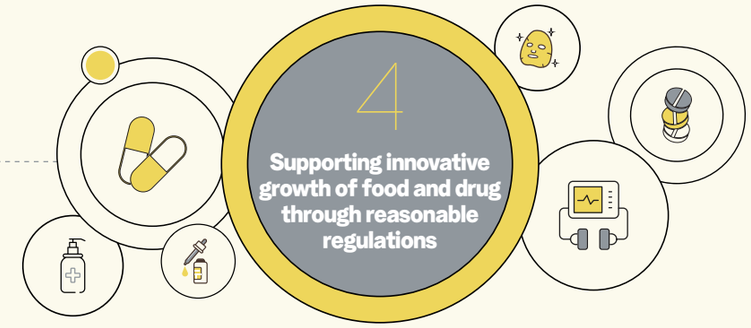


Designation of national essential medical products



Detection rate of illegal drug use





❶ Safety management of high-tech products

Prepared licensing & safety management systems customized for high-tech products such as authorizing the world’s first blood pressure mobile app (’20.4)

❷ Response to changing regulatory settings

Allowed outdoor business of restaurants and shared kitchens Sold personalized health functional foods and cosmetics, and established medi-foods for chronic disease patients (diabetes, kidney failure) (’20.11)

❸ Internationally harmonized regulations

Listed domestic medicines in the EU Whitelist (’19.5) and participated in International Medical Device Regulator Forum (IMDRF, as a chair) and International Cooperation on Cosmetics Regulation (ICCR) – international regulatory councils for cosmetics and medical devices

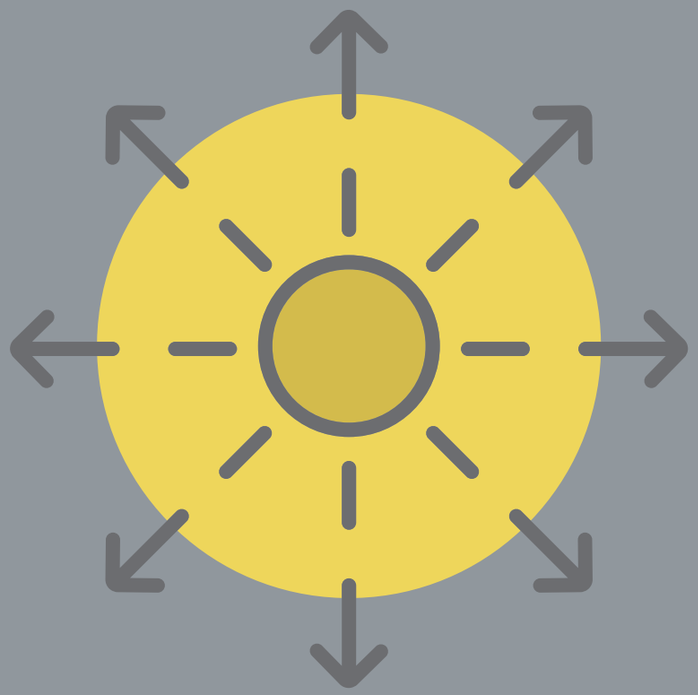
Development period of hitgh-tech medical products

Customized cosmetic store

Build up to export of drugs

II

2021 Work Conditions and Directions



1 Work Conditions

[COVID-19] Demand for the prevention of infection and the introduction of high-tech medical products

◦ (Pandemic) Now that the **spread** of infection, which is difficult to determine and track its **domestic and foreign** sources, and **social distancing** are expected to continue next year, more and more people **desire to return to previous daily life.**
* Monthly confirmed cases (persons): ('20.10) 2,714 → ('20.11) 7,769 → ('20.12) 26,568

◦ (High-tech products) Need to reduce anxiety arising from current **regulatory limitations** of safety assessment on new technologies (mRNA, antibody treatment, etc.) that have unprecedented **short development periods and no experience in use.**
* (mRNA) Pfizer/Moderna (virus vector) AstraZeneca (antibody treatment) Celltrion, etc.

[Society] Minimization of human contact and rapidly increasing interest in health and safety

◦ (Contactless/Online) The online/mobile-based **non-contact & digitalization*** trend **widely spreads and accelerates market change** across the society and economy due to anxiety about coronavirus infection.
* Global market size of contactless medical care ('20, KPMG): ('19) $30.5 billion → ('20) $35.5 billion → ('25) $41.2 billion
* Online mall food transactions (KOSTAT, trillion won): ('18) 13.5 → ('19) 16.8 → ('20.1Q and 2Q) 11

◦ (Healthcare) **More interest in "health and safety"** in daily life due to aging and increasing chronic diseases, frequent infectious diseases such as swine flu ('09)/MERS ('15)/COVID-19 ('19) and others
* Global market size of digital healthcare ('20, KISTEP): ('19) $190.9 billion → ('24) $392 billion

[Economy] Changes in consumption trends and distribution channels amid the crisis

◦ (One-person consumption) With a growing number of single households, the number of people who **drink and eat alone has increased*;** and with higher preference for convenient consumption, the **demand for Home Meal Replacement (HMR) **, meal kits, and delivery food has soared.**

* Percentage of single-person households in Korea ('18, KOSTAT): 29.3% (5,849,000 households)

** Production of HMR: ('15) 1.9 trillion won → ('19) 3.5 trillion won

◦ (Change in distribution channels) The **subscription economy has emerged and used goods transactions* are thriving** as the consumption culture centered on cost-effectiveness spreads, shifting **from ownership of goods to the use of services.**

* Monthly number of users in Karrot Market (second-hand trading platform): ('18.8) 1 million → ('20.5) 7 million

[Technology/Environment] Increase in new risk factors such as convergence products of 4th industrial technology, climate change, etc.

◦ (New technology) **More convergence products** that apply digital technologies* such as **AI, Internet of Things (IoT)**, and 3D printing and bio-technologies** such as **genome editing, cell culture, and alternative meat have been developed.**

* Size of foreign AI healthcare markets ('20, KISTEP): ('15) 80 billion won → ('20) 847.5 billion won

** Market size of genome editing technology ('19, Frost & Sullivan): ('18) $3.62 billion → ('23) $7.12 billion

◦ (Environmental pollution) **Due to climate change** such as rising temperatures and a subtropical Korean Peninsula, **waterborne and foodborne infectious diseases*** and **air pollution**** such as fine particles have increased concerns about human impact.

* Increased food poisoning due to salmonella (47.8%), vibrio parahaemolyticus (19.2%) at a temperature increase of 1℃.

* The International Agency for Research on Cancer (IARC) of the World Health Organization (WHO) classifies fine particles and air pollution as Group 1 carcinogens ('13).

2

Work Directions and Tasks

◈ Concentrate on the supply capacity of vaccines and treatments to terminate COVID-19 early and secure their safety

◈ Reinforce food and drug safety management in step with a change to the post-COVID era

⇒ The MFDS will return healthy lives to the public

1 "Safety first" Introduction of Vaccines and Treatments

Introduce COVID-19 vaccines and treatments for **early termination of COVID-19** and **prepare an entire life cycle safety management system to verification of their effectiveness and safety.**

2 Securing Food Safety for People to Feel Safe

Reform the food safety management system considering the **changed distribution environment** and **expand nutrition and safety management support for vulnerable groups** in the pandemic crisis.

3 Leading Safety of Medical Products with International-Level Regulations

Forge a patient-centered safe environment for using cutting-edge medical products that are emerging with development of advanced technologies such as IT, BT (biotechnology), and NT (nanotechnology).

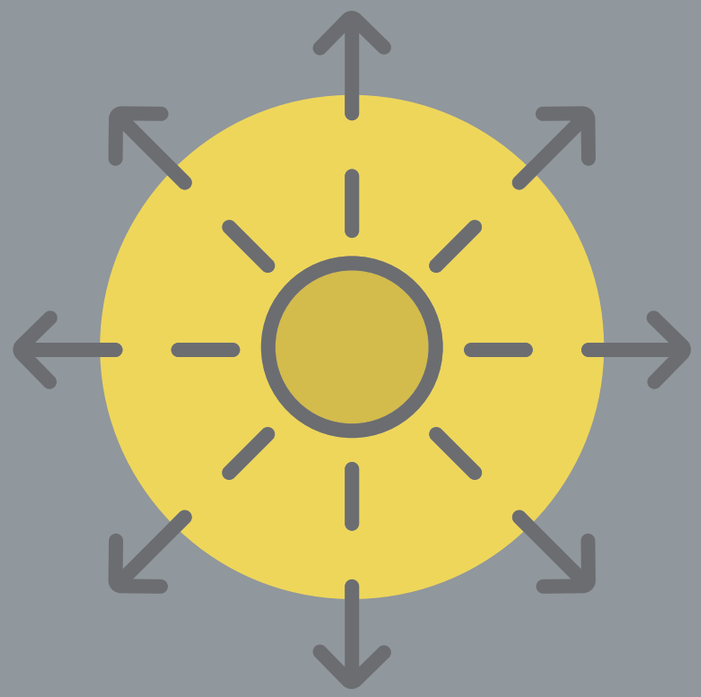
4 Preemptive Creation of a Safety Environment for the Future

Establish a safety management infrastructure that can comprehensively respond to future hazards through **integrated safety management centered on humans**, not products.

III

2021 Key Tasks

1. “Safety First” Introduction of Vaccines and Treatments
2. Securing Food Safety for People to Feel Safe
3. Leading the Safety of Medical Products with International-Level Regulations
4. Preemptive Creation of a safety environment for the future



1

“Safety First” Introduction of Vaccines and Treatments

- Prevent and diagnose COVID-19 and supply its treatments through preemptive safety and quality verification
- Make people feel safe by managing the safety of vaccines and treatments throughout the life cycle
- Establish a system to cope with public health crises such as new infectious diseases

A

Focusing on Preventing and Diagnosing COVID-19 and Supplying Its Treatments

◎ Thorough verification of vaccine and treatment safety through stronger prior review and evaluation expertise

◦ **Organize* and operate a dedicated review team** to ensure that **skilled professional personnel** examine the safety and effectiveness of **COVID-19 vaccines and treatments.**

* AstraZeneca vaccine (from '20.9), Celltrion antibody treatment (from '20.10), Pfizer vaccine (from '20.12)

◦ **Review the data for evaluation before applying for permission*** to **sufficiently verify it** and **shorten the evaluation period** (180→40 days), and conditionally approve vaccines and treatments, if necessary.

* Rolling review: Technique to review prepared licensing data (operated in the US, EU, etc.)

◦ **Set up a special laboratory** (BL3*), **reinforce quality verification infrastructure** such as cell analysis equipment, and **cut back the national shipping approval**** period (90→20 days) for mRNA vaccine** and the like by **devising test methods early.**

* BL (Biosafety Level) 3: Laboratory designed to safely control high-risk pathogens
** mRNA (nucleic acid) vaccine: Vaccine that first applied technologies (Pfizer, Moderna, etc.) to inject immunoreactive genetic material
*** Lot release approval: Approval for using biologics such as vaccines after verifying safety and effectiveness by manufacturing unit prior to sale

◎ Support for the emergency use of medical products before authorization

◦ If necessary, **perform general examination through the state-designated Central Clinical Evaluation Committee** for reducing **differences among reviews and smoothly proceeding with test procedures** (February), instead of clinical trial approval for each hospital.

◦ If there is a request from a doctor or medical field staff to **treat a severe patient**, give approval based on the results of the interim clinical trial (February).

* Approved the hyper immuno-globulin of Green Cross for treating patients with severe disease ('20.10).

◦ **When overseas unlicensed medical products are urgently needed**, assist with their **prompt import * and use** after requesting them to public health agencies, consulting with medical staff, etc.

* Special manufacturing (import): System that supports the use of unlicensed products by manufacturing (import) them in case of a national emergency

◎ Steady prevention and control in daily life until the end of COVID-19

◦ **Regularly inspect whether multi-use facilities** – such as restaurants, cafes, entertainment facilities, etc. – **comply with infectious disease prevention and control rules;** and grant **exemplary shops** such incentives as **reduction of administrative measures** (from May).

* Major franchise coffee shops (about 9,800) are exclusively managed by the MFDS.

◦ **Push for mandatory labeling of imported mask manufacturers** (overseas manufacturers, etc.) (September), and manage the performance and quality of masks on the market, and **promote joint management of prevention and control products by related ministries.**

* Study the development of personal protective equipment to strengthen activities at joint prevention and control sites of ministries ('18-'22).

B

Managing the Entire Life Cycle of New Vaccines and Drugs

◎ Enhanced management of phase-specific risk factors before use

◦ **Phase in mandatory regular reporting** of all **safety information** (DSUR*), **starting from new drugs**, during clinical trials of drugs such as **vaccines and treatments** (September).

* DSUR (Development Safety Update Report) : Analyze and report all safety information including side effects.

◦ **(In case of permission)** Submit a **Risk Management Plan** (RMP*) for drug monitoring of side effects, etc. and for hazard responses, in order to supplement the limitation of the approval process and strengthen the management responsibility of companies.

* RMP (Risk Management Plan) : Comprehensive drug safety management plan to reduce side effects after marketing

◦ **(Before release)** Predict **problems** after marketing (from February) by **reviewing data**

such as **test data** and annual quality examination of **companies along with lot release approval tests.**

◦ (Distribution) **Prepare cold chain maintenance measures**, such as **temperature management standards, mandatory verification of transport vehicles' temperature maintenance**, and administrative discipline in case of violation until the final inoculation in consideration of **different storage & distribution conditions** for each product.

* COVID-19 vaccine storage and transportation and management guidelines (January)

◎ Follow-up measures after using rapidly developed vaccines and treatments

◦ Considering possible **unforeseen adverse reactions** due to prompt commercialization of vaccines and treatments, and **compose and operate a joint ministerial response system* for adverse events.**

* Formulate joint evaluation procedures of the MFDS and the Korea Disease Control and Prevention Agency (KDCA) for adverse events of vaccines.

◦ **Establish** a pan-government **damage investigation and compensation review system*** (March); take **rapid action against adverse events** and arrange **response procedures** that their causality can be demonstrated** (June).

* Experts participate in drug damage compensation—the MFDS, the KDCA, National Forensic Service (NFS) and the Ministry of Justice.

** Revised "Joint Response Manual for Adverse Events and Adverse Reactions of Vaccines."

◦ Conduct **real-time Monitor** safety information like adverse events from **major foreign countries** and **transparently disclose their current status, actions, etc.**

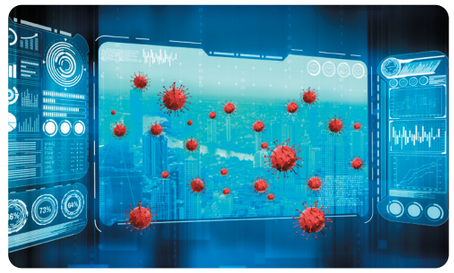
◦ Perform strict management of **distributed vaccines including collection and inspection, quality evaluation of products in question, and their swift recovery and disposal**, considering the timing of vaccination.

C

Switching to the Constant Crisis Response System for Public Health

◎ Creation of a crisis response system regarding new infectious diseases, etc.

◦ **Institutionalize an emergency response system** so that **fast evaluation of medical products, production and import orders, and contactless inspections** conducted during the COVID-19 situation can be **used** for future **infectious diseases.**



* Enact the Special Act on the Promotion of Development and the Emergency Supply of Medical Products for Responding to a Public Health Crisis (February).

◦ Advance risk information monitoring (K-RISS) such as **analysis of big data** and **AI** from around the world to detect crises such as a new infectious disease and to respond to it in advance (October).

* Korea Risk Information Surveillance System (K-RISS): Gather more hazard information by utilizing big data & AI analysis technology, etc. An automatic search and analysis system for hazard information.

◦ Commission **domestic production of essential medicines** (tuberculosis, child anticancer drugs, etc.) with risk of unstable supply, and push ahead with **mandatory reporting of essential medical devices** (artificial blood vessels for children, etc.) **before suspension of supply** (October).

◎ Strengthening regulatory affairs (RA) capabilities to promote development of biohealth products.

◦ **Establish a Vaccine Safety Technology Support Center** (July) including a **clinical sample analysis laboratory** to develop **platform technologies*** necessary for **manufacturing vaccines**, etc. and **commercialize vaccines.**

* Base technology to create a number of candidate materials.

◦ Establish a pan-ministry cooperative system to do R&D on **biohealth product development to go on with regulatory studies**, and **select and operate a food and drug RA training institution** (from March).

* Create and promote RA development strategies (from June) and produce about 600 master- and doctorate-level human resources ('21-'25)

◎ Improvement of working methods in preparation for future infectious diseases

◦ Introduce **non-contact inspection using augmented reality (AR) technology** (AR glass), and carry out **real-time random inspections** and **quick on-site inspections of nonconforming items and manufacturing plants.**

* Revise the Food Sanitation Act, the Special Act on Imported Food Safety Control, and the Pharmaceutical Affairs Act (December).

◦ **Expand mutual recognition of Good Manufacturing Practice (GMP)** for drugs and medical devices with regulators in technically advanced countries and **prepare contactless clinical trial methods** (November).

* Push for a mutual trust agreement on GMP with Switzerland (from Jan. 2020) and mutual GMP recognition with Singapore.

2

Securing Food Safety for People to Feel Safe

◈ Reinforce safety management of food consumption patterns according to contactless trends

◈ Create a safe consumption environment by strengthening nutritional safety management of dining-out and school meals

◈ Provide safety information from the public point of view to guarantee their right to know

A

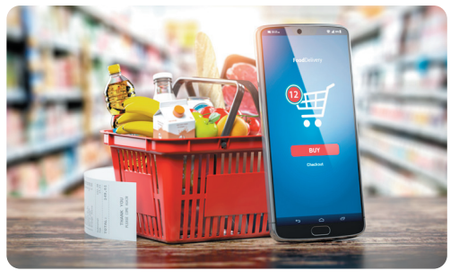
Managing Safety to Meet Changed Distribution Settings Such as Online Transactions

◎ Shift of a management paradigm from manufacturing-oriented to online sales and distribution-oriented one

◦ Including handling and storing food, enhance safety management responsibilities of **online food sales websites** (Market Kurly, etc.), which are similar to large discount stores, to a level of **other food sales businesses** (department stores, marts, etc.).

◦ Push for the **cooking time and sealing labeling of delivery food,** and expand the **disclosure of information on restaurant sanitation grades on delivery apps**

◦ **Make it compulsory to prohibit installation of temperature controllers in vehicles** when transporting refrigerated and frozen products, such as livestock and fishery products and fresh foods; and **intensively inspect preservation and distribution temperatures.**



* Prepare and distribute “Temperature Management Guidelines” for frozen and refrigerated product carriers (May)

◎ Intensive management of imported foods with risk concerns

◦ **Unify the ingredients prohibited from customs clearance** concerning the ingredients bought by agents and individuals (September), and inspect more **foods which are directly purchased from abroad**, among the **foods consumed frequently or by the vulnerable class** (milk powder, health food, etc.) *

* (2020) 1600 cases → **(21) 3,000 cases**

◦ **Reinforce nutrition inspection** on **popular imports in a drastic growth trend** and **food manufacturing materials** with a **history of nonconformities**, and on **children’s favorite foods**, etc.

◎ Prevention of risk factors before distribution and sale

◦ Require food manufacturers to adopt **HACCP** (8 types including instant food), **fully apply GMP** (health functional food) (December), and require **imported food and meat packaging industries** to apply **HACCP**. *

* Enforce the Imported Food Act (from July 2021) and the Livestock Products Sanitary Control Act (from January 2023).

◦ **Require selective packaging further** so that the **eggs** safely processed through **washing and sterilization** are **provided** for households and, later, for **restaurants and meal service centers** (October).

* Currently 65% of all eggs distributed (for households) → Increase it to 85% in future

B

Bolstering Nutritional Safety of Restaurant and Meal Service Foods

◎ Strengthening nutrition and safety management for vulnerable groups such as children and the elderly

◦ Install Children's Food Service **Management Centers** in each **Si** (cities), **Gun** (county), **and Gu** (district) (228) **nationwide**, and **support sanitation and nutrition management** of children's food service centers **regardless of size** (all year round).

* Install the centers at 6 Local governments: (Seoul) Gwangjin/Gangnam/Gwanak, (Incheon) Ongjin, (Gyeonggi) Gwangmyeong, and (Gyeongbuk) Ulleung

◦ In line with the intensive management period such as opening of spring and autumn semesters and holiday seasons, **examine all food service centers for kindergartens and daycare centers**, and strictly inspect **food material suppliers**, etc. (all year round)

◦ **Expand the obligation to label nutritional ingredients and allergies for children's favorite food franchises** to check calories, sugars, and allergens. *

* Franchise with more than 100 shops → Franchise with more than 50 shops

◦ Continue to provide **meal management services*** to **elderly welfare facilities** (500 places) such as nursing homes, and enlarge the scope of support such as **meal sanitation support for the disabled** (December).

* Provide customized diets and recipes for the elderly, manage personal nutrition cards, and operate dietary education.

◎ Improvement of the prevention and response system to forestall food poisoning

◦ Increase food registration* in an early warning system to **prevent the spread of food poisoning among welfare facilities, enterprises, etc.** and mandatorily **verify and inspect food safety, from examination of ingredients to cooking and meal distribution.**

* System registration: ('20) 16% → ('21) 20%, contact registration: ('20) 52% → ('21) 60%

◦ In order to enhance the cause identification rate of food poisoning, **reinforce the food poisoning bacteria database** and **advanced analysis equipment;** and increase preservative food; and widen the scope of investigation to the distributed food materials (January).

* Food poisoning bacteria DB (cases, cumulative) : ('20) 13,560 → ('21) 15,000

◎ Creation of a safe dining-out environment

◦ **Strengthen management of foreign substances in the cooking process** by **establishing the standards for facilities and fines** to prevent rodents in restaurants* and conducting **pilot projects for kitchen disclosure** (CCTV) (April).

* Impose an administrative fine of 1 million won where rodents or their excrement are found in the cooking area.

◦ **Improve the sanitary level of restaurants** by **designating sanitary grades** * **for more franchise restaurants** and **multi-use facilities** frequently used by consumers.

* Cumulative number of sanitation ratings (places): ('19) 5,194 → ('20) 12,774 → ('21) 22,000

C

Providing Information to Match the Level of Consumer Understanding

◎ Expansion of food information that consumers need

◦ Introduce a **use-by date labeling system** that informs **consumers** of **safe food consumption** instead of the sell-by date (June).

◦ **Expand mandatory nutrition labeling targets** by focusing on commonly consumed foods such as **kimchi, rice cake, ketchup, etc.** and **processed foods** that contain a lot of **sodium/sugar** (currently 115 → 176 items).

◦ **Make a plan to strengthen the Perfect Labeling System for Genetically Modified Organisms (GMOs)* by phase based on social consensus** of the working-level consultative council (all year round).

* If a GMO is used, indicate that the ingredient is a GMO even if there is no gene left in the final product.

◎ Active provision of safety information on overseas food

◦ Deliver **"Imported Food Search Lens Service"** that uses text recognition technology to film information displayed in Korean on a mobile phone to verify **non-conforming** information (from February).

◦ Provide **information on harmful products and ingredients** in a **mobile** optimized form through **analysis of big data** —customs clearance and purchase agency data, popular overseas item lists of direct purchase portals, etc. (September)

◎ Smart food information service using DNA (Data, Network, and AI)

◦ Seek to provide **"Health Functional Food Notification Service For My Body"** based on artificial intelligence (AI) that **analyzes individual diseases and life patterns and informs necessary products** (November).

* Develop algorithms that can match and recommend products by analyzing individual eating habits and genetic.

◦ Develop **"Customized Nutrition-Balanced Diet Program"** that analyzes individual diet photos and their nutrition information through AI in collaboration of ministries* (November).

* Advance information provision algorithms, such as linkage of nutrition information by diet and health information (Korea Health Promotion Institute).

◦ **Perform pilot operation of the Food Safety Korea's chatbot service*** that enables information to be found **easily and quickly** based on accumulated **civil service big data** (August).

* Chatbot service: An interactive messenger where AI communicates and answers in everyday languages.

◦ **Link and provide a nutrition information DB** to school meals (Ministry of Education, MOE) and children's meals to **support a healthy and balanced diet** (October).

* Connect nutritional information to the MOE meal service system (NEIS) and a diet preparation program of the Children's Meal Service Management Center

3

Leading the Safety of Medical Products with International-Level Regulations

- Reinforce medical product management based on the information actually used by patients and medical staff
- Strengthen quality control over the production stage of medical products and block illegal distribution
- Sharpen an international competitive edge by implementing the medical product licensing system

A

Enhancing Product Safety Based on Actual Patient Information

◎ Extension of product tracking from medical institutions to patients

◦ **Start long-term follow-up of patients** who are administered with **advanced biopharmaceuticals** to strengthen safety management such as **gene therapy products** that act in the body for a long time after administration * (January).

* (Procedure) Designation of long-term follow-up targets (MFDS) → Planning (company) → Registration of sales and supply details (company) → Registration of administration details (injection hospital) → Report of critical adverse events (company) etc.

◦ **Introduce a damage compensation system** for **implantable medical devices** such as artificial breasts and joints (February) and **require regular submission of usage records** (from June).

◎ Upgrading the high-tech medical product management system by reflecting actual usage information

◦ **Reform the reexamination system to utilize patient information** (RWD*) at the medical site from just confirming safety, etc. with corporate data (June).

* RWD (Real World Data): Information from hospitals, the Health Insurance Review & Assessment Service (HIRA), the National Health Insurance Service (NHIS), etc.

◦ **Implement safety management of the entire life cycle**, such as permission and side effects, based on **information on the use of medical sites**, and including the cause investigation and results in the **adverse event codes of medical devices** (from January).

* ('21) Planning → ('22) Establishment of a management system for permission, post-management, and side effects → ('23) Establishment of an information provision and utilization system

◎ Strengthening the safety accident prevention system including prescription & administration errors, misuse, etc.

◦ **Formulate a development plan for the information on the appropriate use of medicines*** to provide more information such as contraindication (mix, age, pregnancy), etc. in real time at the time of prescription and preparation.

* DUR (Drug Utilization Review): Service for safe drug use
* Number of components subject to the DUR information service: ('19) 2,871 → ('20) 3,205 → ('21) 3,265 (estimated)

◦ **Continue to expand the standards to safely use** medical narcotics such as sleeping pills to **induce appropriate prescription and use** at medical sites including doctors.

* ('20) 6 types including Zolpidem and Propofol → ('21) Add 22 types including narcotic painkillers and anti-anxiety drugs.

B

Creating an Environment to Use Quality-Assured Medical Products

◎ Advanced quality control in the manufacturing phase of medical products

◦ Introduce item-specific GMP examination for Grade 4 medical devices with high risk.

* (Existing) Examine medical devices by 26 items groups → (Changed) Examine 263 individual items including implantable medical devices.

◦ Introduce a **QbD*** system that **predicts and improves quality risks throughout the manufacturing process**, instead of quality control that relies on testing of final products.

* QbD (Quality by Design): Advanced design-based quality management system

◦ Establish a **testing and inspection system for unintentional impurities** arising from the development of test technology and preemptively examine **potentially harmful pharmaceutical materials** (all year round).

* Launch the "Joint Drug Impurity Evaluation Team of the Industry, Academia and Government" (March).

◎ Prevention of consumer damage caused by wrongful advertising and illegal distribution on the internet

◦ Carry out **planned inspection to eradicate wrongful advertisements** such as home shopping advertisements in connection with broadcast, YouTube and social media (SNS), and **toughen discipline on intentional habitual violators.**

◦ To regularly monitor the products that claim online their effect of treating diseases like cancer and the health care products in fashion, **launch "Cyber Citizen Monitoring Team"** and **sternly verify** those products (all year round).

* Select 300 college students nationwide (May) → Educate them (June) → Present best practices (November)
** Expand operation of the private advertising verification team comprising experts (doctors, etc.) (40 persons from 4 divisions → 100 persons from 5 divisions)

◦ Expand the public-private **consultation system** such as **setting the prohibited search words** to **block illegal drug distribution on second-hand item trading** platforms, etc. (March)

* ('20) Online shopping malls such as Naver → ('21) Extended to second-hand item trading platforms

◎ Intensive safety management for products with high consumer concerns

◦ **Check illegal distribution** of drugs with social concerns such as **etomidate and steroids**, and provide mandatory education (up to 200 hours) to prevent repeat crimes against drug addicts (January).

◦ Collect and **strengthen inspection** of commonly consumed and nonconforming **herbal medicines** and **cosmetics that imitate food types** such as jelly and donuts.

C

Reforming the Approval and Evaluation System to Be More Internationally Competitive

◎ Enhancement of the evaluation system to support the development of high-tech products

◦ **Simplify evaluation procedures** for **innovative medical devices**, e.g. priority review and exemption of duplicate documents, and **prepare the clinical and performance standards for digital** (software) **treatment devices** (from November).

* Software for improving alcohol and nicotine addiction disorders, software for improving insomnia improvement software, and more.

◦ **Establish a safety evaluation system for new concepts and convergence products** that combine various characteristics of synthetic and biopharmaceutical – **smart pills* and chemical similars**** – and medical devices (December).

* Microchip-embedded products that monitor administration of therapeutic drugs or diseases when reaching a specific area

** Products that chemically synthesize active pharmaceutical ingredients (APIs) of licensed biopharmaceuticals

◦ Draw up the guidelines for the criteria for assessing the efficacy of **dementia treatments** in connection with rapid aging and the guidelines to prepare the matters for approval for developing **combination drugs for hypertension and hyperlipidemia** (September).

◎ Establishment of a foundation for enhancing expertise of examination and testing personnel

◦ **Improve expertise of examiners** in each field – latest examination technology, clinical trials, side effects, statistics, GMP, etc. – and **promote domestic and foreign* examination cooperation in high-tech fields.**

* Participate in the WHO's Pre-Qualification (PQ) (evaluation of quality & control levels for int'l procurement)

◦ **Heighten testing and inspection capabilities** by **operating a national standards laboratory** and participating in international proficiency programs (WHO, Europe, etc.) to respond to new hazards and resulting accidents.

◎ Strengthening national competitiveness through approval regulations of a global level

◦ Introduce **data integrity assessment and ethical management** principles in pharmaceutical **GMP** and thus prevent moral hazard of businesses and **secure reliable approval data.**

* Implement a pilot project for data integrity assessment guidelines (from October), prepare legal grounds for revoking permission when submitting false data (October).

◦ When applying for approval, require **submission** of the **manufacturing method** of prescription drugs **in Common Technical Documents** (CTDs), and even if the drug has been registered in a **foreign drug formulary, require safety and efficacy data.** *

* Delete exemption provisions from data submission and receive advice from the Central Pharmaceutical Affairs Review Committee.

◦ **Strengthen the assessment of generic equivalence** by continuously **expanding the obligation to check a product's equivalence** with its original to all prescription drugs ** and **restricting the change of the manufacturer of consigned products** (November).

* Bioequivalence: Means that two products with the same main ingredient have equal medicinal effects.
** ('21) Oral dosage forms → ('22) Sterile products → ('23) Other dosage forms

4

Preemptive Creation of a safety environment for the future

◈ Eliminate risk factors in daily life and blind spots in the safety of complex and boundary products

◈ Create an ecosystem for innovative growth of food and drug

A

Reducing Blind Spots of Food and Drug Safety Based on Science

◎ Integrated evaluation and management of common hazardous substances of food and medicine, etc.

◦ **Establish an integrated management system** for human application products to comprehensively evaluate the **effects of common hazardous substances for each product that cannot be avoided** when using food, medicine, cosmetics, etc.

* Enact the Act on the Risk Assessment of Human Application Products (April).

◦ Disclose the results of risk assessment based on toxicity tests and toxicity information analysis by substance, and **discover more substances requiring integrated risk assessment** (December 2021).

* 33 types such as heavy metals and dioxins (April 2021) and 13 types such as PFCs and formaldehyde (December 2021)

◦ **Conduct a fact-finding survey** on the **status of use, adverse events**, etc. of **cosmetics used by infants and children** (from March)

* ('21-'22) Survey → ('23) Work out a plan to reduce harmful elements → ('24) Reduce harmful elements

◎ Elimination of blind spots in the safety of combination and boundary products

◦ (Food + Drug) **Reorganize the management system** for **medical foods** whose control are currently mixed with food (special medical use) and drugs (enteral nutrition) to meet the demand that stems from aging and chronic diseases.

◦ (Medicine + Medical device) **Regularly improve approval & evaluation regulations** by reflecting the characteristics of **convergence medical products** such as microneedles that administer drugs into the body with fine needles.

◦ (Industrial or Sanitary products, Medical equipment) **Promote safety management of home and oral care products** which use technologies such as electricity and lasers, among health and beauty care products used at home.

* Revise statutes and MOUs with relevant ministries such as the Ministry of Trade, Industry and Energy (MOTIE), the Ministry of Health and Welfare (MOHW), etc.

◦ **(Medical device or Medical service)** Set the approval standards for pan-ministry R&D and clinical trials on software medical devices, including digital therapy devices (game-based products, dementia-improving products, etc.) that have different forms, manufacturing processes, etc. from existing devices.

B

Supporting Innovative Growth in Food and Drug Industries through International Regulatory Harmonization

◎ Expansion of infrastructure for assessing food and drug safety

◦ Change the scope of information, such as side effects of licensed medicines and medical devices, from a **passive safety monitoring system through business operators** to an active system that **directly collects and analyzes information used by multiple agencies** (hospital medical records, HIRA-requested data, etc.).

◦ Exactly know about regulatory statutes and procedures, such as long-term medical product approvals, and **train private experts** (RA) **who can develop products, evaluate safety, and plan permissions.** *

* Train private RA (Regulatory Affairs) experts: Help operation and research of RA training programs.

◦ Expand the **internationally accredited recognition of testing institutions** (International Organization for Standardization, ISO) to strengthen international confidence in Korean test results, and **obtain international accreditation of proficiency evaluation of laboratories** operated by the MFDS.

◎ Laying the foundation for food and drug governance through opening and sharing

◦ **Enlarge opening and use of public food safety data** (Open-API) and **assist with users** to make delivery app companies, etc. easily tap into food safety information (discipline history, sanitation grade, etc.).

* Delivery app: (Currently) Baedal Minjok & Yogiyo → ('21) Expand application to Coupang Eats and more.

◦ **Establish a big data database** for food nutrition information such as processed food and agricultural and livestock products, and **prepare the standards for disclosing public nutrition information** (November).

* ('20) 30,000 foods, about 720,000 pieces of data → ('21) Secure 50,000 foods, and 1 million pieces of data

◦ Provide clinical information in **conjunction** with relevant ministries (MOHW, KDCA) so that **pharmaceutical companies and researchers can easily check it** (December).

◎ Higher export competitiveness of K-brand food and drugs

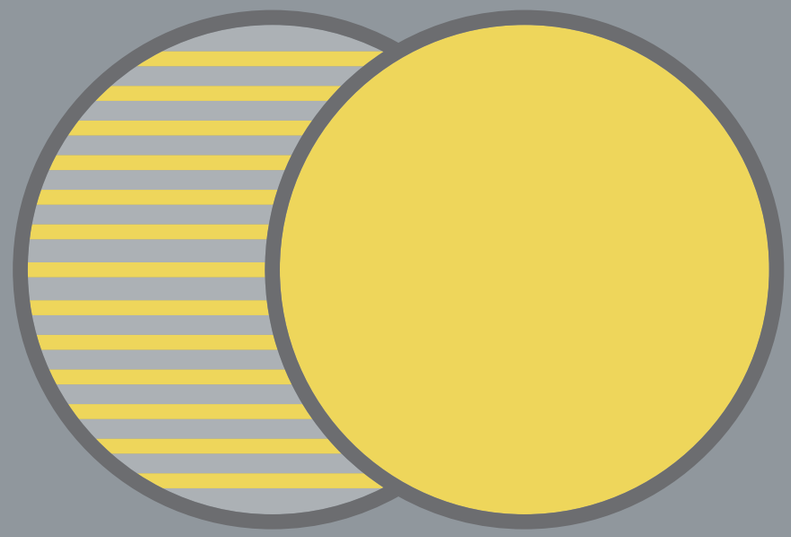
◦ **Develop** internationally acceptable **"food safety certification standards" and support domestic food to enter the global market by recognizing food safety equivalence** with **exporting countries.** *

* Draw up work guidelines for equivalence certification criteria and methods (November).

◦ **Increase national credibility by pushing forward with a mutual trust agreement on pharmaceutical GMP** with Singapore and others in accordance with international cooperation trends including signing RCEP. *

* RCEP: Regional Comprehensive Economic Partnership

IV
Changes in People's Lives in 2021



Changes in People's Lives in 2021

1 "Safety first" Introduction of Vaccines and Treatments

2020	1 treatment	Delivery by individual transport companies
		Evaluation under individual laws
2021	5 vaccines and 3 treatments	Establishment of a public-private cold chain
		Establishment of a public health crisis response system * Fast evaluation, production order system

2 Leading Safety of Medical Products with International-Level Regulations

2020	Manufacturer-centered control	The Children's Food Service Management Centers are not installed in some areas
		Restaurants with a designated sanitation grade '20 : 12,774
2021	Regular examination of online distribution	The Children's Food Service Management Centers are installed nationwide
		Restaurants with a designated sanitation grade '21 : 22,000

3 Securing Food Safety for People to Feel Safe

2020	On-site inspection on an adverse event	No data integrity evaluation for approval
		Application based on similar items
2021	Long-term follow-up of patients who are administered with advanced biopharmaceuticals	Establishment of a data integrity evaluation system
		Arrangement of a safety evaluation system for convergence products

4 Creation of a Safety Environment for the Future

2020	Risk evaluation by product	Open delivery apps and public data (Baedal Minjok & Yogiyo)
		In-house education
2021	Integrated evaluation of risk to the human body	Enlarge opening of public data (Expand application to Coupang Eats and more)
		Produce about 600 master- and doctorate-level professionals ('21-'25)

chapter 2

Food Safety

Section 1

Strengthening the Food Safety Management System

1. Strengthening of Safety of Food Production · Manufacturing

A. Facilitation of the Standards of Food Safety Management Accreditation(HACCP)

1) 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 Food Hazard Analysis and Critical Control Point」in 1996. Furthermore, in August 2003, six items including fish cakes were designated as mandatory items[1] that should comply with HACCP requirements (Kimchi cabbage was added in Dec. 2006). The HACCP system was enforced in multiple phases from 2006 to 2014, based on annual sales and the number of employees at business entities.

In May 2014, 8 items including kids' favorite foods were added to the list of

1 Fish products (fish cakes), frozen fishery foods (fish, mollusks, seasoned products), frozen foods (pizza, dumplings, noodles), frozen sweets, non-heated drinks, retort foods, Kimchi cabbage

mandatory items[2] that should conform to HACCP standards. HACCP is being applied to these items phase-by-phase from 2014 to 2020, based on the annual sales and number of employees as of 2013.

For livestock products, the MFDS applied mandatory HACCP to the milk processing industry from January 2015 (stage 4, January 2015-January 2018) and the egg processing industry in 2016 (stage 2, December 2016-December 2017). Besides, to strengthen the sanitary management of the egg distribution management system after the pesticide detection incident in 2017, the MFDS established a new packaging business for edible eggs and mandated the application of HACCP, and gradually obliges it to meat processing industries such as shredded meat (hamburger patties, etc.) by phase from 2018 to 2024.

2) Achievements

In order to secure efficiency of HACCP-related tasks, the MFDS established the Korea Institute for Food Safety Management Accreditation (KIFSMA) (Feb. 13, 2017) by integrating HACCP certification organizations for foods and livestock products that had been individually operated. This integration also addressed inconveniences of businesses by unifying the HACCP certification process.

Table 2-1 Management System Including HACCP Certification of Foods and Livestock Products and Follow-Up Management

(As of Dec. 31, 2020, Source: Food Safety Certification Division)

Classification	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.

2 Confectioneries/candies, bakery/rice cakes, chocolate, fish sausages, drinks, ready to eat foods, noodles/fried noodles, special purpose foods

In order to stabilize HACCP certification of foods and livestock product manufacturing businesses, encourage voluntary participation in application of HACCP and enable small businesses to acquire HACCP certification smoothly, the MFDS provided various supports through the Korea Institute for Food Safety Management Accreditation. As a result, the number of HACCP-certified companies continued to increase, from 4,828 in 2013 to 13,994 in 2020.

* Manufacturers: Food (food manufacturing and processing industry), Livestock product [Livestock product processing industry (milk industry, meat processing industry, egg processing industry, meat packaging industry)

Table 2-2 HACCP Certification Status

(As of Dec. 31, 2020, Unit: Business entity (cumulative), Source: Food Safety Labelling and Certification Division)

Classification	2013	2014	2015	2016	2017	2018	2019	2020
Total	4,828	5,760	6,870	8,020	9,258	10,427	11,549	13,994
Food	2,408	3,029	3,734	4,358	5,031	5,762	6,566	7,685
Livestock	2,420	2,731	3,136	3,662	4,227	4,665	4,983	6,309

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 to immediately cancel 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 false or unlawful means. After the regulation was introduced, the MFDS canceled HACCP certification of 116 businesses by the end of December 2020.

Also, after the revision of the Food Sanitation Act in February 2016, the MFDS introduced a regulation to set an expiration date for HACCP certification and make it mandatory for businesses to undergo re-examination every 3 years. This regulation has been effective since August 2016. In 2020, the MFDS completed extended examination of a total of 3,768 business entities (2,678 food items, 1,090 livestock products) that applied to extend certification.

In addition, the MFDS maximized publicity effects using terrestrial broadcast, multi-use facilities and social media (SNS) by analyzing publicity methods and preferences by media and age. The Ministry also continued to actively promote the HACCP system through experiential publicity like visiting HACCP-applied companies and providing age-specific education and field campaigns deploying consumer groups, etc.

Table 2-3 Consumer Awareness Survey of the HACCP System

(As of Dec. 31, 2020, Unit: %, Source: Food Safety Labelling and Certification Division)

Classification	2008	2009	2010	2011	2012	2014	2016	2018	2020
Percentage (%)	18.1	25.6	30	40.2	48.3	51.6	64.7	68.9	71.3

3) Implementation plan

A) Expansion of Mandatory HACCP Application 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. 2024) to meat processing businesses depending on their sizes.

Table 2-4 Status of Mandatory HACCP Application

(As of Dec. 31, 2020, Source: Food Safety Labelling and Certification Division)

Classification	Enforcement Date	Size of Target Businesses
Meat processing industry	2020.12.1.(2nd stage)	With annual sales more than 500 million won
	2022.12.1.(3rd stage)	With annual sales more than 1 million won
	2024.12.1.(4th stage)	Other businesses

B) Enhancing HACCP Follow-Up Management (Periodic Inspections · Assessment)

In the aftermath of the incident where HACCP-certified chocolate cakes caused food poisoning to a group of people in Sep. 2018, the MFDS is implementing the "Plan

to Improve HACCP Management" in an effort to appropriately run the HACCP system and reinforce follow-up management. The Ministry endeavors to strengthen 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.

C) Strengthening HACCP Support Projects

To ease the burden on small manufacturing enterprises subject to mandatory HACCP-application, the MFDS offers budgetary assistance 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, the MFDS strives to enhance the role of the KIFSMA and strengthen HACCP examiners' capabilities and skills in order to ensure the reliability of HACCP certification, etc.

D) 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, which would induce the food and livestock product manufacturing/processing industry to participate voluntarily. The MFDS will perform publicity activities via various media to consumers to give them a perception that HACCP products are safe and reliable. It plans to perform customized promotion using strategic mix media by segmenting targets by age group.

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

A. Nationwide Joint Crackdown

In cooperation with local governments, the MFDS regularly conducts joint crackdowns on food facilities that will have a large impact in the event of an adverse incident or are under poor sanitary conditions. Such enforcement aims to prevent food incidents and ensure food safety. In 2020, six joint crackdowns were carried out on 36,384 businesses including facilities supplying holiday · summer foods, school cafeterias preparing for a new semester, and youth training centers. The MFDS identified 421 businesses (violation rate: 1.2 %) with poor sanitation levels and took administrative and improvement measures to rectify them.

Table 2-5 **Annual Performance of National Joint Crackdowns**

(As of Dec. 31, 2020, Unit: Business entity, Source: Food Safety Management Division)

Classification	2016	2017	2018	2019	2020
No. of inspected businesses	31,492	44,915	52,037	51,007	36,384
No. of uncovered businesses	780	1,227	1,001	752	421
Violation rate (%)	2.5	2.7	1.9	1.5	1.2

B. Reinforcement of Safety Management for Alcoholic Beverages

1) Background

The MFDS has signed a Memorandum of Understanding (MOU) with National Tax Service and enacted and enforced a law to classify and manage those with a liquor license to manufacture alcoholic beverages as food manufacturers and food processors (July 2013).

As the MFDS took charge of safety management on alcoholic beverage manufacturers, the overall sanitary level improved. However, the majority of alcohol manufacturers are small-sized business with low production and their awareness and compliance rate of sanitation and safety management is comparatively low.

The survey results show that most of Korean traditional alcoholic liquor manufacturers learn their fermentation technology through their family or by benchmarking other manufacturers, not through systematic education programs. Due to the lack of technical education for safety management and quality improvement of liquor, systematic and professional support systems are required.

Table 2-6 Liquor-Relevant Business by Ministry

(As of Dec. 31, 2020, Source: General Audit and Policy Division)

Concerned Ministry	License (Business) Type	License (Registered) Institution and License Target	Concerned Laws and Regulations and Management
MFDS	Food manufacturing and processing business	MFDS (Regional FDS Office) ▪ When manufacturing liquor in accordance with the Liquor Tax Act	Food Sanitation Act ▪ Business registration and safety management of alcoholic beverage manufacturers
MOEF (Ministry of Economy and Finance) (National Tax Service)	Liquor manufacturing license	National Tax Service (tax office) ▪ General manufacturers, traditional liquor manufacturers, small-sized liquor manufacturers	Liquor Tax Act ▪ Management of liquor manufacturing licenses and sources of tax
MAFRA(Ministry of Agriculture, Food, and Rural Affairs)	Traditional liquor manufacturing license recommendation	National Tax Service (tax office) ▪ Traditional liquor manufacturers (Korean traditional liquor, local liquor)	Act on Promotion of Korean Traditional Liquor Industries ▪ Promotion of liquor industries such as Korean traditional liquor

2) Achievements

A) Continuous Improvement in the Sanitation Level of Alcohol Manufacturers through Differentiated Management by Grade

There are 1,259 liquor manufacturing businesses which register their business as food manufacturer or processor in the MFDS, and 80% of them are small-sized companies with 10 or fewer employees

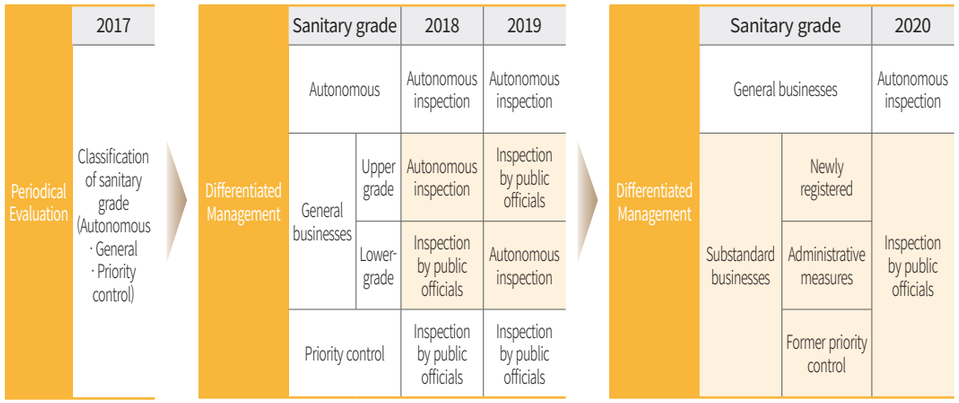
Table 2-7 Registration Status of Food Manufacturing and Food Processing (Liquor) Business

(As of Dec. 31, 2020, Unit: No. of businesses, Source: General Audit and Policy Division)

Liquor Type	Total	Seoul Regional Office	Busan Regional Office	Gyeongin Regional Office	Daegu Regional Office	Gwangju Regional Office	Daejeon Regional Office
Businesses	1,259	212	168	112	164	273	330

Since sanitation levels of alcohol manufacturers vary by company, the MFDS operates a “Sanitary Management Grading System” that differently manages access/inspection of each company to manage the companies efficiently within limited administrative resources. The MFDS categorized sanitation levels into autonomous, general, and priority control in 2017, and manufacturers have been managed differentially by their sanitation levels since 2018. For the last 3 years during which the Sanitary Management Grading System has been carried out, the levels improved but manufacturers with low sanitary level remained at priority control. So, the MFDS reorganized the management system in order to raise the sanitary level by managing those businesses more intensively. For this, public officials inspected businesses that did not meet the grade criteria, such as those that have been given administrative measures or that registered new business, etc., while letting other general businesses carry out autonomous inspection. Through this concentration strategy, the sanitary management level has improved.

Table 2-8 Status of the Sanitary Management Grading System for Alcoholic Beverages



- ✓ Improvement in sanitary management compliance rate (%):
  90.0% in 2017 → 91.1% in 2018 → 93.4% in 2019 → 94.3% in 2020
- ✓ Decreased rate of repeated violation against guidance or crackdowns:
  11.7% In 2017→ 8.3% in 2018→ 6.5% in 2019→ .5.3% in 2020

3) Implementation plan

A) Reinforcement of Safety Management in Alcohol Manufacturing and Distribution

In order to improve the efficiency of alcohol manufacturer safety management and the safety management level, the MFDS plans to continuously apply the reformed safety management grading system, thereby ensuring the autonomy of excellent businesses and intensively strengthening sanitary management of substandard companies. In addition, it will preemptively manage commonly consumed alcoholic beverages according to consumption trends by specific period or season.

B) Support for Alcoholic Beverage Safety Management and Provision of Information

The MFDS is going to distribute a risk prevention management plan by designating and operating alcoholic beverage safety management centers in four regions and provide consulting services on issues on the ground, in order to support small-sized alcoholic liquor manufacturers and establish a safe manufacturing environment. Also, for consumers, it will provide useful life-friendly alcoholic beverages safety information such as how to drink alcohol in a healthy way, how to make homemade alcohol, etc.

C. Reinforcing Collection·Inspection of Foods Being Distributed

In order to secure food safety and promote public health, the MFDS, regional offices of Food and Drug Safety, and Si/Do (Si, Gun, Gu) areas collect and inspect foods being distributed in the domestic market.

In addition, it continuously carries out customized seasonal (periodic) collections and inspections on commonly consumed foods whose consumption increases in summer and during the holidays such as New Year's Day, Chuseok (Korean Thanksgiving Day), etc., by reflecting the consumption trends and overseas information.

In 2019, the MFDS collected and inspected 169,711 items of agricultural, livestock, fishery products, and processed foods to seize or dispose of 1,005 items that are non-compliant with food safety standards and specifications. Therefore, the non-compliance rate of 0.6% remained unchanged from the last year.

Table 2-9 Results of Collection · Inspection by Year

(As of Dec. 31, 2019, Unit: Cases, Source: General Audit and Policy Division, Health Functional Food Policy Division, Imported Food Distribution Safety Division, Livestock Products Safety Division, Agro-Fishery Products Safety Division)

Year	No. of Cases Collected	No. of Non-Compliant Cases	Non-Compliance Rate (%)
2017	172,688	1,083	0.6
2018	172,606	957	0.6
2019	169,711	1,005	0.6

D. Operation of the Food Traceability Management System

MFDS controls information on food traceability from the manufacturing processing stages to the sale stage, and when food safety problems occur, this tracking allows to rapidly take measures such as cause analysis, recalls, etc.

The registration of food traceability data was mandatorily applied by phase to: 1) businesses manufacturing and processing baby foods and health functional foods, import and sales companies and other retailers that directly sold food to the customers from 2014 to 2017; and 2) businesses processing infant formula milk from 2016 to 2018. regarding the Food Traceability Management System, the Ministry made it mandatory from June 2020 for “health functional food distributors” to comply with the food traceability management system so that the Ministry can trace interim distribution stages. And to build a safe food environment, “items with a special medical purpose,” “those for pregnant and lactating women,” and “food with a dietary formula for weight control” were also included as subjects of the traceability system. With mandatory registration of other food sellers, as of 2020, a total of 8,769 food-related businesses including those who manufacture and import (stage 2) “items with a special medical purpose,” “those for pregnant and lactating women,” and “food with a dietary formula for weight control” were registered in the system.

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

To reduce consumer damage caused by hazardous food such as food safety incidents, etc., it is necessary to promptly cut off distribution and sale of nonconforming foods and recall them. To this end, the MFDS shares information regarding hazardous foods in real-time to relevant organizations, distributors, and consumers through the MFDS website and the food safety information portal site.

The MFDS discloses information on foods subject to recall on its website and the food safety information portal site to rapidly recall hazardous foods and to provide customers with information. In 2020, it recalled 165 hazardous foods, etc.

Table 2-10 **Recall Status of Nonconforming Processed Food by Year**

(As of Dec. 31, 2020; Unit: Case; Source: General Audit and Policy Division, Health Functional Food Policy Division)

Classification	2016	2017	2018	2019	2020
Total	283	202	193	223	165
Food	252	169	177	197	158
Health Functional Food	31	33	16	26	7

F. Upgrading the Food Labeling System to Provide More Consumer Information

1) Background

Due to changes occurring in the food consumption environment, food labels are becoming more important to consumers so they can make an informed choice whether to select or consume the food. In view of this trend, the MFDS has been working hard to enhance and upgrade related criteria and in turn, to provide accurate labels.

The MFDS is not only strengthening food 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

In accordance with the enforcement of the「Act on Labels and Advertisements of Food, Etc.,」the MFDS established its legal basis by enacting the Enforcement Decree of the Act on Labels and Advertisements of Food, Etc., the Enforcement Rule of the

Act on Labels and Advertisements of Food, etc., and their subordinate notifications.

Introducing the eggshell labeling system with a laying date printed on the eggshell, the MFDS upgraded the freshness of eggs and contributed to better distribution. Further, with clear specifications of fish species and a mandatory indication of caffein warnings for health functional foods with high caffeine content, etc., it has made efforts to ensure consumers' right to know. Moreover, the public can enjoy better civil application service thanks to the "Food FAQ" and "Food Information Indication Bot" program that offers samples of Korean labels.

On the other hand, the Ministry has operated a dedicated department to protect consumers from deceptive labeling and advertisements and to conduct product demonstrations. It also strived to enhance the system with the advisory committee on labeling and advertising foods, etc., which consists of various experts from consumer groups, academia, industry, etc.

Since 2015, the MFDS has carried out annual educational programs on allergies through food labeling for elementary school students, parents, and school nurses all over the country to prevent food allergies among children. In 2020, a total of 7,028 persons attended the program. Additionally, the Ministry's offline educational sessions and online information sessions on the labeling system for business owners help consumers share accurate information and helped business owners to comply with laws and regulations.

3) Implementation plan

The MFDS will do its utmost to prevent consumer damage from false labels and advertisements through its consumer-centered food labeling system and to raise living quality consumers by providing accurate information so that they can choose products suitable for them.

G. Establishment of a Private and Public Joint Monitoring System

1) Operation of Consumer Food Sanitation Supervisor

Working with members of consumer groups and people with expertise in related fields, the MFDS is operating a Consumer Food Sanitation Supervisory system in order to encourage active participation of consumers in food sanitation monitoring activities and to ensure fairness, reliability, and transparency in these activities.

In 2020, 6,687 persons were newly appointed as consumer food sanitation supervisors, and a total of 105,839 supervisors participated in monitoring activities on a yearly basis. Inspections were carried out on sanitation conditions of 1,107,648 food service businesses including restaurants and cafeterias. The inspections also identified businesses without a license, businesses violating labeling standards, as well as businesses guilty of false · exaggerative advertising activities.

Table 2-11 Activities of Consumer Food Sanitation Supervisors by Year

(As of Dec. 31, 2020; Unit: Person, Case; Source: General Audit and Policy Division)

Year	No. of Appointed Persons	No. of Active Persons per Year	No. of Inspected Businesses	No. of Violating Businesse	Details of Violation			
					No License	Labeling	Advertising	Other Charges
2016	9,307	122,935	606,120	11,244	741	287	33	10,183
2017	9,515	124,734	631,717	7,382	292	128	33	6,929
2018	9,510	100,976	590,783	7,299	415	132	21	6,731
2019	9,417	103,235	635,763	11,657	293	49	7	11,308
2020	8,687	105,839	1,107,648	2,552	206	16	2	2,328

2) Operation of 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. The rewards are in the range of 10,000 won to 10 million won in accordance with the current reward standard and depending on the details of violation of the Food Sanitation Act. In addition, the MFDS has established a system for the Anti-Corruption & Civil Rights Commission to strengthen the system to reward whistle-blowers on food in active cooperation with the commission. In 2020, the MFDS gave rewards of 30,360,000 won on 429 reports.

Table 2-12 Reward Payment Status by Year

(As of Dec. 31, 2020; Unit: 1,000 won; Source: General Audit and Policy Division)

Classification	2016	2017	2018	2019	2020
Number of Reward Payments	309	78	218	511	429
Amount of Reward Payment	18,330	4,340	16,160	21,400	30,360

H. Management of Foreign Substances in Food

In order to promptly 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 foreign substances detected in food to the MFDS and to the competent Si/Gun/Gu office when a business operator receives a consumer complaint.

In 2020, the number of reports on foreign matters found in food was 4,060, and the foreign substances reported were worms (22.1%), mold (18.1%), metals (9.1%), and plastics (9.0%).

Table 2-13 Status of Foreign Substance Reporting by Year

(As of Dec. 31, 2020; Unit: Case; Source: General Audit and Policy Division)

Classification	2016	2017	2018	2019	2020
Total (Number of Cases)	5,332	3,236	3,061	3,898	4,044
Reported by Businesses	2,347(44.0%)	1,048(32.4%)	980(32.0%)	1,220(31.3%)	958(23.7%)
Reported by Customers	2,985(66.0%)	2,188(67.6%)	2,081(68.0%)	2,678(68.7%)	3,086(76.3%)

3. Strengthening Safety Supervision on Health Functional Foods and Reasonable Regulatory Improvement

A. Enhancement of Safety Supervision for Health Functional Foods

1) Background

The Health Functional Food Act, which was enacted in August 2002 and enforced in January 2004, was the start of the health functional food system in Korea. The MFDS has put emphasis on thorough safety supervision on health functional foods from manufacturing to distribution, in order to ensure that safe and functionally guaranteed health functional foods are distributed and sold in the market, thereby enhancing public health and consumer protection.

2) Achievements

A) Completed Mandatory Application of GMP

With revision of the Health Functional Foods Act (February 2016), a gradual mandatory application of Good Manufacturing Practice (GMP) was determined. The year 2020 was the last year to complete it. In 2017, GMP was made mandatory for health functional food manufacturers with sales of 1 billion won, and 40 small

and medium-sized companies (SMEs), which were preparing to acquire GMP designation, were provided with on-site technical support consultations to help the system to be settled and to encourage more participation. As a result, the GMP designation rate among health functional food makers was increased from 58.0% in 2017 to 91.4% in 2020, securing a foundation for safety management to manufacture of health functional foods whose quality and safety are guaranteed.

B) Enhancement of Education and Training Sessions for Quality Control Managers of Manufacturers

Upon request for improvement in training hours and courses so that quality control managers can have and learn appropriate knowledge on the relevant regulation and health functional food manufacturing, the Enforcement Decree of the Health Function Foods Act was amended (June 2020) to increase the training courses for quality controllers from 6 hours to 16 hours. And with the operation of enhanced on-site practice training, the safety management system was also reinforced to make sure that safe foods are manufactured.

C) Tightened Supervision on Adverse Events and Information Disclosure

The MFDS discloses analysis results on reported and accepted adverse events caused due to health functional foods on its website every month. For foods that need to be cautioned by consumers, the Ministry holds a deliberation committee on health functional foods (by adverse events evaluation division, twice a year) to manage adverse events by sharing information.

In addition, the MFDS made it mandatory for not only health functional foods manufacturers and sellers but those who open pharmacies and who import and sell imported foods to report any adverse events they find to the National Food Safety Information Service, an institution designated by the MFDS. And the Ministry also enhanced the adverse event management by revising a relevant law (enforced on Jun. 4, 2020) that requires the reported health functional foods with adverse events to be inspected and analyzed for safety and causal relationship and the results to be publicized.

D) Improvement of the Review System for Functional Ingredients Certification

When it comes to ingredients or materials for unnotified health functional foods, the MFDS reviews the standards, specifications, and data on the relevant product's safety and function submitted by applicants before certifying them as functional materials. In 2020, the Ministry certified more functional materials through a quick and preemptive review process: it received data from internal in-depth reviews and briefings on products, made corrections, and (if needed,) held an advisory meeting with experts. Besides, the MFDS presented a vision for new functional foods with high potential for great industrial demand and prepared a functional evaluation guide that covers human research subjects and major biomarkers for new functionality (regarding respiratory and gum health), raising predictability for functional material certification.

Further, despite the COVID-19 pandemic, the Ministry enhanced prior review by preparing consultation sessions with businesses using contactless or video conferencing programs before they apply for functional materials certification. By doing so, it upgraded civil complaint services including improving accessibility for industries.

E) Thorough Post-Management for Health Functional Foods

The MFDS carries out thorough safety management for health functional foods through inspections and collection tests for manufacturers of commonly consumed health functional foods in preparation for holidays and May, the family month. It also collects and inspects products with frequent adverse events and those on the markets according to any revisions in standards and specifications. The success rate of tests performed on health functional foods on the market reached 99.7% in 2020. The rate indicates that the health functional foods manufactured on an established

institutional foundation reach the quality and safety level that meets the consumers' expectation, confirming that an environment where consumers can buy them without anxiety is in the making.

F) Providing Consumers with Correct Information and Carrying Out Education and Promotion Activities

In order to protect consumers from false and exaggerative advertisements and illegal sale, the MFDS provided consumer-tailored information such as how to make the right choice on health functional foods and how to take them, and how to prevent adverse events caused by their misuse and abuse. Thanks to these efforts, the level of consumer awareness on health functional foods increased to 80.2% in 2020 from 76.2% in 2019, and the reliability of their functionality went up from 49.6% in 2019 to 54.3% in 2020, consecutively.

G) Technical Support for Industries to Promote Functional Ingredients Certification

For the promotion of functional ingredients development for health functional foods, the MFDS prepared opportunities for communication with industries and consumer groups by providing customized consultation (contactless/video conference) for a speedy and phased commercialization depending on technology development levels and by holding a strategic forum. Besides, the Ministry revised and published the "Guide for Preparing Documents for the Certification of Functional Ingredients" and the "Guidance on Functionality Evaluation (10 types including liver and eye health)" to help understanding of applicants about certification rules and requirements for functional ingredients.

3) Implementation plan

A) Enhancement of GMP

Following the schedule of phased completion of mandatory GMP application, the MFDS will support small-sized health functional foods makers (33 companies with sales of less than 1 billion won in 2017), which postponed the mandatory application due to the prolonged COVID-19 pandemic, through one-on-one technical support with the headquarters and regional FDS Offices to complete mandatory GMP application by December 2021.

B) Reinforcement of Adverse Event Management and Information Disclosure

As the health functional food market increases and the number of reports on adverse events grows, the MFDS plans to reinforce safety management for abnormal cases by improving the scientific cause analysis system to define their cause and effect. Moreover, the Ministry will share more information including not only adverse events with clear causal relation but also those caused by intake of multiple health functional foods.

C) Improvement of the Review System for Functional Ingredients Certification

In the functional raw material review stage, the MFDS plans to strengthen the functional ingredients certification review system by preparing an internationally accepted human body application evaluation procedure and an evaluation system that reflects the characteristics of functional ingredients and by applying them to the review. To enlarge the options for consumers, it will also continue to offer information on functional ingredient certification and mistakenly understood functionality through various media both online and offline. And the Ministry is going to increase the role of the private-public consultative body for improving the review of functional ingredients and operate the preliminary review system on new materials.

D) Technical Support for Industries to Promote Functional Ingredients Certification

The Ministry plans to hold briefing sessions with other ministries and development strategy forums to raise the usage of materials developed in Korea. Moreover, through the Commercialization Support Consultative Group, it will provide customized technical support by development stage, and continuously have briefing sessions on civil complaints and meetings with industries. The MFDS will also prepare a guide for developers of health functional food material (draft), and revise and publish existing functionality evaluation guides (on 10 types including healthy sleep, etc.) to support businesses technically.

B. Reasonable Improvement of Regulations Regarding Health Functional Foods

1) Background

The health functional foods area is popular as a high added-value industry. In this regard, the MFDS aims to leave regulations essential for protecting life · safety intact, but reform regulations associated with product development, manufacturing 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

Changes in consumption trends led to the interest in health and, in turn, to an increased demand for personalized small-packaged health functional foods. Small-packaged sale of health functional foods sellers are banned under the current law, therefore, the MFDS applied for regulatory exceptions (regulatory sandbox) for demonstration pursuant to Article 10-3 of the Industrial Convergence Promotion Act to approve 172 stores from 17 companies (by the Deliberative Committee on Regulatory Exceptions on April 27 and August 27, 2020) and tentatively allowed their operation.

3) Implementation plan

In 2021, the MFDS plans to apply for a regulatory sandbox (regulatory exception for demonstration) for "manufacturing and selling combination products", which will be packaged for intaking both functional health products and foods at once, in an effort to increase synergy and satisfy various customer demand.

In addition, the Ministry will enact a system for safe operation based on the results of the regulatory sandbox for the "recommendation and sale of personalized health functional foods" that has been promoted since 2020.

4. Enhancement of Safety Management of Agriculture, Livestock, and Fishery Products from Production to Consumption

A. Safety Management of Agro-Fishery Products in production & Distribution Stages

1) Background

A) Reinforcement of the Role as a Safety Management Control Tower of Agricultural and Fishery Products at Production Stage

According to the amendment of the Government Organization Act in 2013, the MFDS has directed and arranged the safety management of agricultural and fishery

products at all stages including the production stage safety management controlled by the Ministry for Food, Agriculture, Forestry and Fisheries (MIFAFF) and the Ministry of Oceans and Fisheries (MOF). For safety management, three ministries work together; the MFDS takes a charge of safety management at the distribution stage by establishing a basic plan for safety management of agricultural and marine products pursuant to the Agricultural and Fishery Products Quality Control Act, while the MIFAFF and MOF take responsibilities of safety management at production stage through commission and consignment.

When it comes to agricultural and fishery products, it is important to prevent hazardous elements at the production stage as they are distributed as raw materials, and land, fisheries, water, and materials used for production should be thoroughly managed. Therefore, it is important for the MFDS to enhance its function as a control tower for safety management of agricultural and fishery products and to cooperate with relevant ministries that manage their safety at the production stage.

B) Need for Safety Management of Agricultural and Fishery Products by Reflecting Various Changes of the Time

With the consumer behavior has rapidly changed like the increase in online shopping due to the COVID-19 crisis, it is time for us to widen the management scope to include new areas such as foods being distributed online and prepare a non-contact safety management system. In addition, with the increase in consumption of simple processed agricultural and fishery products that can be easily cooked or require no cooking, there are demands for the management of simple processing businesses so that those products can be processed and distributed in a sanitary environment. And it is also required for the Ministry to provide correct information on agricultural and marine products to consumers.

2) Achievements

A) Expansion of Legal Foundation for Reinforcing Safety Management of Agricultural and Fishery Products

The MFDS has continued its effort for institutional improvement of laws and regulations regarding the quality management of agricultural and marine products. The Ministry entirely revised the “Guidance for Residue Investigation of Harmful Substances in Agricultural Products” to carry out residue surveys on agricultural products at the distribution stage starting from 2020. It also amends some part of the “Guidance on Safety Investigation of Agricultural Products, Etc.” and efficiently optimized administration by streamlining the signature procedure for the specimen collection statement, etc. In addition, to specify the authority and entry-and-exit point for safety investigation public officials and to prepare a foundation for administration execution for rapid disposing of inappropriate agricultural and fishery products, the amendment for the Agricultural and Fishery Products Quality Control Act is now being reviewed in the National Assembly, and the MFDS has made its effort for its passage.

B) Reinforcement of the Role as a Safety Management Control Tower of Agricultural and Fishery Products at Production Stage and of Communication among Relevant Ministries

For organic safety management at all stages from production and consumption of agricultural and marine products, cooperation is important between the MIFAFF and MOF that take responsibilities of their safety management at the production stage through commission and consignment and the MFDS which takes charge of their safety management at distribution stage. To this end, the manager-level consultative group and working-level consultative body have meetings and lead the coordination among ministries to discuss the requirements for institutional improvement of laws, how to enhance safety management at production and

distribution stages, and matters requiring cooperation to cope with various accidents and incidents.

The public trust in the government has grown thanks to the MOU signed between the MFDS, MIFAFF, and MOF in 2019, which prepared a communication channel with a fixed number of people, developed problem-solving policies, and jointly came up with consistent measures to address accidents and incidents together. Thus, these achievements were acknowledged during the review of the Ministry of the Interior and Safety in December 2020, and the people corresponding to the cooperation quota became full-time officials.

C) Enhancement of Inspections of Intermediate Points (Wholesale Market, Etc.) from Production to Distribution

About 63% of domestic agricultural products are distributed at the public wholesale markets (32 markets). The MFDS has subsidized government expenditure of 9.1 billion won (at 13 markets) to local governments and as of 2020, on-site inspection stations were placed at 26 out of 32 public wholesale markets, enabling inspections of approximately 97% of agricultural products being distributed at those markets before distribution. These efforts continuously drove up the prevention rate of non-compliant agricultural products before distribution and made a contribution to the remarkable achievement of 72.1% in 2020. Moreover, the MFDS connected on-site inspection stations and large distributors as members of Korea Chain Store Association for coordinated inspections, resulting in 1,300 inspections at 14 distribution centers in 2020. The Ministry plans to have more coordinated inspections.

On top of it, by benchmarking the operation of on-site inspection stations for agricultural products, the MFDS is planning to establish on-site inspection stations for fishery products. For this, in 2020, as the first step to set up on-site stations to enhance inspections of marine products before distribution, the Ministry carried out residue status investigation on drugs for animal use in marine products distributed at wholesale markets, etc., while conducting policy research to develop a rapid inspection kit for fishery products.

D) Safety Management of Distributed Agricultural and Fishery Products Responding to Changing Consumption and Production Environments

In 2020, the MFDS collected and inspected a total of 72,295 agricultural and marine products and detected 562 cases non-compliant to standards and specifications to recall, seize, or disuse them. Those products, which were found to be non-compliant at the distribution stage, were reported to the MIFAFF and MOF in charge of safety management at the production stage to find out the cause for noncompliance and carry out training sessions for producers so as to prevent reoccurrence.

The MFDS has concentrated its effort for safety management on items such as agricultural products for children' meal services when schools begin, goods for holidays and gifts, seasonal agricultural products that are commonly consumed, and agricultural and fishery products with frequent adverse events, etc. The Ministry has also preemptively responded to changes in consumption and production environment including safety management for agricultural and marine products being distributed online whose sale surged due to the prolonged COVID-19 crisis.

In order to create a safe environment for producing and supplying agricultural and marine products, the MFDS has enhanced the capability of voluntary safety management for agricultural and marine products by carrying out sanitary education and promotional activities for greater awareness of distributors and sellers and providing education sessions on test methods to institutions that analyze producer groups.

Moreover, the Ministry provided sanitary management consulting services to producers (60 companies) of simply processed agricultural and marine products such as salted cabbages, peeled chestnuts, gim (dried seaweed), gwamegi (half-dried herring), etc. In doing so, the Ministry has actively supported those producers so that they can manage safety of production processes on their own.

E) Preemptive Safety Management that Predicted Accidents and Incidents

Listeria infection broke out by raw food intake of domestic enoki mushrooms exported to the U.S., which brought about food poisoning deaths. In response, the MFDS investigated farms to find their cause; collected and inspected domestic enoki mushroom products; required marking on the product with a cautionary note by revising the "Standard Agricultural Products" (MAFRA); and promoted consumers to wash or cook them without fail. As a result, there have been no relevant accidents in Korea as of the end of 2020.

In 2019, the number of hepatitis A patients increased rapidly, so the MFDS implemented the salted clam test order system to distribute finished salted clam products manufactured in Korea only if the hepatitis A virus is not detected. In addition, it adopted a pre-examination system that requires fishermen and others to check for hepatitis A virus detection before delivering baby clams to salted clam manufacturers. Consequently, the number of hepatitis A patients drastically reduced from 17,589 in 2019 to 3,516 in 2020.

Vibrio vulnificus sepsis occurs a lot in summer due to the consumption of seafood contaminated with vibrio vulnificus. Hence, the MFDS conducted vibrio vulnificus tests on fishery products sold near the coast and aquarium water in sushi stores using food poisoning bacteria quick test vehicles, and promoted a need to be cautious about eating marine products in summer along with examination of their producers. Using the vibrio vulnificus prediction system, the Ministry released the vibrio vulnificus prediction index, and strived to prevent food poisoning through intensive management of high-risk areas according to the forecast index.

After the Board of Audit and Inspection (November 2018) pointed out that safety management is needed to eat fish caught at the fishing spot, the MFDS tightened the inspection from 2021 by jointly checking the operation status of restaurants and actual consumption of the fish. The Ministry also toughened inspections from 2021; it came up with the "Safety Management Plan for Fishery Products at the Fishing Spot" that mainly includes strengthening inspections at the import stage (Ministry of Oceans and Fisheries, MOF) and conducting inspections at the distribution stage (MFDS).

F) Safety Management Together with Consumers regarding Radioactivity in Food

To make the public more aware of safety management policies on food radioactivity and raise their reliability and transparency, the MFDS collected the results of food radioactivity tests conducted by 26 institutions – the MFDS (distribution, import stages), MAFRA (production stage), MOF (production stage), and each Si/Do (distribution stage) – and released them every two weeks on the MFDS website, conducted 13 field experience events for radioactivity safety management, and offered online education materials to school meal managers and students.

3) Implementation plan

A) Expansion of Legal Foundation for Stronger Safety Management of Agricultural and Fishery Products

The MFDS plans to lay the institutional foundation for creating a safe agricultural and fishery production environment and continuously improve the safety management system to prevent harmful factors for agricultural and fishery products. In case that nonconforming agricultural and fishery products are probably caused by force majeure such as heavy metal contamination in the abandoned mine area, the MFDS will allow Si/Do governors or the heads of a Si/Gun/Gu to purchase and dispose of those products. It will create a basis for charging the fees for changes in designated matters while clarifying a legal ground for charging the fees for re-designation of safety inspection agencies.

Apart from it, the MFDS plans to keep finding and revising the provisions to be improved, and make further efforts to enact legislation that stipulates the safety management of agricultural and fishery products in close consultation with the MAFRA and MOF.

B) Identification of Vulnerable Areas in Safety Management and Strengthening of Radioactivity Safety Management

The MFDS plans to enhance safety management of agricultural and fishery products by responding to changes in the distribution environment and strengthening the planned collection and inspection of potentially hazardous items by season. It will collect and inspect more agricultural and fishery products, examine whether their transport vehicles with their preservation and distribution temperature, and help online shopping malls build a safe distribution system on their own by producing and distributing the guidelines for labeling those products.

In addition, the Ministry will work with the MOF to expand the inspection of marine products in preparation for the release of radioactive water from Japan, and try to ease public anxiety by transparently disclosing information on food radioactivity and staging events for consumers' field experience.

C) Focusing on Inspection of Agricultural and Fishery Products at Distribution Points

Due to the nature of agricultural and fishery products, there is a limit to follow-up measures about nonconforming items, so the MFDS plans to continuedly beef up the inspection at their distribution points. The MFDS will prepare the standardized guidelines to enhance the operation of inspection centers in the public wholesale market for farm products, and consistently expand quick inspection for 20 distribution centers of those retailers before sale.

To bolster the inspection of distribution points for fishery products like agricultural products, the MFDS intends to secure a budget for 2022 and set up on-site inspection centers for fishery products. In 2021, it will develop a quick inspection kit for animal medicines remaining in fishery products and pilot a quick inspection in the wholesale market, and construct on-site inspection centers in seven wholesale markets by 2024. Along with it, the Ministry plans to focus its inspection capabilities on primary distributors and big supermarkets, such as markets and collectors in production areas.

D) Data-Based Scientific Safety Management

The MFDS will perform a real-time upgrade of information related to agricultural and fishery product safety (temperature, water temperature, monthly nonconformities, seasonal pest outbreaks, etc.) and link some unreconnected information to the integrated food safety information network, and develop a system that can screen out inspection subjects.

In addition, it plans to reflect environmental factors added to the vibrio vulnificus prediction system to improve the incidence prediction rate and use them to devise safety management measures for future climate change.

B. Safety Management of Livestock Products in production & Distribution Stages

1) Background

A) Strengthening a Safety Management Foundation for the Production & Distribution Stage of Livestock Products

In 2020, the domestic production of livestock products (about 46 trillion won) was 32% of the total food (about 141 trillion won), up 1.6% year-on-year. Besides, consumption of livestock products such as meat, milk and eggs has been steadily increasing over the past decade, so close cooperation between departments in charge of the production and post-production stage is important for safety management of the entire life cycle of food.

B) Safety Management of Livestock Product Distribution Reflecting Environmental Changes Such as Consumption Trends

Online transactions are growing as non-contact consumption becomes common due to social distancing caused by COVID-19, and data released by the KOSTAT showed that online shopping for agricultural, livestock and fisheries products

increased 111% from KRW 360 billion in September 2019 to KRW 760 billion in September 2020. Demand for convenient and diverse Home Meal Replacement (HMR) is expanding due to the increase in single-person households and home-cooked meals, and the meal kit market is rapidly growing as well. Reflecting these social consumption trends, livestock safety management should be more focused on new areas and possibly vulnerable areas.

2) Achievements

A) Bolstering Safety Management of Livestock Products in Production Stage

First of all, the MFDS allowed its sanitation-related officials to enter all livestock farms, not just farms for egg laying chickens, and disclosed information on farms which produce harmful livestock. Further, the MFDS extended the order of temporarily suspending the sale of livestock products to livestock breeders, which was only possible for livestock product processors.

The Ministry controlled egg safety more sternly by requiring pre-certification from the Korea Agency of HACCP Accreditation & Service specialized in HACCP certification, instead of selective egg packaging operators preparing and operating HACCP standards.

The MFDS also strengthened the safety management of milk. In the past, veterinarians belonging to the dairy farm used to conduct regular inspections (private inspections) and discarded nonconformities. However, the MFDS introduced and implemented the National Residue Program (NRP) in which the government additionally verify nonconformities (Jul. 1, 2020).

B) Improvement of the Livestock Product System in Distribution Stage and Systematic Year-Round Safety Management

Safety management certification standards (HACCP) became mandatory for meat processors who make packaged or crushed meat (phased in by sales from January 2023) along with self-quality inspection (June 2021). The MFDS strengthened the safety of meat processing products by expanding the scope of meat industry targets for HACCP certification from more than 2 billion won to 500 million won (December 2020).

In addition, to ensure the safe and sanitary management of livestock products throughout the year, the Ministry monitored sanitation of livestock product workplaces and examined livestock products in cooperation with local governments. Considering the characteristics of each time, season, and region, it performed sanitary inspections of 27,411 firms and detected 743 companies with insufficient sanitary management (2.7% in violation rate), taking administrative and improvement measures. Moreover, it collected and inspected 17,773 livestock products, and 52 cases (0.3% in nonconformity rate) were inadequate, so actions such as recovery, disposal, and administrative measures were taken against operators.

The Selective Egg Packaging Distribution System, which was introduced for the sanitation and safety of eggs, was implemented in Apr. 25, 2020, after a one-year guidance period. Although businesses requested an additional guidance period owing to difficult conditions such as COVID-19, the MFDS reached a consensus on safe supply of eggs and operated the scheme as planned.

C) Safety Inspection of Livestock Products at Production, Distribution Stage

The MFDS inspected safety of livestock products such as meat in cooperation with the MAFRA and local governments to ensure systematic safety control from production to distribution. In the previous year, the inspection was conducted on a total of 340,379 cases: 315,741 cases in the production stage and 24,638 cases in the processing and distribution stage. 1,151 (0.3%) cases were found to be nonconformities.

D) The Role as a Safety Management Control Tower and Closer Inter-Ministerial Collaboration

For close-knit safety management of the pre-production, distribution, and

consumption stages, the MAFRA and the MOF and the MFDS have been operating a quota of four people for cooperation (2 from the MFDS, 1 from the MAFRA and the MOF each). In particular, the MFDS runs four related regulations jointly with the MAFRA and introduced the NRP for milk, following meat and edible eggs, by enacting the "Regulations on the Inspection of Residues in Milk (joint notification)." In December 2020, the Ministry of the Interior and Safety evaluated performance of these achievements made by the cooperative quota, the fixed number of people were recognized as full-time officials.

E) Enhancing the Vitality of the Livestock Industry through Rational Regulatory Improvement

The MFDS intended to promote industrial vitality by easing procedural regulations that are not directly related to safety in the COVID-19 situation. First of all, when food sales business operators sell milk at a group cafeteria, the MFDS exempted them from the existing mandatory report for milk sales business.

Besides, in consideration of COVID-19, the Ministry deferred their education period to allow them to be trained within a certain period after the start of business, and permitted real-time online education, not face-to-face education.

3) Implementation plan

A) Strengthening the Livestock Product Safety Management System

If temporary standards and specifications are recognized or approved by fraudulent means, the MFDS plans to provide a basis for their cancellation or applicable punishment, and a ground for punishment to eradicate illegal activities such as reporting business closure to avoid administrative sanctions or manipulate temperatures in vehicles carrying frozen and refrigerated livestock products.

Since the introduction of the Livestock Product Foreign Substance Control System in June 2019, the MFDS plans to prepare a "Manual on Livestock Product Foreign Substance Control (guidelines for public officials)" and distribute it to related agencies such as each Si/Do.

B) Safety Inspection of Livestock Products in Production and Distribution Stages through Selection and Concentration

The MFDS will carry out inspections considering efficiency of tests, including monitoring results of frequently used domestic animal medicines and intensive tests on items with high detection frequency. In addition, in 2021, the MFDS plans to conduct collection tests to reflect consumption trends and social phenomena such as HMR and online distribution livestock products, and expand the Selective Egg Packaging Distribution System, which only applies to eggs for households, to eggs for stores for safer egg supply.

C) Driving Livestock Industry Development through Better Procedural Regulations

The MFDS plans to improve institutions to support and drive the development of livestock products during the post-COVID-19 era. Reflecting the recent consumption trend, the MFDS will establish a new type of livestock product "meal kit" so that businesses can produce the products with just a license for livestock product production industry or meat packaging industry without a license for food manufacturing and processing. Originally, if livestock products and foods were stored in frozen and refrigerated warehouses, they had to get an approval to change the site area every time the volume changed. The MFDS, however, will improve institutions to have sealed livestock and food be stored separately so that they do not have to obtain such an approval.

Section 2

Enhanced Safety Management of Imported Food and Securing of Distribution Safety

1. Enhanced Safety Management of Imported Food

A. Legal Reform for Stronger Safety Management of Imported Food and Rational Regulatory Improvement

As imports continued to increase because of the launch of the World Trade Organization (WTO) and the signing of the Free Trade Agreement (FTA) in 1995, the Special Act on Imported Food Safety Control (hereinafter referred to as the "Special Act on Imported Food" (February 2016) was implemented. Nevertheless, there is a need for further improvements tailored to changes in domestic and international conditions.

The MFDS established legal grounds in April 2020 for mandatory application of the Hazard Analysis and Critical Control Point (HACCP) as the safety control certification standard of commonly consumed food; pushed to introduce non-contact inspections of foreign manufacturers; established administrative measure standards for undeclared operation by online purchasing agencies (July 2020); in case

of nonconformity attributable to the detection of harmful substances, decided to perform thorough inspection of all products of the relevant overseas manufacturing establishment for two years; expanded the scope of conditional rapid customs clearance to prevent disruptions in supply and demand of raw materials following COVID-19; and revised disciplinary measures to an equal level for areas where they differ from other laws, such as the Food Sanitation Act (July 2020).

To stabilize HACCP, the MFDS will do the following things: to introduce detailed procedures for investigating and evaluating HACCP of imported food; grant an incentive for reporting non-registration and undeclared violations and impose fines for noncompliance with inspection orders; introduce a pre-registration system for Original Equipment Manufacturing (OEM); and clarify targets for lifting import suspension.

B. Preparation for Changes in Trade and Efforts to Cooperate with Foreign Countries

Through a briefing session on trade affairs at foreign embassies in Korea, the MFDS shared major pending issues such as non-contact inspections. In 2021, the MFDS will open cooperation channels with foreign missions in Korea that represent major importing or exporting countries (about 20 countries including Canada and Australia) to quickly communicate and respond to emergency situations such as nonconformities. On top of this, the Ministry will pursue a stronger international collaboration system such as sharing safety policies of imported food and working through policy briefing sessions and meetings for foreign missions and businessmen in Korea.

C. Enhancement of Safety Support for Livestock Export

Since countries have different import regulations and sanitary requirements for exports, government-level assistance is necessary for smooth export. In June

2020, the government's support led to Singapore's completion of the equivalence assessment and in turn, export of processed domestic pork products (ham) for the first time. The European livestock sanitary assessment for exporting Korean ginseng chicken soup awaits the next step, i.e. import permission in the European import registration process.

In addition, the Ministry attained the export support budget (200 million) for the first time to strengthen the international competitiveness of export foods. It gave a boost to export support of the MFDS: providing on-site consulting service for exporters and investigating and analyzing import regulations by country and offering information.

D. Construction of an Intelligent Imported Food Integration System

The MFDS is required to set up a database on a lot of hazard information at home and abroad, and analyze hazards and thus prepare a focused safety management and policy foundation for imported food by utilizing high-tech technologies such as big data and artificial intelligence. Therefore, it established a "Quick Response (QR) code-based sample delivery service" to apply blockchain technology for preventing forgery of sanitary certificates issued by the export country and to assist with field work. It provided more information by opening the "Imported Food Information Yard" website so that people, including imported business owners, could easily access imported food information.

The MFDS plans to establish an online remote system to facilitate contactless on-site inspections owing to COVID-19, and provide customized information through specialized systems for consumers, importers and officials in charge. In addition, it will discover future smart management techniques according to the government's Digital New Deal Declaration (July 2020) through "research on a risk prediction model for imported food," "research on a convergence big data platform for imported food," and "research on diversification of interfaces for delivering imported food safety

information." By doing so, the Ministry will lay the foundation for safety management of imported food needed in the Fourth Industrial Revolution Era.

E. Continuous Enhancement of Safety Management of Radioactivity in Imported Food

The MFDS will conduct radioactivity tests on imported food, disclose policies transparently such as providing customs information on imported food relating to radioactivity tests, and continue to communicate with the public including investigating radioactivity awareness.

2. Reinforcement of Imported Food Safety Management before Customs Clearance

A. On-Site Inspection of Overseas Manufacturers (Workplaces) for Imported Food, Etc.

The MFDS is strengthening its pre-import safety management system by mandating registration of overseas manufacturers (workplaces) that export food to Korea, and continuing to enlarge sanitary management through on-site inspection of overseas manufacturers that may cause harm such as nonconformity in import customs inspection.

The MFDS had the information on overseas manufacturers be registered before reporting imported food: business names, locations, production items, and business types. It, too, systematically manages new manufacturers to prevent false registration by requiring them to submit the factory documents issued by exporting countries and by verifying their location through check for its latitude and longitude. Further, when registering overseas workplaces for imported livestock

products, the MFDS registers them only if it is confirmed through the government of the exporting country that the workplace is safely controlled according to import sanitation requirements.

Table 2-14 Registration Status of Overseas Manufacturers (Workplaces)

(As of Dec. 31, 2020; Unit: Places; Source: On-Site Inspection Division)

Total*	Agricultural Product	Marine Product	Processed Food	Health Functional Food	Food Additive	Utensil / Container	Livestock Product
42,158	3,531	5,878	21,113	1,678	4,221	12,182	2,220

* Excluding the businesses overlapped by item

The MFDS is checking whether food is sanitarily manufactured in the export country's production stage, focusing on production of products that are exported in large volumes to Korea or that have a history of non-compliance with customs clearance and distribution; or on foreign manufacturers related to domestic and foreign hazard information and media issues. If there is a possibility of refusal, obstruction, avoidance, or non-response to on-site inspection, or harm as a result of inspection, the Ministry blocks domestic distribution of the product by suspending its import and canceling registration of the foreign manufacturing business.

Table 2-15 Status of On-Spot Inspection on Overseas Manufacturers (Workplaces)

(As of Dec. 31, 2020; Places; Source: On-Site Inspection Division)

Classification		2017	2018	2019	2020
Total		406	407	458	460
Overseas Manufacturer	Food	234	237	286	289
	Marine Product	85	86	86	85
Overseas Workplace	Livestock Product	87	84	86	86

Especially, in 2020, on-site visits to exporters were restricted due to the global

spread and continuation of COVID-19 and the resulting inter-country entry bans and self-isolation measures, the MFDS kept controlling food safety before import by replacing the existing face-to-face on-site inspection with non-contact inspection. As a result, the Ministry executed 460 non-contact inspections of 33 countries to ensure safety of imported food by suspending import and canceling registration of substandard overseas manufacturers and by strictly inspecting those which failed to submit documents.

In preparation for the spread and prolonged COVID-19, the MFDS plans to conduct contactless inspections of overseas manufacturers such as examination of documents, video inspection, etc. It will also analyze domestic and foreign information on non-compliance with import customs and distribution inspections, and carry out non-contact on-site inspections to intensify safety management for overseas manufacturers that arouse concern about harm.

B. Evaluation of Import Sanitation of Livestock Products and Special Sanitary Management Foods

To ensure safety management of livestock products and special sanitary management foods, the MFDS adopted an import sanitary evaluation system as an import permit procedure by country, allowing import of livestock products and special sanitary management foods from countries with the same sanitary level as Korea, after six stages of evaluation.

As of the end of December 2020, 116 import sanitary evaluations of 55 countries, including the U.S., Australia and Argentina are under way. In 2020, the Ministry evaluated Finnish poultry meat, edible eggs, and processed egg products, Lithuanian poultry meat, and Uruguayan fishery by-products (fish heads and offal), and made the exporting country equivalent to Korea in sanitary control through consultation.

Table 2-16 Status of Import Sanitary Evaluation

(As of Dec. 31, 2020; Cases; Source: On-Site Inspection Division)

Total*	Application for Import Permission	Sending the Questionnaire (Stage 1)	Review of the Reply (Stage 2)	On-Spot Inspection (Stage 3)	Decision on Import Permission (Stage 4)	Discussion on Sanitary Requirements/ Certificate Forms (Stage 5)
116 cases from 55 countries	11/14	33/46	29/42	1/2	2/2	5/10

Besides, the MFDS prepared a standard form of the export sanitary certificate to prove that processed livestock products are sanitary and safely managed, from slaughter and milk collection to manufacturing, processing, and transportation. It concluded an agreement with 37 countries which export livestock products to Korea.

In the future, the MFDS will carry out evaluation according to the given procedures, such as reviewing the answers of the other country and conducting on-site investigations, regarding 116 cases from 55 countries under assessment and new countries and items requesting import permit. Additionally, it will make it mandatory for the export country to issue export sanitary certificates for all livestock products to import safe livestock products, thereby reinforcing its responsibility for proving the sanitary status of products.

3. Reinforcement of Safety Management in Customs Clearance Stage of Imported Food

A. Reinforced Customs Inspection on Imported Food

As of 2020, the number of import cases was 750,994 and the volume of imports reached 18,334,000 tons, up by 20.1% and 6.2% respectively from 2016. For more selective and focused inspection, the MFDS analyzed the histories of imported foods

by country · item · detection of hazardous substances; differentiated their random sample testing rates depending on the hazard levels; and identified items that required in-depth inspection.

Table 2-17 Status of Inspection on Imported Foods (including Livestock and Fishery Products) for the Recent 5 Years

(As of Dec. 31, 2020, Unit: Case, thousand tons, million dollars, Source: Imported Food Inspection Management Division)

Classification	2016	2017	2018	2019	2020(p)
No. of inspections	625,443	672,273	728,114	738,082	750,994
Weight	17,261	18,296	18,554	18,441	18,334
Amount	23,438	24,972	27,337	27,473	27,736
No. of rejections	1,250(0.2)	1,279(0.2)	1478(0.2)	1,295(0.2)	1,083(0.1)

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

The MFDS established a comprehensive plan to build an Intelligent Integration System for Imported Food and organized and has operated a dedicated task force (December 2018). It is to integrate and manage the entire imported food cycle from the export country to domestic distribution and to integrate systems by sector (food, livestock, and fishery products) using fourth industrial revolution technologies like AI (November 2018). The Ministry constructed a foundation for an integrated system (stage 1, operated in March 2020) and a new technology-based management system (stage 2, operated in December 2020) as well. In 2021, it will push for a third construction project to strengthen customized information services for people and importers.

The MFDS tried to set up an exchange and certification system for electronic sanitary certificates. This move aimed to prevent loss, forgery, and alteration of certificates by electronically exchanging and recognizing certificates that must be submitted to government agencies in each country when exporting and importing livestock products, etc. and to relieve the time and economic burden of importers having to submit paper documents.

After signing an agreement in June 2019 between Korean and Australian governments to make the two countries to promote cooperative exchange and certification projects for electronic sanitary certificates, the MFDS established the Electronic Sanitary Certificate Exchange System as part of the Intelligent Integration System for Imported Food and linked it with the Australian government.

Currently, the system has applied first to meat products such as mutton and beef and exported foods such as ramen, and target countries and items will expand in the future.

B. Expanded Inspection Orders for Food Importers with Risk Concerns

The Inspection Order System designates imported foods that are subject to repeated nonconformities or risk in the customs inspection so that operators can inspect products before import, through testing agencies at home and abroad, and report them only when appropriate. In 2020, the MFDS newly designated four new items, including Chinese goji berries and powder natural spices, Thai basil, and all countries' krill oil. The Inspection Order System is being in place for 18 items so far and will broaden its target scope.

Considering hazard information and a history of nonconformities, the MFDS plans to gradually expand the list of "inspection orders" conducted in advance by operators, except current 18 items, to improve the efficiency of inspection work and increase operators' safety awareness of imported food.

C. Initiation of the Rapid Clearance System for Planned Import

The MFDS introduced the Rapid Clearance System for Planned Import. Under this system, the Ministry made regulatory amendments and thus allowed food imports of reliable business operators, which have imported safe food for a long time with no record of non-compliance, to be exempted from document and field inspections as well as conventional random examinations so that they can pass the customs clearance procedure immediately after import declaration. As a result, 1,281 imported cases (34,130 tons) from excellent importers were quickly cleared of customs in 2020.

Such action will make it possible to 1) increase exemplary importers by giving them benefits for safe products eligible for "planned import rapid customs clearance," 2) strengthen safety management responsibilities of importers for products, and 3) enhance and expand inspections on the products that are likely to cause nonconformities.

D. Expansion of a Sanitation Agreement with the Countries that Export Marine Products

According to the sanitation agreement on marine products, only the products made at production facilities (including ships) under control of the exporting country's government can be exported to Korea. Every export case requires a sanitation certificate issued by the exporting government, and in the event of nonconformity, import of the relevant products is temporarily suspended until cause analysis and corrective action are confirmed. This mechanism has been effective in securing safety of marine products from the production stage by obligating the exporting government to control safety.

The MFDS has signed "Sanitation Agreements on Imported and Exported Marine Products" with the main exporting countries from 2000 and seven agreements, which were concluded with 6 exporting countries such as China, Vietnam, and Thai, are in place (by cooperation between the MOF and MFDS). The MFDS entered the "Food Safety Agreement on Imported Marine Products" with the Chile SERNAPESCA in 2019 and signed a sanitation agreement with the Norwegian Food Safety Authority in September 2020 to be effective in September 2021.

In preparation for the enactment (September 2021) of this "Food Safety Agreement on Imported Marine Products" signed with the Norwegian government,

the Ministry will arrange its smooth implementation by adjusting details. This includes modes of how Norway will notify Korea of registered fishery product production facilities and how Korea will notify Norway of a nonconformity case in the clearance stage and identify its cause. Furthermore, the MFDS will tighten precautionary safety management of imported marine products by concluding more agreements on sanitation of marine products with major exporting countries.

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

A. Improving the Safety Management System and Responding Quickly to Hazardous Food

In addition to safety control at exporting countries and customs clearance inspection of imported food, management of import food sellers is also very important.

In 2020, the MFDS implemented non-contact instruction and inspection, following a pilot project, so as to efficiently guide and inspect operators in light of the spread of COVID-19. As a result, 22.4% of the total inspection facilities went through contactless instruction and inspection, exceeding 17% against the 2020 target (1,500 locations). The Ministry plans to continue to expand them.

Table 2-18 2020 Instruction and Inspection of Imported Food Sellers

(As of Dec. 31, 2020, Unit: Case, Source: Imported Food Distribution Safety Division)

Classification	Total	Import/Sale Business	Reporting Agency	Online Purchase Agency	Storage Business
No. of businesses	57,412	47,153	1,025	8,455	779
No. of inspected businesses	1,750(3.0%)	1,494(3.2%)	65(6.3%)	154(1.8%)	37(4.8%)
No. of businesses under contactless inspection	393(22.4%)	348(23.2%)	10(15.4%)	35(22.7%)	-
No. of non-conformities	35(2%)	18(1.2%)	-	17(11%)	-

In order to ensure safety in the distribution stage, the MFDS frequently collected and inspected safety of imported foods, which have an increased consumption trend on certain days, such as Lunar New Year's Day and Valentine's Day and which are often nonconform. It also collected and inspected imported foods that may be harmful, by gathering and analyzing information on overseas hazards and nonconformities in customs clearance and distribution stages. As a result, the Ministry collected and inspected 7,842 cases, blocking the distribution and sale of 79 non-conforming products. In particular, in 2020, a number of nonconformities occurred in popular krill oil products, which led to both operator inspection orders and government collection and inspection, and quick disclosure of the inspection results to prevent the spread of consumer anxiety.

In the future, it will collect and inspect commonly consumed foods such as children's favorite foods, the products with information on domestic and foreign recalls and nonconformities, nonconforming products in the distribution and customs clearance stages, and imported foods consumed at certain times holidays, new semesters, the Month of Family, etc.; continuously conduct distribution management surveys and safety inspections on main ingredients of kimchi and low-cost imported kimchi; and check nutritional and functional components of imports and their highlighted ingredients by examining whether the information is correct.

B. Stronger Management of Undeclared Imported Utensils for Food

Importers and customs officials were not aware of some utensils for food as import declaration targets designated by the MFDS, so the products continued to be imported to Korea without safety inspections. In 2020, the Ministry quickly recalled and seized 16,504 undeclared products (14.5%) on the market from 15 importers that brought 113,886 utensils (such as ice makers) into the country without declaration, and blocked the distribution and sale of risky products.

To prevent the recurrence of undeclared cases, the MFDS intensified education and

promotion of importers and customs officials, and improved the system to make it easier for them to recognize that their products are subject to import declaration by revising “Integrated Notifications” (notified by the MOTIE). It is also pushing to link customs clearance information of the Korea Customs Service (KCS) to erect a system that can periodically investigate companies suspected of not declaring food utensils.

The MFDS plans to push for education and promotion of importers and customs officials, overhaul of integrated notifications, and specify more items to be checked by the KCS Commissioner. It will share customs clearance information with the KCS to periodically investigate and jointly examine suspected undeclaring companies.

C. Intense Safety Management of the Foods Directly Purchased from Overseas

The number of directly purchased food imports from abroad increased every year, reaching 17.7 million cases in 2020. It accounted for 30% of the total overseas direct purchase market and ranked first in consumer purchases. Since COVID-19, the size of direct purchases from overseas is expected to grow further, the MFDS and six related ministries, including the Office for Government Policy Coordination and the KCS, mapped out a plan to improve the system step by step through four-step analysis of purchase, customs clearance, distribution, and consumer damage relief from the viewpoint of consumers.

Table 2-19 **Improvement Plan for Safety Management of the Foods Directly Purchased from Overseas**

(As of Dec. 31, 2020, Source: Imported Food Distribution Safety Division)

Step	Description
Purchase step	Develop a web to comprehensively provide a consumer-friendly food information Impose mail-order brokers an obligation of checking if their foods are harmful
Customs clearance step	Prepare the guidelines on the criteria for selecting components that are banned from customs clearance
Distribution step	Double purchase inspections compared to last year
Consumer damage relief step	Impose an obligation such as suspension of business when purchasing harmful food as an agent

To check safety of overseas direct purchase foods, the MFDS examined 1,630 cases (up 25.4% from a year ago) in 2020 to confirm 148 harmful foods (up 18.4% from a year ago). With regard to hazardous food, the Ministry asks the KCS to block customs clearance in real time and the Korea Communications Commission and the relevant Internet sales site to stop its sale.

Table 2-20 **Shutoff of the Hazardous Foods Directly Purchased from Overseas**

(As of Dec. 31, 2020, Unit: Case, Source: Imported Food Distribution Safety Division)

Classification	Sum	Until 2016	2017	2018	2019	2020
Total	2,417	1,035	322	296	309	455
Noncompliance in purchase/inspection	1,072	529	163	107	125	148
Foreign hazard info	1,345	506	159	189	184	307

In addition, the Ministry provided the list of the harmful foods directly purchased from overseas to the Food Safety Korea and the Imported Food Information Yard and promoted the list through videos, card news, and planned articles to ensure that consumers confirm them before purchasing foreign foods.

In 2021, the Ministry will diversify and increase inspections from existing products that claim benefits such as a better sexual function to 3,000 cases, and develop a consumer-friendly web to allow consumers to easily access information on overseas direct purchase foods. Moreover, the MFDS intends to toughen the safety management of overseas direct purchase foods by arranging objective grounds for prohibited ingredients for foods, which are brought in for self-consumption, and by imposing an obligation to prohibit harmful food sale on online purchasing agents.

D. Shutting Out Distribution/Sale of Undeclared Imported Food through Stricter Crackdown on Foreign Food Stores

In August 2018, African Swine Fever (ASF) that broke out in neighboring countries like China entered Korea. This posed a significant social issue: how to control safety in distribution including shutting out distribution/sale of undeclared pork brought illegally by overseas tourists.

In response, the MFDS cracked down (two regular inspections by local gov'ts, joint gov't crackdowns with the MAFRA, etc.) on the undeclared food sale of 1,400 or so nationwide foreign food stores (free business, less than 300 m^2) in the areas populated by foreigners that had a high probability of selling undeclared/illegal livestock products, taking action on the violators (seizure or disposal) in spite that the 2nd inspection of and promotion period for foreign food stores expired on June 30, 2020. The Ministry also constantly monitored websites (including shopping malls and personal social media) and requested the Korea Communications Commission to shut down the websites suspected of sale of illegal livestock products.

To prevent ASF from entering Korea, the MFDS will ban the import of processed pork products, etc. from countries affected by ASF, crack down on the sale of undeclared illegal food imports (including blocking illegal sale websites) and conduct preventive PR activities to raise public awareness on prohibited sale of illegal food imports and the like.

5. Reinforcement of Safety Management for Novel Foods Including Genetically Modified Foods

A. Reinforcement of Safety Management for Genetically Modified Foods

In 2020, the MFDS approved 14 genetically modified (GM) foods – 7 cases of initial evaluation and 7 cases of reevaluation[3]. Since 2000, the MFDS has approved a total of 211 GM foods including 178 agricultural products (corn 92, bean 29, cotton 20, canola 17 cases, etc.), 7 microorganism cases, and 26 food additive cases originating from GM microorganisms.

Table 2-21 Approval Status of GM Foods

(As of Dec. 31, 2020, Unit: Case, Source: Novel Food Division)

Classification	Total	Agricultural Product	Microorganism	Food Additives Originating from GM Microorganisms
Number of approved foods	211	178	7	26

B. Implementation of the Labeling System of GM Foods, etc.

It had been required to submit either a separate distribution certificate or a government certificate to be exempted from labeling genetically modified foods. However, with the revision of relevant articles of "Labelling of Genetically Modified Foods, etc.," a testing or inspection report of a testing and inspection agency designated by the MFDS is also accepted, allowing sellers to choose to submit one of the documents. (Aug. 27, 2018)

> *Article 3, Paragraph 2, Subparagraph 1, Item C: Testing or inspection reports that verify the item is not a subject of the labeling of GM foods and that are issued by designated or assumably designated testing and inspection agencies pursuant to the Article 6 and Article 8 of the Act on Testing and Inspection in the Food and Drug Industry

The Enforcement Rule of the Special Act on Imported Food Safety Control that defines the range of documents exempted from labeling was revised and

3 A system that reexamines GM foods, etc., which are sold on the market after safety evaluation, every ten years to reflect the latest safety information, science and technology, etc.

implemented (Feb. 9, 2018) prior to the revision of this public notification. Accordingly, the relevant regulations were also revised.

In addition, the "Consultative Group on the Review of the GM Foods Labeling System,"[4] aiming to pursue proper policies and gather opinions from various groups, was disbanded in May 2018, and a new consultative group was launched in December 2018. While the disappeared organization consisted of consumer groups, industries, and experts from the academic sphere, the new one is centered around direct and practical stakeholders. It was formed following the government announcement on May 8, 2018, that declared it would make constant efforts to reach a social consensus through a new consultative body. It was a response to the petition submitted to Petition to the Blue House and signed by over 200,000 people calling for a complete GM foods labeling system. The new group has been monitoring the status and issues related to the GM foods labeling system, discussed ways to improve the system by reviewing overseas cases, and formed a social consensus to strengthen the current labeling system. Yet, detailed action plans still need further discussion.

C. Safety Management Including Import of GM Foods

The MFDS provided guidance and conducted inspections twice a year to confirm whether businesses handling genetically modified organisms (GMO) complied with the management standards on handling and storage including airtight storage (transport), separation management, and environmental monitoring. In addition, the Ministry also carried out training and held a meeting once a year for staff of handling companies and civil servants in charge to enhance their understanding and management ability with regard to the safety of GMOs.

4 In April 2013, the group was organized with 20 stakeholders: consumer groups (8 people), industries (8 people), and academia and others (4 people) (operated 32 times)

Table 2-22 Import Status of GM Agricultural Products for Food over the Recent 5 Years

(As of Dec. 31, 2020, Unit: Case, thousand tons, thousand dollars, Source: Imported Food Distribution Safety Division)

Classification		2016	2017	2018	2019	2020
Total	Case	105	123	116	109	110
	Weight	2,004	2,254	2,207	2,155	2,004
	Amount	596,899	664,639	692,540	637,994	615,502
Soybean	Case	40	40	40	39	39
	Weight	982	1,043	1,049	1,003	986
	Amount	397,757	436,455	451,958	397,514	402,386
Corn	Case	65	83	76	70	71
	Weight	1,022	1,211	1,158	1,152	1,018
	Amount	199,142	228,184	240,582	240,480	213,116

D. Follow-up Management Including Labeling of GM Foods, etc.

The MFDS and local governments have constantly provided instruction and performed inspections on labeling of GM foods, etc. in the manufacturing/distribution stages to guarantee safety and raise consumer confidence.

Table 2-23 Status of Instruction and Inspection of the GM Food Labeling System

(As of Dec. 31, 2020, Unit: Case, Source: Imported Food Distribution Safety Division)

Classification	Total	2016	2017	2018	2019	2020
Instruction and inspection	11,134	2,169	2,022	2,682	2,127	2,134
Collection and examination	3,644	726	688	913	429	888
Violation	36	13 (No labeling 13)	6 (No labeling)	10 (No labeling 9, etc. 1)	2 (No labeling 2)	3 (No labeling 3)

Table 2-24 Status of GM Agricultural Product Labeling Inspections

(As of Dec. 31, 2020, Unit: Case, Source: Imported Food Distribution Safety Division)

Classification	Total	2016	2017	2018	2019	2020
Instruction and inspection	15,079	3,007	3,019	3,014	3,015	3,024
Collection and examination	1,251	533	373	194	82	69
Violation	-	-	-	-	-	-

E. Temporary Standards and Specifications for Novel Food Ingredients

In 2020, the MFDS held preliminary consultations and briefings for government agencies and local governments such as “Technical Consulting Outreach” and “Chaeum Discussion” to facilitate the development of novel food ingredients. Total 10 novel raw food ingredients were approved including mycoleptodonoides aitchisonii. The defatted flour of larvae of giant American leeches and pupae of male bees, in particular, are accepted in cooperation with the Rural Development Agency.

Section 3

Scientific Management of Standards and Specifications for Food

1. Improvement of 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 continually 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 it is expected that the possibility of food poisoning, which has never taken place in Korea, would increase, it is needed to review the strengthening of safety management of microorganisms including expansion of the range of foodborne pathogens under control.

There is also the need to resolve trade conflicts deriving from different standards and country-wise specifications and to reevaluate safety of conventional raw materials for food based on new scientific facts. Against this backdrop and given

the need to invigorate the food industry, the MFDS should reinforce food safety standards and rationally revise them by reflecting the reality of the food industry. Such efforts are required to deal with the development of new products on the ground and address the inevitable regulatory concerns deriving from production, distribution and consumption processes.

2) Achievements

A) General Foods

As a measure of institutionally supporting the food industry's competitive edge, the MFDS made efforts to identify and improve regulations on the standards and specifications for food to facilitate development of various foods in a safe range. For instance, with the rapid increase in consumption of HMR, the MFDS newly established the food type of "meal kit" and broke down patient food types by disease by expanding and revising the type of foods with special medical purposes so that characteristics of each disease are reflected.

B) Food Ingredients

The MFDS reassessed 600 food ingredients such as sweet wormwood based on data on their impact on the human body like adverse events and results from toxicity tests. Also added lotus seeds, whose safety has been confirmed, to the list of food ingredients. To prevent the distribution of hemp products containing cannabidiol (CBD), which is a pharmaceutical ingredient, the MFDS created the CBD standard for hemp products.

C) Foodborne Pathogens

The MFDS investigated contamination levels of 4,335 cases in 35 food types concerning five types of foodborne pathogens such as salmonella. Based on the findings of those investigations until 2019, the Ministry applied a statistical concept to the specifications for clostridium perfringens, which are present in Kimchi and pickled foods. On top of it, the Ministry created the "processed foods containing milk" type to apply necessary standards and specifications to the products so far in blind spots (salmonella, listeria, etc.).

D) Health Functional Foods

To promote the health functional food industry, the MFDS upgraded various types of products containing propolis extracts for the oral antibacterial effect, allowed liquid-type probiotics products, permitted to introduce a company's own test method and to submit it, and added new functional descriptions to the already approved functional ingredients.

The Ministry also reevaluated 12 functional ingredients including red ginseng, disclosed the results (Nov. 29, 2020), and reported major details via media. Based on the 2019 reevaluation result, the MFDS amended cautions for nine ingredients including beta-carotene as well as functional descriptions on chromium.

E) Pesticide residues

The MFDS was committed to make the tentative Maximum Residue Limits (MRLs) into formal standards. The MRLs were introduced to resolve issues such as a temporarily insufficient supply of domestically registered pesticides when the Positive List System (PLS) for agricultural products was fully implemented (January 2019). The MRLs became formal standards by evaluating data submitted through the RDA tests for ex officio registration and the application for the import tolerance. In addition, the MFDS also set new standards for the pesticides newly required on site. Furthermore, for the complete implementation of the PLS, the Ministry did not spare efforts for training and advertising to the domestic agricultural industry, foreign embassies in Korea, and import companies.

F) Residual Pesticide and Veterinary drug in Livestock and Fishery products

The MFDS created a list of 177 substances that cause no harm to human bodies or do not remain in livestock or fishery products to exempt them from the MRLs. It was to form the foundation of the PLS for residues in livestock or fishery products (veterinary drugs and pesticides). In addition, following the request to set the standards for domestic permission and imported foods, the Ministry established or revised the standards for residues in 11 veterinary drugs including lincomycin.

In cooperation with relevant ministries, the MFDS made a joint announcement on the introduction of the PLS for veterinary drugs for major livestock products (cow, pig, chicken, milk, and eggs) and fishery products with priority (effectuated on January 2024). Prior to it, it shared information on the new system by explaining the government's safety management plan on veterinary drugs to stakeholders such as producer organizations, importers, veterinary medicinal product associations, and embassies.

G) Food Contaminants

To manage the exposure level of Koreans to food contaminants (19 types), the MFDS monitored the contamination level of foods such as the HMR and reevaluated the standards and specifications for aflatoxin (three types).

Further, it strengthened the standards for 3-MCPD in soy sauce and cadmium in squids, expanded the specifications for lead in candies and jellies to include candies popular with kids, and set up the standards for a toxin (amnesic shellfish poison) subject to the concerns related to climate change. The MFDS added X-ray to the type of food irradiation, and revised the heavy metal substances in fish oils under management (total arsenic → inorganic arsenic) to conform with the international standards.

H) Support for Invigorating the Food Industry

To actively reflect opinions of the food industry, the MFDS has organized, and is running, the "Council for Improving the Standards and Specifications for Food, Etc." from 2013 that consisted of industry officials. The Ministry accepted and reflected 21 cases out of 31 proposals to better the standards and specifications. It also added 10 marine products, 2 agricultural products and 12 microbes through safety review to develop various foods.

Externally, the MFDS held the 10th meeting with China to remove non-tariff barriers in food standards; discussed import and export issues with Vietnam, Australia, and Germany; and translated into Korean the information on food standards and specifications issued by the Philippines, one of Korea's FTA signatories, to provide it to the domestic companies.

3) Implementation plan

The MFDS will reassess the standards and specifications for food, etc. according to The 2nd Standards and Specifications for Food, Etc., formulated in 2019. To that end, the MFDS will reevaluate the standards and specifications for contaminants by analyzing the total dose of hazardous contaminants, In particular, it will inspect the level of food contaminants not only in frequently consumed popular foods but also in the HMR in order to set up a management plan for the food contaminants that can respond to the changes in the consumption trend following the increase of one-person households. Moreover, the Ministry established the safety assessment guidelines for novel food ingredients like alternative protein foods and restructured the special medical foods into a separate type. Accordingly, it plans to add the food standards for patients such as cancer patients and operate a support system to identify difficulties and possible improvement ideas with regard to the development and commercialization of foods for patients. As the food distribution via delivery has soared since the outbreak of COVID-19, there are rising concerns over the temperature management of chilled or frozen foods. Thus, it will also come up with reasonable and realistic guidelines for handling and transport of chilled or frozen foods.

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 enacted and amended standards and specifications by reviewing safety of food additives, designating new food additives and revising 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 has been staging a campaign to improve public awareness on food additives through various communication channels.

2) Achievements

The MFDS newly set up the regulations on the total amount of edible pigments because there are concerns over the pigment overuse when mixed. As for food sanitizers and sanitizers and disinfectants for utensils, which recorded frequent misuse cases, the MFDS created regulations about matters of caution to prevent safety incidents caused by food additives. On top of it, by developing and sharing the guidelines for food sanitizers and the sanitizers and disinfectants for utensils, etc. along with food companies and local governments, it enabled safe management of food additives.

For the prevention of misuse of nitrous oxide as a hallucinogen, the Ministry notified relevant associations, coffee shops, manufacturing companies, and local governments to manufacture and distribute it only in high-pressure metal vessels of 2.5 L (enforced on Jan. 1, 2021). It also published card news and advertised on the visual display of the Government Complex Seoul to fully implement the regulation.

The MFDS formed a new regulation: if preservatives not used in the food manufacturing process are detected (propionic acid of 0.10 g/kg or below), the food is recognized, without proving documents, as originated naturally. It also revised regulations: the Ministry allowed the production of powder flavors by accepting dextrin, etc. as flavor diluents and permitted the use of edible pigments with different colors for surface decoration of coffee (latte art).

To raise awareness of food additives, the Ministry created card news and contents with expertise knowledge and published them on social media such as Facebook and representative websites of the Ministry including Food Safety Korea. At the same time, it provided training on food additives (68 sessions) to heads and teachers of daycare centers, and meal service personnel who belonged to the Children's Food Service Management Centers nationwide as well as parents, food sanitation-related civil servants, and sanitation inspection agencies to change negative images of food additives.

3) Implementation plan

To boost the bio-industry, the MFDS will improve the audit regulations on the bio food additives, prepare the standards on the use of food additives for bio foods, and make constant efforts to set the food additive standards and specifications conform with the international standards while advancing them.

The Ministry will verify the suitability of ingredient specifications and use standards for 20 items including acidity regulators among food additives through scientific reevaluation and amend the standards and specifications, if necessary, to strengthen the safety standards.

It will continue to produce and provide online publicity content to improve the Korean consumers' awareness of food additives by providing accurate information.

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

1) Background

Countries across the world have reinforced the control standards for utensils, containers, packaging and raw materials and the safety standards for hazardous substances. For its part, Korea is strengthening safety management of hazardous substances in terms of public understanding, and working out better standards and specifications for utensils, containers, and packaging to harmonize with international institutions.

Additionally, the MFDS is carrying out education and promotion including provision of life-friendly information, to enable people comfortably use utensils, containers, and packaging and to address anxiety caused by incorrect information from social media, personal media and the press.

2) Achievements

For more effective and reasonable safety management of utensils, containers, and packaging for food, the MFDS has constantly endeavored to improve the standards and specifications. Specifically, it created the standards on the total volatilization amount of a pacifier (0.5% or below) for the safety of infants in the lactation period as well as the regulations for the tolerance of substances derived from utensils for better safety standards on harmful substances in foods (elution specifications by material, or maximum 30 mg/L). As for the utensils, containers, and packaging, the Ministry divided the common production standards into three categories of raw materials, manufacturing and processing, and recycling.

As waste plastics increase in recent years, the MFDS amended the recycling standards to allow remnant plastics from food container production to be used. According to the revised standards, physically recycled materials can also be used for parts that do not directly contact foods.

When it comes to food utensils, containers, and packaging associated with 3D printers, based on the inquiries and answers via e-People and phone, it published and distributed the “Q&A on the Standards and Specifications for Utensils, Containers, and Packaging Associated with 3D Printers for Food” to enhance public and industry understanding.

In addition, to promote correct use of utensils, containers, and packaging for foods, the MFDS provided safety information closely related to people’s lives such as “How to Use Food Containers Specialized for Microwaves,” “How to Check whether Your Kimchi-making Mat is for Food-making,” “Information on Plastic Dishes,” and ““What is a 3D Printer for Food.”

3) Implementation plan

The MFDS intends to improve safety management of utensils, containers, and packaging for foods according to the standards and specifications required in the era of post-COVID-19. The popularity of the HMR and use of containers for delivery foods have increased due to COVID-19, resulting in more waste plastics. Therefore, the Ministry will develop and review the guidelines on the use of recycled synthetic resin for utensils, containers, and packaging to further promote recycling. It will also reassess eight materials including glass to evaluate the appropriateness of the current standards and specifications for utensils, containers, and packaging for foods.

On top of it, to address people’s vague concerns over utensils, containers, and packaging due to incorrect information from the media and the Internet, the MFDS will communicate with people by constantly providing information that is highly relevant to their lives and easy to understand such as how to use them correctly.

Section 4

Expansion of Healthy Dietary Environment

1. Strengthening Children's Food Safety Management

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

1) Background

For children who are the future of a nation, it is essential to provide food safe and healthy to eat. Infancy and childhood are very important periods to develop senses of food and healthful dietary habits. Thus, it is crucial for them to eat balanced and nutritious foods. Also, as childhood is the starting point of children's health management to develop their capability for maintaining a healthy life throughout the life cycle, both parents and the country should pay active attention to this period.

Meanwhile in Korea, with increasing participation of women in society, the number of children cared for in kindergartens and childcare facilities soared from 800,000 in 2005 to 1.96 million in 2020, leading to a larger demand for better childcare services. However, the food poisoning case from a kindergarten in Ansan in June 2020 raised parents' concerns over children's food services and gathered the attention of society, highlighting the importance of safe management of food services.

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 Children's Food Service Management Centers 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.

2) Achievements

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

Starting with 12 centers in 2011, the Children's Food Service Management Centers opened 228 new centers in 2020, providing the children's food service management to 40,154 small children's meal facilities and 1.23 million children.

The main role of the Children's Food Service Management Centers is to regularly visit children's meal facilities such as daycare centers and kindergartens. On their visits, they give instructions on their sanitary safety and nutrition management; provide sanitation and nutrition education by subject (children, meal service personnel, facility heads, and parents); and support the overall operation of meal services including developing menus and recipes for children's meal service and consulting on sanitation and nutrition.

The MFDS has been disseminating press releases to publicize online the significance and role of those centers in charge of sanitation and nutrition education for children who will grow to be leaders in the future.

B) Mandatory Installation and Registration of Children's Food Service Management Centers

To improve the safety management of children's meal in kindergartens and nurseries, the Ministry made a joint announcement with relevant ministries (the MFDS, Ministry of Education, and MOHW) on the "Improvement Plan for the Safety Management of Food Services in Kindergartens and Nurseries" in the 12th Ministerial Meeting for Social Affairs held on Aug. 12. For the registration of Children's Food Service Management Centers, which is one of the improvement plans, and the expansion of on-site supports for food services, the Special Act on Safety Management of Children's Dietary Lifestyle (announced on Dec. 29, 2020, effectuated on Dec. 30, 2021) was revised. The amended act provides the basis to strengthen the sanitary and nutritional supports and to eliminate blind spots of safety management by installing Children's Food Service Management Centers in all Si, Gun, and Gu and by making it mandatory for food service facilities without a dietician to register.

In addition, to prevent further spread of COVID-19, the Ministry used its own self-check list for sanitary and safety management so that food service facilities can manage sanitation on their own, provided contact-free remote supports by dieticians at the centers, and made efforts to facilitate children's dietary lifestyle education interconnected with families, when the attendance is limited, using online programs (videos and kits provided).

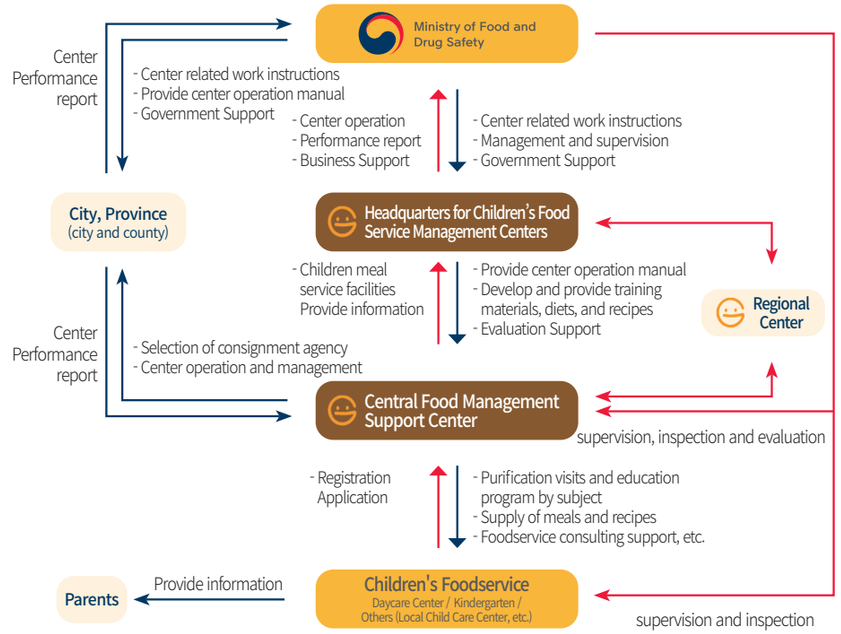
C) Installation and Operation of Headquarters for the Children's Food Service Management Centers

The MFDS has established and operated the Headquarters for the Children's Food Service Management Centers from 2016 to systematically support and supervise centers across the nation (228). The headquarters is being operated as a foundation under the MFDS as a body specialized in the safety management of meal services beginning since Jan. 1, 2020.

The headquarters runs a curriculum (on/offline) to boost competence of the regional center staff, and offers consulting and technical support to regional centers to help them supervise meal service facilities. The headquarters develop and supply the "Guidelines for Operating and Controlling the menus of the Children's Food Service Management Centers," customized menus (recipes) by age and education materials.

The establishment and operation of the Children's Food Service Management Centers and their headquarters made it possible to consider nutrition safety in the long term by means such as guiding children to desirable dietary life by rationally distributing work and efficiently running the centers. Thus the activities are not limited to safety management simply concentrating on sanitation. The MFDS expects that the safety level of children's dietary life will ultimately improve through various activities of regional centers.

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



3) Implementation plan

For the seamless support for small-sized children's meal facilities without a dietician such as a kindergarten and a nursery, the MFDS plans to set up Children's Food Service Management Centers in every local government by the end of 2021 and expand the existing and operating local centers. Further, the Ministry wants the Headquarters for the Children's Food Service Management Centers to play the role as a control tower of children's food service safety while enhancing the capacity and effective management of local centers. The fundamental goal of such efforts is to enable children's meal facilities to provide sanitary and quality meal services and to build an efficient management system to assure parents regarding safe food provided for children.

B. Strengthening the Safety of Children's Diet

1) 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.

The paradigm of food safety has changed from providing safe food to providing healthy food. Accordingly, the MFDS has recognized the necessity to build a comprehensive and systematic plan for children's food at the government level and plays its role as a control tower for children's food safety and nutrition.

2) Achievements

A) 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 sale around schools beyond parents' protection. Thus, the MFDS designated the areas within 200 m around schools and nearby facilities as Green Food Zones to create a safe and clean environment for food sale. The areas with cram schools were also temporarily designated as Green Food Zones.

As of December 2020, there were 7,513 Green Food Zones nationwide and 147 temporary Green Food Zones such as cram school areas. Also, 2,889 dedicated officials are managing cooking and selling businesses there.

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

In Korea, the dietary pattern has been being westernized with a rising popularity of snacks such as confectioneries, drinks, bread, and ramen, and fast food and soda consumption have constantly increased as well.

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

Besides, beginning from 2014, children's favorite foods containing high caffeine have been restricted or prohibited from being sold in schools and exemplary shops, and their promotion including broadcast is limited.

To guarantee consumers' right to know and convenience of sellers, the Ministry regularly updates and announces the list of high-calorie, low-nutrition foods on its webpage.

In addition, it also prohibits selling foods that may have a negative impact on children's healthy emotions. Such prohibition includes selling foods that their alcohol bottle-shaped containers may incite early drinking or foods that may harm sound emotions of kids by promoting gambling or causing sexual curiosity.

C) Restrictions on Advertising Related to Children's Favorite Foods

Based on the "Special Act on Safety Management of Children's Dietary Lifestyle", MFDS 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. 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 ads are immediately banned.

D) Expansion of the Quality Certification System for Children's Favorite Foods

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.

It evaluates whether a food conforms to the 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. As of December 2020, 302 food products of ten types such as fruit and vegetable juice and fruit and vegetable drinks were certified.

E) 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 oflocal 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.

The 2020 survey is currently underway, and its outcome will be published in 2021.

3) Implementation plan

A) Designation and Management of Green Food Zones

The MFDS will inspect foods for sale as well as cooking and selling businesses in schools and in school areas to improve the dietary environment closely related to children. As for the businesses that need constant management such as snack bars and school cafeterias, it will keep monitoring them for improvement. Also, in the case of the temporary Green Food Zones in cram school areas where children spend a long time, like schools, the Ministry plans to encourage local governments to designate and expand the zones while keeping carrying on intensive inspection in preparation for the school opening.

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

The Children's Dietary Safety Index is surveyed every three years to objectively monitor children's dietary safety and nutrition. The result serves as basic national statistics and is reflected in the policies for children's dietary lifestyle. This year's survey is underway on the recognition and actions regarding the dietary lifestyle of elementary school students, and the result will be announced in 2021.

C) 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.

D) Improvement of the Distribution and Consumption Environment for Children's Favorite Foods

The MFDS plans to create a healthy distribution/consumption environment for children's favorite foods. For this, the Ministry will expand mandatory targets for labeling nutrition facts and allergens of children's favorite foods, from franchises with more than 100 member stores to franchises with stores of 50 or more.

E) 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 highcalorie, 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.

F) Expansion of the Quality Certification System for Children's Favorite Foods

The MFDS will further promote the Quality Certification System for Children's Favorite Foods. To do so, it will encourage businesses to participate voluntarily and further promote the certificate in a way closely related to people's lives so that people may notice the quality certified foods when grocery shopping. Furthermore, the Ministry plans to boost the certification system via reasonable regulatory revision including a new procedure for expanded expiration dates.

2. Prevention of Food Poisoning through Building up Hygienic Surroundings of the Restaurant and Meal Service

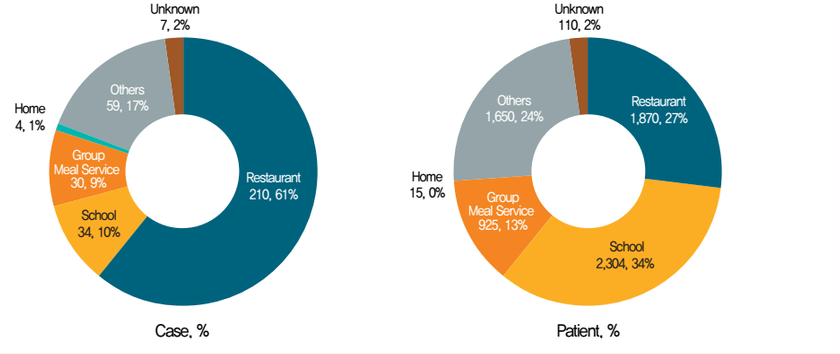
A. Preemptive Safety Management to Prevent and Reduce Food Poisoning Cases

1) Background

According to an analysis on the food poisoning cases of the recent five years on the annual average basis (2015-2019), restaurants accounted for 61% (210 cases), schools 10% (34 cases), meal service facilities such as companies 9% (30 cases), and other facilities 17% (59 cases), by the standard of causative facilities. The highest percentage of the food poisoning patients, which is 34% (2,304 people) of the total, experienced food poisoning from school meal service facilities.

* Case: Restaurants (61%) > Other facilities (17%) > Schools (10%) > Meal service facilities such as companies (9%) > Unknown (2%)
* Patient: Schools (34%) > Restaurants (27%) > Meal service facilities such as companies (13%) > Other facilities (24%) > Unknown (2%)

Image 2-2 Food Poisoning by Causative Facilities on the Five-Year Average (2015-2019)



Among the causative agents of food poisoning, norovirus was the biggest contributing organism at 15% (52 cases), followed by E. coli at 13% (44 cases), and

parasites like kudoa at 10% (36 cases).

* Case: Norovirus (15%, 52 cases) > E. coli (13%, 44 cases) > Parasites (10%, 36 cases)

According to an analysis on the food poisoning status of the recent five years, it was necessary to intensify sanitary inspection of meal service facilities including schools while focusing on education/advertisement to prevent the spread of infectious agents such as norovirus and food poisoning.

2) Achievements

In 2020, the tentative figures related to food poisoning are as follows: 178 food poisoning cases, 2,747 patients, and 53 patients per million people, which are the lowest number of cases and patients recorded in 10 years. When breaking the figures down by facility, the cases from schools reduced dramatically to 448 patients from 16 cases (1,214 patients from 24 cases in 2019). As for the causative agents, norovirus accounted for 239 patients from 26 cases (1,104 patients from 46 cases in 2019) and E. coli 532 patients from 15 cases (497 patients from 25 cases in 2019), recording a major decrease compared to the previous year.

It is analyzed that the reported cases diminished following better personal hygienic behaviors including handwashing due to COVID-19, decreased school attendance, and reduced number of days with a heat wave as well as the various efforts of the MFDS to prevent food poisoning.

A) Establishment of the Preemptive Prevention System Including Intensified Sanitary Inspection of Meal Service Facilities

The MFDS conducted a joint examination of schools and food material suppliers (14,019 places) together with the Ministry of Education and local governments at the start of school terms in spring and fall. Also, in the wake of the food poisoning case from a kindergarten in Ansan (June), it intensified examination and management of facilities with food poisoning risks by inspecting all kindergartens and nurseries (44,162 places).

To prevent an outbreak of norovirus in underground water, it tested the virus in underground water at 680 places including food manufacturing companies using underground water and distributed kits consisting of disinfecting fluid and sanitary products for disinfection and handling of vomit in order to prevent the spread and secondary infection of the norovirus.

Furthermore, for effective food poisoning prevention and countermeasures, it held a meeting three times a year to discuss countermeasures against food poisoning at the pan-government level. The meetings were held with 10 ministries, including the Ministry of Health and Welfare, the Ministry of Education, and the Ministry of National Defense, and 17 cities/provinces and relevant associations. The meetings enabled the MFDS to build a system in which relevant organizations can cooperate closely to prevent food poisoning.

B) Training and Advertisement to Prevent Food Poisoning

To raise people's awareness in prevention of food poisoning and encourage preventive actions, the MFDS provided relevant education to those who operate meal service facilities or restaurants and those who are related to cooking. In addition, considering difficulties in carrying out offline training due to COVID-19, it utilized video training when offline training was impossible, so that training vacancy would be minimized.

The MFDS also offered training on the food facility sanitary management and food poisoning prevention to 72,293 persons concerned with school meals such as school principals, dietitians (nutrition teachers), and cooks as well as 13,339 persons at social welfare facilities including meal service managers and cooks. On top of it, the Ministry operated a course for instructors specialized in the prevention of food poisoning for civil servants at local governments and education offices (92 trainees completed the course). Besides, it taped two video contents on food poisoning prevention so as to expand the constant non-contact training infrastructure and to allow the public, workers at food service facilities/restaurants, and relevant civil

servants to utilize it.

To encourage people to take action on food poisoning prevention and to provide information on it, the MFDS made a series of videos on the prevention and broadcasted them via various media including TV, radio, and social media. The Ministry made a total of 15 videos including “Things Always End Up with Hygiene” and “Are You Safe from Norovirus?”

The videos were broadcasted 515 times a year via ground wave, cable, and radio broadcasters. The information on the prevention of food poisoning was also provided via various media such as YouTube, Korea Train eXpress (KTX), and exterior media (office advertising, convenience stores, marts).

Image 2-3 Broadcast of Videos on Food Poisoning Prevention

Monitors in KTX

Advertisement in subways

Exterior visual display

Naver

Convenience stores

Monitors in airports

Further, in cooperation with other ministries and institutes, it produced two episodes of “Dispatch, Safety First” of KTV and one episode of cartoons on government policies in cooperation with the Ministry of Culture, Sports and Tourism. The content was broadcasted on websites of seven associations including the Korea Chefs Association, the Korean Dietetic Association, and Children’s Food Service Management Centers.

In particular, the Ministry described the information on the cause of causative agents and preventive measures of food poisoning of each month in the graphic to promote people’s understanding while providing it to relevant institutes to be used as training material.

The MFDS advertised the importance of personal hygiene management by carrying out offline advertisements and events, including creation/distribution of advertising materials considering the subject, timing, and occasions of food poisoning outbreaks, and by manufacturing/distributing hand sanitizers. The Ministry’s efforts went so far as to make posters of “Six Principles to Prevent Food Poisoning,” “Foodborne Pathogens You Should Watch Out When Cooking Chicken on Dog Days,” and “How to Prevent Norovirus in Winter” to Si/Do education offices as well as local governments.

The Ministry also encouraged people to wash their hands through its social media event in collaboration with kid YouTubers targeting infants/children. At the same time, it promoted actions to prevent food poisoning in real life by developing and distributing card news (15 articles including how to correctly wash food) that are highly relevant to people’s lives for intensive advertisement during summer.

Image 2-4 Posters on Food Poisoning Prevention

Six principles to prevent food poisoning (Poster)

Foodborne pathogens you should watch out when cooking chicken on dog days (Poster)

How to prevent norovirus in winter (Poster)

C) Prevention of Food Poisoning Using Rapid Testing Mobile Vehicle

Using rapid testing mobile vehicles for food poisoning, it conducted rapid testing

(108 tests) including testing of vibrio that occurs frequently in summer as well as the examination of food boxes provided to Korean expatriates who returned to Korea for COVID-19 and stayed in temporary living facilities. In addition, it advertised food poisoning prevention (588 times) and rapid testing (108 tests) 696 times in total at places where it could reach out to people including highway service areas with large floating populations.

The Ministry also made additional rapid testing vehicles for food poisoning and deployed them at the Daegu FDS Office (December), thereby establishing the rapid testing system in five areas (Gyeongin (Gyeonggi-do/Incheon) area excluded) out of six areas (Seoul, Headquarters, Gwangju, Busan, Daegu, and Gyeongin).

Image 2-5 Operation of Rapid Testing Vehicles for Food Poisoning

3) Implementation plan

A) Strengthening of Food Service Safety Management at Kindergartens/Nurseries

The MFDS plans to carry out inspection of all kindergartens/nurseries at least once a year beginning from 2021. In addition, in order to reinforce self-safety management of meal service facilities, it set up a list of items for self-check and regulations on the inspection standards following the revision of the Enforcement Rules of the Food Sanitation Act. The Ministry is also going to tighten the safety management for children's meal services by obliging kindergartens and nurseries to have a dietician and keep preserved food by amending the School Meals Act and the Child Care Act. It has already toughened punishment such as fines for not keeping or throwing away/spoiling preserved food.

B) Promoting Recognition of Food Poisoning Prevention Management

The MFDS is planning to constantly spread the six principles to prevent food poisoning; magnify the effectiveness of the promotion by branding the food poisoning prevention advertisement through character/slogan development; conduct advertisement throughout a year with consistency; and deepen its strategic communication with people. To implement COVID-19 prevention and control in daily lives and reflect consumption trends, it will advertise food poisoning to relevant industries while strengthening the drive using social media and the Internet portals.

The Ministry will regularly conduct a survey on public awareness of food poisoning prevention to measure the effectiveness of the advertisement, check the level of people's participation, and develop promotion strategies to improve their participation.

B. Prevention of Spread/Recurrence of Food Poisoning with Rapid Response and Analysis of the Cause

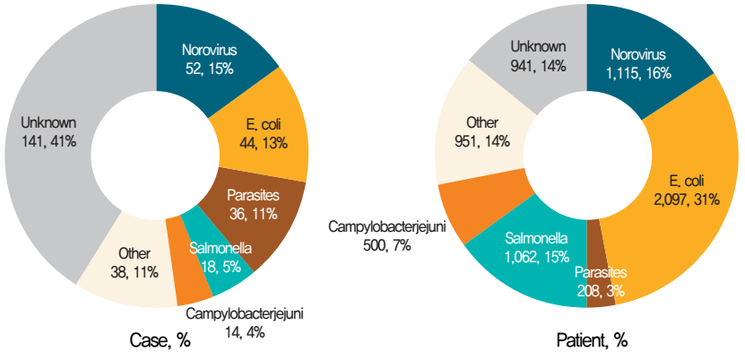
1) Background

A) Necessity to Prevent Food Poisoning Spread with Rapid Early Response

According to an analysis on the average food poisoning cases in the recent five years, food poisoning by norovirus and E. coli including EHEC accounted for 47% of total patients (total of 6,874 patients; 2,097 patients by E. coli, 1, 115 patients by norovirus).

* Patient: E. coli (31%, 2,097 patients) > Norovirus (16%, 1,115 patients) > Salmonella (15%, 1,062 patients)

Image 2-6 Food Poisoning by Causative Agent on the Five-Year Average (2015-2019)



EHEC and norovirus, in particular, are highly infectious and can spread through not only those who eat contaminated food but also those physically contact vomit or feces of a patient or a doorknob the patient touched. Thus, it is crucial to respond quickly, analyze the cause, and prevent secondary infection when it comes to food poisoning.

B) Need to Improve the Food Poisoning Identification Rate

In order to stop the spread of food poisoning at the early stage and prevent an outbreak of similar cases, it is important to identify the causative food and root out the source of contamination at the manufacturing-distributing-processing phase. The domestic identification rate is 29.7% (2019), which is higher than 13.8% of EU (2018) but lower than that of Japan (47.4%, 2018) and the US (42.8%, 2017). It is also necessary to improve the rate of identifying the cause from patients, which is to detect causative pathogen from patients. For reference, the percentage of successful identification of causative agents from patients is 80% in the US (2017) and 98.2% in Japan (2018), which are higher than 64.3% in Korea (2019).

2) Achievements

A) Prevention of Food Poisoning Spread with Efficient and Rapid Response

In June 2020, with the outbreak of mass food poisoning from a kindergarten (203 patients) assumed to be caused by foods contaminated with E. Coli O157:H7 (EHEC), an early warning was promptly announced to 108 places including nearby meal service facilities and food material suppliers. The MFDS took samples from food materials, cooking facilities' environments, and patients' bodies for rapid testing. After confirming that EHEC was the causative agent, it closed the kindergarten in consultation with the Ministry of Education and the local government, thereby preventing secondary infection at an early stage. And then, it analyzed the provided foods to examine the distribution process and swiftly published press releases to raise people's awareness of E. coli food poisoning.

Additionally, to promptly respond to additional food poisoning cases, the Ministry formed the Food Poisoning Task Force; established a close cooperation system; inspected all kindergartens and nurseries across the nation (44,162 places inspected, 953 places identified with violation); reinforced and expanded the obligation to keep preserved food; built a system to examine all the relevant facilities; and developed a comprehensive plan to manage food services of kindergartens/nurseries including intensified investigation of causative food.

To prevent the spread of food poisoning from an early stage, it expanded the range of facilities and food material suppliers to be registered with the early warning system for food poisoning. As a result, in the case of food poisoning at meal service facilities such as kindergartens/nurseries, the early warning is sent promptly to not only food facilities related to the same food material suppliers, but also all the meal service facilities in the nearby area (Si/Gun/Gu).

B) Establishment of the System to Identify the Cause of Food Poisoning

After the food poisoning case from a kindergarten in Ansan, the MFDS reinforced

safety management of food services, and expanded the investigation scope of the cause to improve its identification rate: It used to be site-oriented and centered around preserved food and managers/other staff members, but now it includes the food material distribution phase as well. In addition, the MFDS revised its Standard Work Guidance on Food Poisoning (December 2020) to enable itself to form a joint task force to investigate the cause and carry out epidemiological research, if necessary, in case of food poisoning from not only schools or mass food poisoning with patients of 50 or over, but also the outbreaks from kindergartens/nurseries.

C) Enhancement of Ability to Promptly Respond to Food Poisoning

For a swift response to food poisoning, joint simulation training was conducted by the local FDS Offices (July - August) and Si/Do (June - December) (twice a year, 208 institutes). The MFDS also provided training courses on the identification of food poisoning causes (three times, 66 trainees) to strengthen the on-site response capacity. As for civil servants newly assigned for food poisoning related works at the local FDS Offices and local governments, the Ministry made and distributed videos on the investigation of food poisoning causes for training (December 2020) so that they can easily learn the on-site procedures to respond to food poisoning even though the opportunities for face-to-face education decreased due to COVID-19.

D) Establishment of Infrastructure for Tracking Foodborne Pathogen and Preventing Recurrence

To enable traceability of food poisoning and raise the rate of determining its cause, the MFDS thoroughly monitored whether there are foodborne pathogens in agricultural/livestock/fishery products at the production stage as well as production conditions like soil and water at farms, ranches, and slaughterhouses (13,431 cases investigated), and laid the foundation to establish an information DB on genes of food poisoning bacteria (13,560 cases, cumulative). The accumulated information on foodborne pathogens will be used to identify the cause of food poisoning in the future.

3) Implementation plan

A) Better Registration Rate of the Food Poisoning Early Warning System

Since it is crucial to stop the spread of food poisoning at an early stage with prompt response, the MFDS intends to constantly expand the registration of meal service facilities including kindergartens/nurseries in the food poisoning early warning system in order to enable meal service facility staff to take preemptive and preventive measures by sharing the information on food poisoning. The Ministry also plans to have food service staff actively take preventive actions by spreading specific information during early warning for more effective preventive measures.

B) Reinforcement of the Basis for Analyzing the Food Poisoning Cause

The MFDS will place the latest equipment that can swiftly examine and analyze suspicious foods (microorganism mass spectrometry, real-time PCR system) at the National Institute of Food and Drug Safety Evaluation and six local FDS Offices in order to strengthen rapid investigation capacity, thereby increasing the rate of identifying the causative food.

C. Establishment of a Sanitation Management Base to Create a Safe Environment at Restaurants

1) Background

A) Improvement of a Sanitary Level of Restaurants by Promoting the Sanitation Grading System and Reforming Food Culture

While more and more people dine out, the highest percentage of food poisoning occurred at restaurants. Furthermore, according to the survey of consumers on the “factors that undermines the credibility of food and beverage franchise brands,” the sanitation of cooking facilities and food materials ranked top at 62.8%. It reflects

social demand on safety management of restaurants. (2019 Survey on the Awareness of Food and Beverage Franchises, Embrain Trend Monitor)

Table 2-25 Food Poisoning from Restaurants

(As of Dec. 31, 2020, Unit: %, Source: Foodborne Diseases Prevention and Surveillance Division)

Classification	2015	2016	2017	2018	2019	2020
Percentage of food poisoning from restaurants out of total cases	60	63	66	56	61	58 (tentative)

The MFDS needs to further improve consumer satisfaction by enhancing the sanitation of restaurants through voluntary competition. It also has to promote the grade system and encourage more restaurants to receive a sanitation grade to make an environment safe for consumers.

2) Achievements

A) Stable Settlement and Revitalization of the Restaurant Sanitation Grade System

The MFDS selected priority areas, provided intensive support including sanitation consulting for restaurants in the areas, and encouraged franchise restaurants to join the system by designating more of them.

In addition, it expanded the designation of restaurants with the sanitation grade through interconnection of projects and regulations with relevant institutes including the Ministry of Culture, Sports and Tourism, the Korea Tourism Organization, and the Korea Expressway Corporation. It also provided technical support such as training on evaluation items to sanitation staff at the headquarters of franchises to encourage franchise stores to join the system by brand, thereby promoting voluntary competition.

As a result of these efforts, the number of participant restaurants in 2020 increased by 320% (9,991 places) compared to the previous year, and 15,185 stores (accumulated) received the grades.

Table 2-26 The Status of Restaurants with the Sanitation Grade Designation

(As of Dec. 31, 2020, Unit: Place, Source: Foodborne Diseases Prevention and Surveillance Division)

Classification	Total	2017	2018	2019	2020
Designation	15,185*	710	1,359	3,125	9,991

* Among designated stores (15,185 places, accumulated), 12,782 stores kept the designation (designation of 2,403 places canceled, the reasons for cancellation include business closure)

Moreover, the MFDS provided field-customized technical support for evaluation items/standards for 807 small businesses that wanted to join the system.

In 2020, 13,815 restaurants applied for the designation of a sanitation grade. As a result of assessing 11,549 of them, 9,991 restaurants received grades and their grades were: Excellent (★★★) - 2,754 places; Very good (★★) – 5,854 places; and Good (★) – 1,383 places.

Image 2-7 Signs for the Restaurant Sanitation Grade System

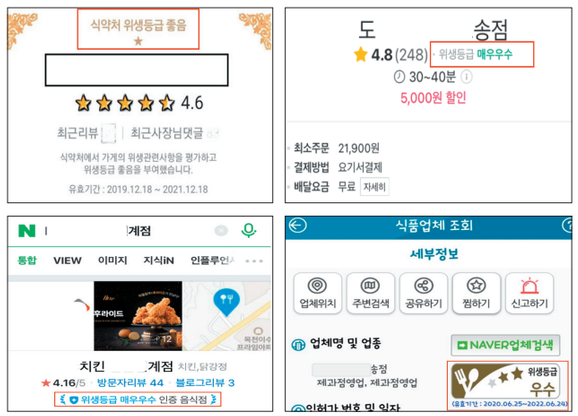
Excellent Very Good Good

B) Establishment of Safe Environment for Restaurants in Association with Disease Prevention and Control in Daily Lives

The Regulation on the Designation and Management of Sanitation Grades of Restaurants (public notice) was revised (Jul. 31), taking COVID-19 outbreaks into account. Major revisions include distancing of tables by at least 2 m when evaluating the sanitation grade, designating personnel in charge of disease control and prevention, and granting additional points for the implementation of everyday disease control and prevention measures such as regular disinfection of shared items and tables.

The MFDS also constantly promoted principles for disease prevention and control in daily lives by staging campaigns for better social distancing in restaurants.

Image 2-8 Promotion of Social Distancing in Daily Lives in Restaurants



C) Raised Awareness of the Restaurant Sanitation Grade System

The restaurants with a sanitation grade are now marked in delivery applications, Naver Place, and the Korea Tourism Organization so that people can easily identify them.

In addition, the Ministry broadcasted training/promotion videos to explain the sanitation grade system and its evaluation items during statutory training sessions for relevant associations, the Korea Agency of HACCP Accreditation and Services, and local governments to deepen the understanding of business operators.

3) Implementation plan

A) Designation of Sanitation Grades to More Delivery Food Stores

In 2021, the MFDS will intensify sanitary management for delivery foods reflecting surging non-contact distribution/consumption in the era of “New Normal,” develop areas that require sanitary management, and raise public awareness of the sanitation grade system so that it can be a standard to select a restaurant.

The Ministry will also provide technical support for restaurants that need the designation among those registered as delivery applications while expanding the designation centered around delivery food brands such as chicken and pizza following the change in the consumption pattern and increased sale of delivery foods due to COVID-19.

For better sanitation of restaurants and promotion of the restaurant sanitation grade system, the Ministry plans to have presentations to business operators and civil servants in charge and double its consulting efforts for small restaurants and those with pending grades.

At the same time, it will allow restaurants to mark the grade they receive on the packaging and expand the exposure of the grades in delivery applications.

3. Strengthening of Safety Management for Nation’s Nutrition

A. Leading Koreans to Moderately Consume Potentially Hazardous in Moderate

The MFDS succeeded in reducing sodium intake and constantly raising public awareness of reduction of sodium consumption through the projects to lower the consumption of nutrients that may harm the health of people. The daily sodium intake of Korean people decreased by at least around 32% from 4,831 ㎎ in 2011 to 3,274 ㎎ in 2018 while the awareness of sodium and sugar reduction increased from 62.6% in 2019 to 62.9% in 2020 and from 53.3% in 2019 to 53.5% in 2020, respectively.

To raise public awareness and encourage voluntary participation with regard to sodium/sugar reduction, the Ministry ran the “Hall of Minasu to Reduce Sodium/Sugar” by theme and subject. It also opened five online booths with diverse

themes such as correct information and practices on sodium/sugar and reduction actions as well as safety management of children's dietary lifestyle and provided various experiences to 50,000 citizens. Further, it operated an experience program to improve dietary habits under the theme of "As Much As Na 3,000 ㎎" with the participation of citizens who are very willing to exercise a healthy diet. It also held various events to attract people's interest in a healthy diet through talk concerts on health (twice) and "Minasu Cooking Classes with Chefs" (three times) using low-sodium/low-sugar recipes.

The annual event of "Sam-sam (not salty or mild in Korean) Cooking Contest," which aims to develop low-sodium recipes and encourage people's participation, was hosted in 2020 under the theme of "Playbook for Eating Alone" to discover and share recipes that consider sodium/sugar reduction and nutrition of a meal for people eating alone. The 40 selected low-sodium/low-sugar recipes among the prize-winning ones and entries were published as a cooking book titled "Sam-sam Diet IX." The book was also made into an e-book and distributed in online bookstores so that anyone can easily refer to it whenever they want.

In 2020, to form the nationwide consensus on sodium/sugar reduction, the Ministry made promotion videos throughout the year to be played via media highly relevant to people's daily lives such as media boards of apartment buildings and convenience stores, visual displays, subway screen doors and IPTVs for better understanding why lower sodium/sugar intake is necessary.

On top of it, the MFDS used social media such as YouTube (Minasu TV), Facebook (https://www.facebook.com/mfdsna), and a blog (https://blog.naver.com/mfds_nadown) as a part of its efforts to promote awareness of the necessity for the reduction among consumers. Via social media, it is actively communicating with people by regularly providing information on how to reduce sodium/sugar as well as low-sodium, low-sugar recipes.

Using vehicles for education that can be extended to the size of a classroom, the "Strong Eating & Drinking Exploration Teams" visited primary schools/nurseries and demonstrated how to read nutrition labels and cooking based on low-sodium, low-sugar recipes to prevent nutritional imbalance and obesity among children. The program that began in 2013 was provided 758 times and reached the total classes provided of 3,863 in 2020 (about 90,000 students). Based on such education on dietary habits, the Ministry guided children to consume sodium/sugar moderately. 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 to improve their nutrition/dietary life. The training program was held 20 times (286 trainees) and covered topics such as how to manage excessive or insufficient nutrients, tips for grocery shopping, how to store food materials, and the preparation of healthy snacks.

The MFDS develops and disseminates various content on the reduction of sodium and sugar. Its efforts include the development of tools for assessing salty and sweet taste, tools for teaching sodium/sugar reduction, and guidebooks for primary school teachers, sodium/sugar reduction practice/game tools connected with the curricula. The MFDS also holds quarterly national contests for UCCs and handwriting/calligraphy to promote policies to reduce sodium and sugar consumption and strengthen the practice of dietary safety among children.

The Ministry is committed to cutting sodium and sugar in food. It developed a technical guidebook for less sodium and sugar in hamburgers and soups/stews in HMR and delivered on-site technical consulting services, especially to small businesses. As for sugar reduction, the MFDS wrote a technical guidebook for fruit & vegetable drinks, coffee, and fermented milk and provided technical information to businesses that voluntarily joined the program including by analyzing the environment for producing products with less sugar content.

To reduce sodium and sugar in group meal services and eat-outs, the MFDS has been drawing up and distributing operation guidelines for Sam-sam Group Meal Services and restaurants which want to serve low-sodium dishes and providing on-site consulting and other support measures for nationwide meal services and

restaurants to help them reduce sodium. In particular, to expand the designation of participating restaurants, the Ministry mainly consulted franchises including Yellow Chicken and Ihwasoo Yukgaejang. To cut sugar content in the food served at franchise restaurants, the MFDS assisted in both developing low-sugar dishes but promoting and marketing the reduction by forging an environment where consumers would choose less-sweet drinks over soft drinks that come with a set menu and select additional sugar when ordering a drink.

B. Expansion of Nutrition Labeling of Children's Favorite Foods and Restaurants and Provision of National Nutrition Service

As a part of comprehensive measures to ensure children's food safety, the MFDS implemented voluntary nutrition labeling, beginning from January 2008, first for fast food companies, and then for pizza shops, coffee shops, and confectionery/bakery companies. In accordance with the Special Act on the Safety of Children's Eating Habits, starting January 2010, the Ministry made it mandatory to indicate the per serving content of calories, sugar, protein, saturated fat, and sodium for businesses (with stores of 100 or over) preparing and selling hamburgers, pizza, confectionery/bakery products, and ice cream among kids' favorite foods. Further, from 2008, the Ministry has been making efforts to induce the industries to join voluntary nutrition labeling by test-operating the policy at multi-use eat-out facilities and has developed and provided guidance on voluntary nutrient labeling for participating restaurants.

The Food Nutrient Database built by the MFDS aims to provide information on the nutrient content and consists of raw material, processed food, and eat-out menu databases. Via the Food Safety Korea, consumers can now easily utilize the database and find the nutrient content of the foods they consider buying. As for the Food Nutrient Database, the Ministry updated the raw material database, conducted system maintenance, and refined the processed food database per serving size, in pursuit of effective the databases.

The MFDS also provided guidelines on how to select and use foods for patients as well as support to promote relevant industries. Such efforts are aimed at the nutrition management of the vulnerable in terms of nutrition, which is an emerging issue following social changes including an increasing elderly population and a higher morbidity rate of chronic diseases. The guidelines on patient food choices for health experts and on the method of using patient foods for general patients and their families were developed and distributed to hospitals and health centers. To encourage the industries to participate in the market, the Ministry published and shared the guidelines on patient food export, recipes for people with dysphagia or chewing difficulties, and tailor-made diet management for people aged between 50 to 64.

chapter 3

Medical Products Safety

Section 1

Ensuring a Healthy Life for People through Safe Medicines

1. Advancement Of Pharmaceutical Manufacturing and Quality Control

A. Strengthening International Competitiveness in Pharmaceutical Manufacturing and Quality Control

1) Background

A) Improvement and International Harmonization of GMP Regulations for Pharmaceutical Products

Korea announced “Korean Good Manufacturing Practices (KGMP)” in Mar. 1977 as an established rule (No. 373) of Ministry of Health and Social Affairs (which is now the Ministry of Health and Welfare) and announced the “KGMP Guidance” in Jul. 1978 to have manufacturers voluntarily implement GMP.

In Jul. 1994, the country issued Article 7 of 「Enforcement Rule of Pharmaceutical Affairs Act - [Annex 4] 「Good Manufacturing Practices of Pharmaceutical Products」 to mandate manufacturers of finished products to comply with GMP and to evaluate

GMP practices by dosage form as a requirement for approval of finished products. Additionally, Korea adopted the GMP evaluation system based on six categories of dosage forms in 1997 to streamline the evaluation procedures, and obligated GMP compliances on active pharmaceutical ingredients (APIs) since 2002.

In Jan. 2008, the amendment of the 「Enforcement Rule of the Pharmaceutical Affairs Act」 introduced a “new GMP” which switched GMP evaluation from dosage forms to products, adding new concepts such as process validation, annual quality review and change controls, which in turn established a global level of GMP system.

The “new GMP” applied to new drugs in Jan. 2008, prescription products in Jul. 2008, non-prescription drugs in Jul. 2009 and active pharmaceutical ingredients in 2010. Therefore, pre-approval GMP evaluation and validation have been adopted to all pharmaceutical products, and ensure overall quality from API to finished products.

B) Support for the Entry of Local Pharmaceutical Companies into Overseas Markets

As a member of the Pharmaceutical Inspection Cooperation Scheme (PIC/S), the MFDS has been actively engaging in PIC/S activities since 2014, and supporting a variety of policies to upgrade Korea’s global reputation and enable domestic pharmaceutical companies to enter overseas markets.

2) Achievements

A) Internationally Harmonization of GMP Standards

Since Korea’s accession to the PIC/S in 2014, the MFDS has been striving to improve the GMP system such as revising rules to achieve the harmonization between domestic and international standards.

(1) Amending the 「Regulation on Safety of Pharmaceutical Products」, Etc.

In the case of specialized medicines produced under a contract according to the same process by the manufacturer of licensed items, the MFDS reformed the

regulation to have business establishments submit "GMP" data (three manufacturing units) for review and approval so that the Ministry can supply the medicines to the market after it confirms their quality.

(2) Amending the「Regulation on Good Manufacturing Practices of Pharmaceutical Products」

The main details are to clarify the GMP under the drug quality system and the scope of responsibility between the contractor and subcontractor and to specify cross-contamination prevention measures, actions against product defects, and follow-up study procedures.

(3) Establishment of Guidelines on Supporting Pharmaceutical GMP System

The GMP Guidance for Drug Substances (for the public) were amended to ensure quality and safety of drug substances through impurity control based on risk assessment of drug substance manufacturers (Mar. 20, 2020).

In addition, to raise the GMP level of manufacturing and quality control of generic drugs manufactured by Contract Manufacturing Organizations (CMOs), the Guidelines for Contract Manufacturing was published (Jul. 3, 2020).

(4) Communication and Cooperation with Industry for Improving GMP System

The MFDS operated a public-private consultative body for improvement and international harmonization of the GMP system throughout the year, and revised regulations, and prepared the Q&A through meetings and on-site visits; and heightened transparency and predictability of the GMP system through policy briefing sessions.

B) Preparation for Establishing QbD-based Pharmaceutical Smart Factories

The MFDS has been developing QbD application models and foundational technologies by dosage form since 2015, and posted the results on the MFDS website for the pharmaceutical industry. In 2020, the MFDS developed a model for laboratory-scale transdermal absorbers and eye drops, and carried out the "Process Validation Study of QbD-Applied Medicines" as a foundational technology.

The MFDS also held theory and practical training sessions on QbD for the pharmaceutical industry to foster QbD professionals, signed an MOU with the Ministry of SMEs and Startups (May 12, 2020) to increase QbD-based smart factories, and has supported SMEs and venture companies in food and drug and medical devices.

C) Support for the Entry of the Pharmaceutical Industry into Overseas Markets

(1) Effectuation of the Korea-Swiss Mutual Trust Agreement on GMP

The MFDS signed the first mutual trust agreement with Switzerland on pharmaceutical GMP on Dec. 18, 2019, and on Jan. 15, 2020, the "Mutual Trust Agreement on GMP Survey Results between the South Korean Government and the Swiss Confederation" came into effect. As a result, the two countries mutually acknowledged the results of GMP surveys on medicines, replacing GMP evaluation with GMP certificates.

(2) A Pilot Project to Sign the Korea-Singapore Mutual Approval Agreement on GMP

The MFDS has been pushing for a pilot project since Aug. 1, 2020, to sign a mutual approval agreement with the Health Sciences Authority (HSA) of Singapore. This is a process that evaluates whether the two countries' GMP regulations and systems are equivalent and conform to international standards. The MFDS and the HAS are reviewing GMP certificates and fact-finding reports issued by the other country.

(3) Activities as a Member of PIC/S

The MFDS was selected as a host for the 2023 annual seminar at the 2019 PIC/S Committee Meeting. However, due to a change following the COVID-19 pandemic, Korea has been finalized as host country for the 2021 PIC/S annual seminar.

(4) Korea-ASEAN Cooperation Project

Since 2015, the MFDS has invited ASEAN GMP investigators to Korea to visit domestic pharmaceutical sites, share the latest trends of GMP in each country and the inspection cases of Korean manufacturers. However, in 2020, the MFDS held the "Education Session and Conference for Korea and ASEAN GMP Investigators" in the non-contact (online) manner considering the COVID-19 pandemic situation.

3) Implementation plan

A) Continuous Efforts on Internationally Harmonized GMP Standards

MFDS will periodically review the amendments of PIC/S guidances to reflect them on domestic GMP regulations and guidelines so as to continue to achieve the international harmonization of the GMP system.

B) Establishment of QbD-based Pharmaceutical Smart Factories

MFDS will continue to develop and provide QbD models and basic technologies by dosage form to support the implementation of the QbD system, a core technology for pharmaceutical smart factories.

C) A Pilot Project to Sign the Korea-Singapore Mutual Approval Agreement on GMP

This year, the MFDS will keep implementing the pilot project to sign the Korea-Singapore Mutual Approval Agreement on GMP, which has been conducted from last August, and prepare a pilot project analysis report with the HAS.

D) PIC/S Activities

MFDS will attend various PIC/S activities such as sub-committee on training as a host of the 2023 PIC/S Committee Meeting and Annual Seminar to promote MFDS's recognition in the international community.

E) Korea-ASEAN Cooperation Project

The MFDS will strengthen GMP cooperation with ASEAN members to find ways to prevent overlapping GMP inspections between Korea and the ASEAN by training ASEAN GMP investigators and hosting Korea-ASEAN GMP conferences.

F) Securing a Route to Enter Emerging Countries by Establishing an International GMP Network, Etc.

The MFDS will expand its base for supporting domestic pharmaceutical companies to enter overseas markets by establishing an international GMP network, including pharmaceutical MOUs for GMP cooperation with Russia and Latin American countries.

2. Advancement of Pharmaceutical Approval and Review System

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

1) Development of the Guidelines for Approval and Evaluation through International Harmonization

The MFDS clearly presents the criteria for approval and evaluation of medicines and provides the guidelines for pharmaceutical approval and evaluation to enhance their predictability. Recently, the MFDS is seeking to enhance global competitiveness of the pharmaceutical industry by reflecting the industrial environment and the new and revised guidelines of the International Council on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH).

The MFDS has updated the Good Review Practice (GRP)-MaPP every year after

expanding and reorganizing pharmaceutical GRP into the GRP-MaPP, including item authorization and management tasks in 2015. Following the launch of the "Innovative Combination Product Support Unit," the Ministry separately registered 10 types of approval (9 types of licensing work and 1 type of information disclosure) in 2020 and formulated a new manual about the operation and procedure of the Innovative Product Coordination Council in July 2020.

To strengthen the global competitiveness of the domestic pharmaceutical industry, the MFDS continues to reflect science and technology development and the enactment and revision of ICH guidelines on Korea's pharmaceutical regulations and guidelines. In 2020, it enacted and revised 20 guidelines and guidelines, including the "Guidelines for Establishing New Drug Standards," applying the ICH guidelines.

The MFDS plans to continue to institute and amend global-level evaluation guidelines, including actively introducing the ICH guidelines. In 2021, the Ministry will revise 10 types of drug approval criteria and 13 types of evaluation, and actively reflect the ICH guidelines to its evaluation guidelines. Further, the MFDS is set to make its approval and evaluation guidelines more effective by collecting opinions from the pharmaceutical industry through briefing sessions and meetings while developing guidelines.

2) Providing Information on Safe Use of Medicines

Since 2010, the MFDS has published and provided drug safety manuals on various topics to help consumers use them safely and correctly in real life.

In 2020, the MFDS reinforced consumer accessibility by offering information in more diverse ways and utilizing the MFDS social media, card news, blogs, Instagram, and electronic boards. It delivered the safety information on dementia, Parkinson's disease, strokes, hyperlipidemia, high blood pressure, osteoarthritis, and senile depression for older people as well as the information on attention deficit hyperactivity disorder (ADHD) and cold medicines for children. Additionally, it provided the information on drugs for depression and panic disorder, which have emerged as a social problem due to the prolonged COVID-19, and correct usage of povidone iodine.

In 2021, the MFDS will provide information on how to safely use medicines for real life by investigating cases of misuse and abuse of daily medicines such as anti-smoking aids, constipation drugs, hyperhidrosis drugs, and insect bite medications.

3) Establishment of a Global-Level Evaluation System and Strengthening of Evaluation Expertise

The Korean pharmaceutical industry is promoting its status through "Korea's response" to the COVID-19 crisis, including an increase in export of domestic medical products. The MFDS is pushing to establish an advanced evaluation system based on sophisticated expertise to add to global competitiveness of the domestic pharmaceutical industry and support its continuous growth.

The MFDS set up an efficient and unified examination system by operating dedicated divisions in each field, including the evaluation of clinical protocols and the quality examination of advanced and generic drugs. It also actively utilizes external expert advisory groups in detailed fields such as quality, non-clinical trials, clinical pharmacology, and clinical statistics for scientific examination that reflects the latest information. In 2020, the Ministry concluded an MOU with state-run medical institutions to establish a continuous cooperative system such as personnel exchange and expertise sharing for the advice on drug licensing and clinical trial.

Based on the efficient evaluation system established in 2020, the MFDS will push for advanced examination measures, e.g., evaluation centered on drug products, safety and efficacy based on scientific evidence, etc.

4) Facilitation of Support for Rapid Medical Product Commercialization

The MFDS established the "Preliminary Consultation Division" as of Aug. 31, 2020, to support rapid commercialization of bio-health medical products. The division is in charge of consulting on the scope and requirement for future permission and clinical trial approval in the development process of medicines and medical devices. In an effort to overcome the COVID-19 pandemic early, it is operating the "GO/Fast Program" to promote high-intensity commercialization of treatments and vaccines.

The MFDS conducted 23 medical product development consultations and 109 clinical statistics consultations in 2020. For active preliminary counseling, it strove to strengthen communication with pharmaceutical and medical device industries and related agencies, and to listen to difficulties in the field and find solutions through briefing sessions and meetings. Moreover, it ran the "GO/Fast Program" to support rapid development of treatments and vaccines in the face of the COVID-19 pandemic, assisting with development consultations of 74 items (49 treatments and 25 vaccines).

The MFDS will continue to prepare measures for managing a regulatory history of the entire cycle, etc., in pursuit of more professional counseling and a stronger link to post-consultation licensing tasks in developing new technologies and medical products.

5) Establishment of a Fast Medical Product Evaluation System

On Aug. 31, 2020, the MFDS established the Fast Evaluation Division, and designated fast evaluation targets and worked out for an exclusive fast evaluation system for: a) medicines for treating life-threatening or critical diseases (including orphan drugs and development-stage orphan drugs), b) medicines for preventing or treating infectious diseases with a potential that may pose serious harm to public health, c) new drugs developed by innovative medical companies, d) Humanitarian Use Device (HUD), e) innovative medical devices, and f) innovative combination medical products.

In 2020, the Ministry designated four items, including selumetinib (orphan drug), etc. for fast evaluation, and standardized its work further by enacting fast evaluation guidelines. In 2021, it plans to strengthen the open examination system and secure transparency in the fast evaluation process by promoting external expert cooperation in new technology and new concept fields and setting the standards for preparing drug designation review documents for fast evaluation.

6) Efforts for International Harmonization of Pharmaceutical Evaluation

A) Korea's Activities at ICH

The MFDS has participated in the meetings of the International Council on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) since 2006, and became the 6th regulatory member in November 2016. Starting from 2011, the MFDS has been involved in the collaborative joint development of 31 ICH guidelines. It also jointly developed a total of 15 guidelines in 2020, including the final-approved guideline on reproductive toxicology (S5 (R3))", "nonclinical safety testing (S11 in support of development of pediatric pharmaceuticals, and "M7 assessment and control of DNA reactive (mutagenic) impurities in pharmaceuticals to limit potential carcinogenic risk—questions and answers (M7Q&A)."

The MFDS developed "APEC Harmonization Center (AHC)-ICH Online Training Program" together with the ICH. The program has been available through the AHC e-Learning center from August 2016 to provide education on the safety information management (ICH E2) guideline. The Ministry has developed and offered ICH guideline education programs and stability testing (ICH Q1), QbD quality evaluation (ICH Q8, Q9 and Q10) and toxicity test (ICH S2, S3, and S7) from August 2017. Since 2018, the MFDS has held "ICH guidelines training" sessions, and in 2020, it held contact-free sessions due to COVID-19 and broadcasted them online to the world via YouTube.

The Ministry (Health Insurance Review and Assessment Service) will attend ICH

Committee meetings in June 2021 (non-contact meetings) and November 2021 (face-to-face meeting in Canada).

B) Further Activities at APEC Harmonization Center (AHC)

The APEC Harmonization Center (AHC)[1], which was established under the NIFDS in June 2009, co-hosted 45 workshops and Center of Excellence (CoE) pilot training programs until 2019. The AHC provides regular online training programs for various countries by updating the ICH guidelines for safety (ICH S2, S3, S7), quality (Q3) and composite (M7) through AHC e-Learning Centers. The AHC plays a key role in promoting a roadmap for regulatory coordination and convergence in the APEC region by discovering performance indicators and measuring the status of implementation through the APEC Regulatory Convergence Key Performance Indicator (KPI) Project. It offered information necessary for domestic medicines to enter foreign markets by publishing "12* Approval Guides for Major Exporting Countries of Korea" in English and Korean.

* (12 Approval Guides) WHO, European Medicines Agency (EMA), South African Development Community (SADC), Gulf Cooperation Council (GCC), France, Germany, Italy, United Kingdom, Switzerland, Turkey, India, and Iran.

In 2021, the AHC plans to hold seven international workshops, including "Post-Pandemic Regulatory Reform and Convergence Discussions," and study the APEC KPI Project and trust-based regulatory convergence. In addition, it will prepare a revised version of the licensing guides for 10 APEC countries to provide details on changes and latest information in regulations on drug approval and evaluation.

1 The APEC Harmonization Center (AHC) is a standing official education institute of the APEC. It was endorsed at the APEC ministerial meeting and leaders' meeting and established within the MFDS (NIFDS).

B. Vitalization of Cooperative Projects with Global 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 sharing tasks and exchanging information, and organized working groups by field such as monitoring drugs and vaccines to provide a high-level leadership for solving regulatory or safety problems. ICMRA members have shared the status of each country and discussed their way forward.

The year 2020 is facing an unprecedented global crisis due to the coronavirus (SARS-CoV-2) pandemic. The ICMRA has strengthened global cooperation with state regulators to promote the development and evaluation of vaccines, treatments and diagnostic devices to prevent or treat coronavirus infections.

B) Achievements

The ICMRA held meetings to cooperate and share information among regulators since March 2020 to resolve a crisis caused by the unforeseen coronavirus pandemic. In 2020, it held 18 policy meetings, and eight workshops on vaccines, treatments, observational studies and real world research (RWE). The MFDS is also actively participating to share information and continue international cooperation to overcome COVID-19 by developing treatments, vaccines, and diagnostic devices.

C) Implementation Plan

Due to the prolonged coronavirus pandemic, the MFDS will continue to attend regular meetings and workshops in 2021 to cooperate and share information among

regulators on the development of COVID-19 treatments, vaccines, diagnostic devices and drug monitoring.

2) Cooperation with the Drug Information Association (DIA)

A) Background

The Drug Information Association (DIA) is a non-profit organization in pursuit of presenting directions for pharmaceutical safety and development, which has been expanding its range of activity serving as a venue to exchange advanced development information in the United States in 1990s; to exchange global information in 2000s; and to share fast-developing science and technology involving medicine in the 2010s.

The DIA holds an annual meeting around June every year. Last year, it was held by teleconference due to COVID-19.

B) Achievements

The MFDS attended the Committee of the Regulator (COR) meeting as part of the DIA annual meeting and discussed its main issues with pharmaceutical regulators of the US, the EU, and Japan.

C) Implementation Plan

The MFDS plans to regularly attend the COR to discuss regulatory issues with advanced countries in the pharmaceutical field, since a number of pharmaceutical experts and companies from many countries participate in the DIA conference, a representative occasion for medical products.

3) Further Cooperation with Overseas Regulators

A) Background

Thanks to growing R&D capacity of Korean pharmaceutical companies, domestically developed medicines with global competitiveness have been making inroads into overseas markets. The following preconditions are important for faster advance of these domestic medicines into the overseas markets: 1) securing the international credit rating of Korea's pharmaceutical safety management system and responding to non-tariff barriers in exporting countries; and thus 2) cooperative relations such as information exchange with the pharmaceutical regulators.

B) Achievements

The MFDS signed an MOU with Mexico (2016) for mutual cooperation in the GMP area, 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 and personnel exchange and capacity building. Additionally, the MFDS signed a memorandum of confidentiality with the European Directorate for the Quality of Medicines & Healthcare (2019) and the French National Agency for Medicines and Health Products Safety (2019) and the Danish Medicines Agency (2020) to exchange confidential information.

For Japan, Korea and Japan reached a consensus about more cooperation including simultaneously joining the PIC/S in 2014. Based on this, the MFDS signed the "Agreement between the MFDS and the Japanese Ministry of Health, Labor and Welfare to Establish a Foundation for Dialogue and Cooperation for Regulating Medical Products" in 2015. Besides, the Ministry designated drugs, drug substances, biological products, regenerative medical products, etc. as cooperation subjects and has hosted Korea-Japan Director general-level (annual) meetings. Together with this, it has held a public and private joint symposium with related associations of both states

to further private exchanges and has shared recent pharmaceutical regulatory trends.

For China, the MFDS signed an MOU with the country in April, 2009. In December 2013, the MOU was revised into the "Agreement on Food, Medicines, Cosmetics and Medical Devices between the Korean MFDS and the Chinese CFDA (China Food and Drug Administration), following the elevation of both agencies to a minister-level. According to reorganization of the Chinese government, the MFDS concluded a MOU in February 2019 with the CFDA regarding regulatory cooperation on medicines, medical devices, and cosmetics.

Vietnam pushed for a revision of its public bidding regulations for drugs since 2017 with increasing Korean pharmaceutical exports. The consequent lowest bidding rating of Korean medicines raised concerns over a drop in the Korean export worth about 140 billion won. The MFDS actively coped with it by leading Korea to join the PIC/S and the ICH, operating an internationally harmonized drug safety management system, and explaining excellent quality of domestic drugs. So, it could make Vietnam announce a revision which states that it would maintain the existing grade 2 for Korean products. In the process, the MFDS amended a MOU with the country in 2018 to hold a regular director general-level meeting to facilitate exchange of regulatory information and cooperation.

Apart from this, to lower the export barrier against countries in Central and South America, the MFDS registered Korea as an automatic pharmaceutical approval country for Ecuador in March 2014 and in turn, the MFDS drug approval has the same effect there. The cycle of Mexico's regular GMP inspection on Korean medicines became longer from 2 to 5 years through a GMP MOU with Mexico's Federal Commission for Protection against Sanitary Risk (COFEPRIS) in April 2016. This measure reduced the burden of time and cost for Korea's pharmaceutical companies. In 2015, the MFDS entered an agreement with Peru to approve Korea as a hygienically advanced country and registered the Korean Pharmacopoeia (KP), laying the foundation by which the KP can be officially recognized in Peru, like the U.S. Pharmacopeia or the European Pharmacopeia.

In 2018, the MFDS discussed cooperation methods among new ICH members at a bilateral meeting with Brazil and strengthened collaboration between agencies with Indonesia. In 2019, the Ministry shared recent pharmaceutical regulatory trends and cooperative measures by holding separate director-general meetings with China and Japan, apart from public and private joint symposiums. In each working-level meeting with Indonesia, Denmark, the Netherlands, and Russia, Korea and the other party discussed bilateral cooperation areas and had opportunity to explore emerging markets.

In 2020, the European Medicines Agency (EMA) signed a temporary agreement to maintain confidentiality in the exchange of information on COVID-19 diagnosis, prevention and treatment and associated infectious diseases, continuing to share information with the EMA regarding COVID-19 treatments and vaccines.

C) Implementation Plan

Based on improved confidence in the domestic pharmaceutical management system, such as ICH and PIC/S regular membership and listing on the EU Whitelist, the Ministry plans to establish an international cooperation system with Vietnam and Russia, which are promising export countries to the New South and the New North. Utilizing an MOU signed with the Vietnamese Ministry of Health in 2018, the MFDS is reinforcing cooperation in the pharmaceutical sector, and seeking to lay the foundation for pharmaceutical collaboration with Russia by exchanging information on drug regulations and systems and manufacturing on-site inspections.

The MFDS will continue to expand information exchanges on drug safety management based on confidentiality agreements with the European Directorate for the Quality of Medicines & Healthcare (EDQM), France and Denmark.

C. Expansion of Patients' Treatment Opportunities through Better Quality of Clinical Trials

1) Creating a Safe Environment for Clinical Trials that Are Trusted and Attended by the Public

A) Background

Clinical trials are crucial in expanding treatment opportunities by "development of new drugs" and creating social values such as higher productivity. Therefore, the MFDS is committed to giving more treatment opportunities for patients with rare diseases, safeguarding trial subjects' rights, boosting pharmaceutical development capability and enhancing Korea's competitive edge internationally.

B) Achievements

(1) Establishment and Implementation of the 5-Year Clinical Trial Development Plan

To formulate a safe clinical trial environment in which people participate with trust, the MFDS came up with the "5-Year Clinical Trial Development Plan" based on opinions from experts and civic and patient groups (August 2019). According to the plan, the Ministry will require regular reporting of all safety data evaluation results on clinical trial drugs; convert the current approval system on changing clinical protocols to a reporting system; acknowledge non-clinical trial data of non-OECD members; and conduct the preliminary clinical trial review system.

C) Implementation Plan

The MFDS will make "Development Safety Update Report (DSUR)" mandatory by phase for new drugs, to reinforce monitoring of clinical trial clients and ultimately ensure trial subjects' right to health.

Moreover, the MFDS will enhance status inspections on clinical trials of high risk such as those on domestically developed medicines according to their risks, which will contribute to intensifying credibility of clinical studies and protecting public health.

For Good Clinical Laboratory Practices (GCLPs), the Ministry plans to establish a roadmap for building an "international quality management system for clinical sample analysis" and manage it so that GCLPs can be fostered at a global level. The MFDS will separate sample analysis items from the Good Laboratory Practice (GLP, MFDS notification) and prepare GCLP management regulations in consideration of the characteristics of clinical trials like safety protection of subjects.

2) Improvement and Reorganization of the Regulatory Environment from Rapid Approval of Clinical Trials to Their Quality Control

A) Background

Public consensus has been formed that there should be a procedure to offer treatment opportunity for rare and intractable disease patients with no alternative treatment, such as terminally ill cancer patients.

B) Achievements

The MFDS changed the approval period for clinical trial drugs from "7 days" to "immediate approval" for patients in emergency conditions so that patients whose life is at risk or who have no alternative treatment including terminally ill cancer patients can use the drugs (May 2019). Also, it arranged an amendment to the Pharmaceutical Affairs Act to establish and operate a state-designated clinical trial review committee (Jul. 3, 2020).

The Ministry carries out detailed initiatives under the "5-Year Clinical Trial Development Plan" and supports the pharmaceutical industry to develop new drugs by improving regulations, including simple procedures for changing the designation of clinical trial education agencies (June 2019) and rational training hours of for employees and their recognition scope (January 2019).

C) Implementation Plan

The MFDS will improve the approval process to use clinical medicine for emergency patients and others. Multi-institutional clinical trials will be replaced with one-time central review by the Central Clinical Evaluation Committee. The MFDS expects this will enable seamless clinical trials.

3) Stricter Post-Management to Enhance Reliability and Performance Quality of Clinical Trials

A) Background

As domestic clinical trials increase, there is a growing interest in the system to protect the right of patients participating in clinical trials. Though the MFDS introduced the Human Research Program (HRPP*) to protect patient rights (2016), it should be improved given that it is limited to educational institutions. Moreover, patients, families and medical staff should be more aware of ethics and patient rights. So, the MFDS needs to develop effective education and promotional content.

COVID-19 and the resulting difficulty in on-site inspections have generated blind spots in management. As a result, in preparation for crisis situations, there emerged the need to operate a substantial non-contact survey.

B) Achievements

HRPP operating institutions expanded from 4 in 2017 to 15 in 2019 to improve the quality of clinical trials and protect the subjects more safely.

The MFDS introduced a differential management system from 2013 to conduct a survey on all institutions performing clinical trials, and established a mid- to long-term plan from 2019 to 2024, building a safety management foundation to ensure consistent management depending on grades.

In 2020, the Ministry surveyed 42 clinical trial institutions and 19 GCLPs regarding their operational status and compliance with clinical trial standards. It discussed the necessity of creating a remote monitoring environment for the quality and safety management of clinical trials to establish a basis for remote monitoring, such as verification of clinical trial evidence documents (November 2020).

C) Implementation Plan

Under the “5-Year Clinical Trial Development Plan,” the MFDS will make various system improvements to enhance domestic and foreign confidence in clinical trials, such as improving their quality and securing treatment opportunities for patients. At the same time, it plans to help Korea develop new drug development capabilities and position itself as a leader in the pharmaceutical bio industry.

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

A) Increasing Public Demand for Assured Use of Safe and Excellent Drugs

Owing to aging populations, higher incomes, and increasing chronic disease patients, there is more interest in medicines that support longer lives.

Besides, the increased desire for health and safety as basis of human life emphasizes a nation’s responsibility to help its people lead a healthy life by providing safe and excellent medicines and creating an environment where they can use medicines with confidence.

As pharmaceutical import and export are on the rise across borders in this globalized age, the MFDS aims to strengthen safety management of the entire cycle

of medicines from manufacturing and import to distribution and consumption, to meet the public demand for safe drug use through international-level safety management.

2) Achievements

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

In the manufacturing sector, 2020 is the last year of on-site surveillance based on risk assessment in conjunction with GMP conformity decisions (2018-2020). Therefore, the MFDS efficiently managed manufacturing sites through pharmacovigilance considering potential hazards. In other words, it monitored high-risk manufacturers more frequently for focused and repeated inspections of the entire fields, and intensively monitored essential areas for low-risk manufacturers.

N-nitrosodimethylamine (NDMA), an unintentional impurity, was continuously detected from drugs every year, from a hypertension drug Valsartan in 2018 to a diabetes drug Metformin in 2020. To cope with such a situation, the Ministry quickly decided to suspend manufacturing and sale of products that exceeded the provisional management standards and required the submission of data to verify manufacturing processes. Further, it proactively undertook the management of unintentional drug impurities by instructing the industry to evaluate the possibility of nitrosamine impurities, such as NDMA, and to conduct tests for all synthetic drugs used as main ingredients.

In addition, to enhance transparency in pharmacovigilance and support drug exports, when a pharmaceutical manufacturer calls for GMP survey reports at the request of foreign regulators, the MFDS provides the firm with them including the MFDS monitoring details.

In the import sector, the MFDS implemented a registration system of overseas manufacturing plants and their on-site inspection system in accordance with the Pharmaceutical Affairs Act (amended on Dec. 11, 2018, enforced on Dec. 12, 2019) to provide systematic on-site post-management of imported medicine manufacturers at the same level with Korean manufacturers.

As only manufacturer-registered medicines could be imported (Dec. 12, 2020), 1,884 overseas manufacturers (58 countries) were registered (as of Dec. 31, 2020). In the case of on-site inspection of overseas manufacturers, the Ministry conducted a pilot project (5 locations) for non-contact inspections due to the prolonged COVID-19, and reviewed data submitted (43 locations).

The MFDS selected importers for priority monitoring so that their on-site monitoring is conducted once every three years. It monitored warehousing, storage, and distribution, focusing on quality control of imported medicines.

In the renewal area, the MFDS assessed the outcome of operating the approval & renewal reporting system for medical products for three years (2018-2020). As a result, it found that 35% of medical products subject to renewal had expired due to a lack of manufacturing and importing performance, etc. This way, the renewal system has served as a mechanism to control medical products more safely.

In addition, it was mandatory for a pharmaceutical company's safety management officer to submit the results of analyzing and evaluating side effects as data on renewal applications (Regulation on the Renewal of Medical Products (Aug. 28, 2020); reformed regulations for stably implementing the renewal system by revising the relevant guidelines (Comprehensive Guidelines for Evaluating Drug Renewal (Dec. 22, 2020)) in order to clarify the procedures for renewal and the methods and standards for reviewing submission data. By providing information such as a civil petition guide, the MFDS improved the understanding of the renewal system and the predictability of renewal.

B) Reinforcement of User-Centered Safety Management of Pharmaceuticals

In the distribution area, the MFDS revised the recall guidelines for six regional FDS Offices to prepare unified procedures to ensure that the need for drug recall

and the reasons and grades for recall could be determined consistently. (Operating Guidelines for Recall/Disposal of Medical Products, Nov. 30, 2020).

The Ministry installed a system to block the sale of hazardous medicines at more drug stores and wholesalers (90.7%→93.2%) by crafting and publishing a system manual and upgrading system functions. In full operation of the cooperative system with the Korea Customs Service, it blocked the distribution of hazardous drugs quickly and thoroughly, by providing hazardous information promptly, etc. to manage medicines more safely at the customs clearance stage.

The MFDS operates a public-private consultative body for monitoring quality, which consists of medical experts and consumers, and thus collects and inspects distribution drugs, which reflect public interest and issues by time and season, to create a safe environment for using quality medicines.

In the labeling area, the MFDS set the guidelines for the location of braille (June 2020) to help the blind properly take drugs and understand drug information; and according to the implementation of the Full Ingredient Labeling System (July 2020), it guided the industry to carry out the post-measures thoroughly and promoted the system to the public.

In the advertising area, the Ministry continuously operated the “Public-Private Advertising Council” and the “expert communication channel” to collect opinions on the advertising system and the information guidelines and respond to changes in the advertising environment. Besides, it improved the review criteria for exaggerated advertisements (Aug. 23, 2020) to update the detailed review criteria for drug advertisements and clarify the criteria for non-conforming advertisements, aiming at that more fair and reasonable evaluation.

The MFDS tried to raise consumer awareness of drug safety. In addition to public relations on eradication of illegal distribution of drugs, it promoted drug safety management policies such as the Full Ingredient Labeling System and the grace period for registration of overseas manufacturers. Apart from life-oriented media such as subway electronic boards, it promoted communicative publicity via social media utilized by drug safety guards that are composed of ordinary people such as college students.

In particular, in 2020, the MFDS concentrated on social issues such as risky misuse and abuse of illegal steroids and etomidate, moving away from just promoting eradication of illegal distribution of drugs; It contributed to creating a culture of safe use of medicines in the amidst of COVID-19 by conducting non-face-to-face promotion using social media such as YouTube in on-site PR that involves consumers.

3) Implementation plan

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

As for the manufacturing area in 2021, the MFDS will convert the field monitoring method of pharmaceutical manufacturers into a “quality”-oriented monitoring system to improve some matters identified during risk-based field monitoring and will strengthen selection and concentration. On top of it, the MFDS plans to establish a testing and inspection system for impurities and proactively manage impurities that can be unintentionally mixed into drugs by forming “Industry-Academia-Government Drug Impurity Assessment Group” comprising related industries, academia and MFDS officials.

In the import area, the MFDS plans to continue stable operation of the registration system for overseas manufacturing sites, and to provide legal grounds and concrete measures for alternative implementation of on-site inspections in case of a long-term inability to conduct them due to COVID-19. This move is to make sure that there is no concern about a lack of safety control.

In the renewal area, to secure an effective renewal system, the Ministry plans to make it mandatory to submit additional sales performance data in addition to current manufacturing and import performance data; and secure safety and validity through regular renewal. Through these efforts, the MFDS will enhance

safety management of pharmaceutical products based on actually produced and distributed items.

B) Reinforcement of User-Centered Safety Management of Pharmaceuticals

In the distribution area, the MFDS plans to strengthen the Korea Good Supplying Practice (KGSP) by ensuring that storage temperatures are observed when transporting medicines to improve drug quality levels and distribution management, along with installing more systems to block the sale of hazardous drugs.

In addition, the Ministry will step up the management of customs clearance by solidifying a cooperative system with the Korea Customs Service, and to block illegal distribution points in advance by continuously harnessing and analyzing supply performance reports from the Health Insurance Review and Assessment Service (HIRA).

In the labeling area, the MFDS will amend the "Pharmaceutical Affairs Act," which mandates braille labeling of medicines for vulnerable people to easily understand drug information and by operating a consultative body for coming up with the "Code Labeling Guidelines for Converting Voice and Sign Language Videos" to deliver information more efficiently.

In the area of advertising, the MFDS will continue to operate public-private meetings and a communication channel with advertising experts to supplement advertising cases and standards in preparation for new settings.

In the consumption area, the Ministry plans to further expand collaborative and participatory promotions with people and related associations to promote new policies on drug safety management and spearhead a culture for consumers' safe use of medicines.

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

1) Background

The MFDS is collecting information on side effects of medicines in Korea for safety management. The information gathered is developed into safety information after assessing its validity by analyzing and reviewing the literature, investigating foreign licenses, and seeking expert advice. Then, it conducts safety measures such as changing licenses, ordering research, suspending sale, and recall and disposal, and provides information to relevant institutions, doctors, pharmacists and consumers.

2) Achievements

A) Collection of Pharmaceutical Safety Information

The MFDS established the Korea Institute of Drug Safety Risk Management (January 2012) dedicated to collection, analysis, and management of safety information, including side effects of medicines, and expanded the number of regional pharmacovigilance centers. As a result, domestic reports on side effects increased 2.8 times from 92,375 in 2012 to 259,089 in 2020.

B) Safety Measures Based on Domestic Pharmaceutical Safety Information Reports

After statistical analysis and literature review based on domestic side effect reports collected from consumers, hospitals, clinics, pharmacies, pharmaceutical manufacturers (importers), and regional pharmacovigilance centers, the MFDS developed safety information after consultation with the Central Pharmaceutical Affairs Review Committee, and took 21 safety measures in 2020, including changes in permission matters.

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

The MFDS collected foreign safety information through real-time monitoring of international organizations and foreign governments and foreign media, and distributed safety letters about lorcaserin in 2020 and changed precautions for propofol, a body anesthetic.

D) Provision of DUR (Drug Utilization Review)[2] Information

The MFDS has developed and provided DUR information since September 2005, after the "Service for Development and Provision of Standards of Using Drug Products" was transferred to the MFDS (then Korea Food & Drug Administration) from the Ministry of Health and Welfare (HIRA). This DUR information on inhibited mix, etc. is available to doctors/pharmacists in real time through the "System for Supporting Prescription Dispensing of Drug Products" of the HIRA. The Ministry is continuing to develop DUR information in new areas while gradually expanding the scope of targeted drugs.

E) Providing Pharmaceutical Safety Information Customized to Consumers

To prevent consumer damage by providing safety information tailored to consumers' characteristics, the MFDS conveyed various content: anti-smoking supplements safety leaflets and card news, gout medicine Allopurinol, Cefaclor antibiotics, influenza treatments, and cold medicines, and safe pharmaceutical use for couples in childbearing years and pregnant women.

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

The MFDS offers the analysis result on the correlation between use of drug products and side effects using the claims data of the National Health Insurance Corporation and the HIRA. In 2020, the MFDS conducted linkage analysis for sulphonyl urea and so on.

2 DUR (Drug Utilization Review): An institution or system to guarantee that drug prescription is appropriate and necessary in terms of medicine and do not yield improper medical results.

3) Implementation plan

The MFDS established medical information on 19 million patients from 15 medical institutions nationwide as a Common Data Model (CDM) by 2020, and plans to involve more institutions. Besides, to prevent predictable side effects and protect national health, the MFDS will devise a second DUR information development plan for the mid- to long-term (2021-25) to continue information development for the vulnerable and by reflecting social needs.

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

1) Background

When unpleasant adverse reactions may occur even with proper use and there are victims who die or become disabled or hospitalized, the MFDS introduced and enforced a damage relief system for adverse drug reactions from Dec. 19, 2014, by which the government compensates the damage. The relief system operates without any legal proceedings, backed by contributions from pharmaceutical companies.

2) Achievements

Since the implementation of the side effects relief system, the scope of compensation gradually expanded to pay patients and bereaved families the death compensation, temporary compensation for disability, funeral expenses, and medical expenses. From 2015 to 2020, 702 applications were filed for damage relief, and 502 cases were paid 8.47 billion won.

3) Implementation plan

In 2021, the MFDS plans to open a new counseling phone channel (14-3330) exclusively for damage relief and keep promoting customized public relations. In addition, it will gradually increase target drug ingredients provided through the DUR service to avoid recurrence of side effects in victims.

D. Stable Supply of Rare and Essential Medicines

1) Background

A) Establishing the Foundation for National Supply of Rare and Essential Medicines

It is a vital national obligation to expand proper treatment opportunities for patients to maintain people's right to life. However, due to high dependence of rare and essential medicines on foreign countries, the supply and price of medicines were unstable depending on drug inventory affected by overseas situations, causing difficulties in stabilizing supply and demand.

As a result, the MFDS formed the Council for the Stable Supply of National Essential Medicines, involving nine ministries and five professional organizations in March 2016 after mutual consultation.

Currently, 504 items by field, including infectious disease control and industrial health, were selected as national essential drugs, and 333 items were selected as rare drugs through recommendations from relevant ministries and professional organizations. And they were designated through procedures under the Pharmaceutical Affairs Act and its sub-regulations.

2) Achievements

A) Acquiring Treatment Opportunities for Patients through National Supply of Rare and Essential Medicines

As of 2021, there are 504 national essential medicines and 333 rare medicines. In July 2020, as a supplementary budget, the MFDS secured 4.2 billion won for drug costs of the Rare Essential Medicine Center. This allowed the Ministry to store adequate inventory for the use of three months and establish a timely supply system. In addition, the MFDS became able to supply medicines more reliably next year by consulting with the Ministry of Economy and Finance (MOEF) to use the cost which is recovered after the sale of rare and essential drugs, instead of returning it to state coffers as before.

To support stable supply of essential drugs, the MFDS proceeded with consignment manufacturing business along with the pharmaceutical industry, and continued to support patients' treatment by commissioning the manufacture of tuberculosis therapies (60,000 ampoules) and children's anticancer drugs (8,000 vials) in 2020.

To gain treatment opportunities for COVID-19 patients, the MFDS additionally designated COVID-19 treatment drugs and vaccines as national essential drugs in July 2020 and February 2021, respectively.

3) Improvement Plan

In 2021, the MFDS plans to further enhance supply stability of national essential drugs. To do so, it will strengthen the supply management system by devising three-year comprehensive management measures, improve the drug stockpile management system of each ministry, and support the manufacture through the domestic pharmaceutical industry. Besides, the MFDS plans to actively operate the supply management system by utilizing the ministerial cooperative mechanism to

expand patient treatment opportunities by holding regular meetings of the Council for the Stable Supply of National Essential Medicines and updating the national essential drug list.

4. Sharpening the Competitive Edge of Pharmaceutical Companies by Supporting the Response to and Use of the License and Patent Linkage System

A. Sharpening the Competitive Edge of Pharmaceutical Companies by Supporting the Response to and Use of the System

1) Background

According to the Korea-US Free Trade Agreement (FTA) signed in 2007, the License-Patent Linkage System, in which the patent is considered during the pharmaceutical licensing procedure, was introduced to protect patent rights associated with 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 licensing of priority sales items, were revised in Mar. 2015. After the implementation of the license-patent 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 license-patent linkage system that led to the emergence of patent issues in the development and launch of pharmaceuticals, the MFDS has been investigating and analyzing information on domestic and foreign patents and licenses related to pharmaceuticals to support the development of pharmaceutical firms.

The MFDS also provided specialized education sessions four times to support pharmaceutical companies to effectively cope with and utilize the system by understanding the license-patent linkage system and respond to patent disputes and improve business capabilities.

3) Implementation plan

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

The Ministry will regularly analyze and disclose license · patent information such as list of drugs whose generics have not been released though the patent of the original drug had expired, and examine and analyze success stories of receiving US pharmaceutical patents.

MFDS will establish patent information on newly listed drug products and investigate and analyze overseas case information. Through these measures, the Ministry will offer more information for product development and export.

Further, the MFDS will continue efforts to reinforce competitiveness of the pharmaceutical industry. To this end, it will share recent issues and trends in responding to the patent-license linkage system and discuss cooperation measures through a policy forum and private-public consultative body, and provide relevant education to system-related personnel in pharmaceutical companies.

5. Laying the Foundations for Safe Use of Narcotics

A. Pan-government Coordination for Safety Control of Narcotics

1) Background

Now that surging misuse and abuse cases of illegal narcotic drugs—including a traffic accident and narcotics inhalation of a worker at an industrial complex—the public has become more concerned about them. In view of the circumstances, the MFDS responsible for their safety control has run the "Narcotics Handling Reporting System," the world's first computerized system for reporting thereof. However, in a situation where drug crime continues, it is necessary to establish an efficient crackdown system by sharing information with investigative agencies such as prosecutors and police through a narcotics council.

2) Achievements

A) Building up Prestige as a Pan-government Control Tower of Narcotics Safety Management

The Narcotics Safety Planning Director, in charge of the whole cycle of narcotics safety management, is the assistant administrator of the "Narcotics Council" and is intensifying its role as a control tower of narcotics safety management by expanding the "Working-Level Narcotics Council" and supervising performance of related ministries.

In 2020, policy importance was highlighted by establishing the measures for drug safety management and holding a special enforcement coordination meeting (chaired by the Prime Minister) and a vice minister meeting (chaired by the head of the Office of the Prime Minister) one time each. Through this pan-governmental national policy, the Ministry gained achievements by conducting a joint crackdown with related agencies to eradicate the distribution of narcotics as discussed at the vice-ministerial meeting, arresting 2,701 illegal drug users, arresting 542 people and confiscating 72.2 kg of psychotropic drugs (48.8% from a year ago) and 81.8 kg of hemp (64.1% from a year ago).

B) Establishing a Cooperation System for Pan-government Information Sharing and Monitoring/Investigation to Eradicate Illegal Narcotics

Cooperation between government ministries is very crucial in sternly shutting off illegal narcotic drugs. Therefore, the Narcotics Safety Planning Director began operating the "Pan-government Enforcement Council" since March 2019. It consists of six agencies – the MFDS, Supreme Prosecutors' Office, National Police Agency, Korea Coast Guard, Korea Customs Service and National Forensic Service. It has constructed an occasional cooperation system between drug control and inspection agencies, shared drug big data, and discussed and cooperated on the direction of monitoring and investigation, with an aim of fostering close collaboration among member agencies to promptly respond to narcotics issues at home. To tackle narcotics issues as a responsible ministry of narcotics safety management, the MFDS has operated the "Narcotics Handling Reporting System," which is the world's first computerized system.

3) Implementation plan

With the Narcotics Integrated Management System (NIMS) for reporting their handling, a base was forged for scientifically and systematically controlling the whole cycle of narcotic drugs. The MFDS will build and maintain a methodical safety management framework e.g., drug monitoring, enforcement and investigation by utilizing the big data from the system and providing it to related agencies and establishing a cooperative mechanism.

Additionally, as a national control tower of narcotics safety management, the

MFDS will operate the "(Working-Level) Narcotics Council" on the regular basis and thus have in-depth discussions to comprehensively respond to drug issues, and strengthen the institutional cooperation system through these processes.

Further, it will share latest information on narcotics and the hazard of new drugs with relevant government agencies using various information magazines.

B. Expanding Support for Rehabilitation of Drug Addicts

1) Background

A) Growing Need of Rehabilitative Education for Drug Offenders and Addicts

Since the number of drug offenders in Korea exceeded 10,000 in 2015 with 11,916, the number of drug offenders exceeded 10,000 every year, marking the highest number ever with 18,050 in 2020. Korea can no longer be called a drug-free country, and four out of ten drug offenders incur social costs, including high medical expenses, due to the recurrence of crimes.

In the past, drug offenders were handled as criminals and controlled mostly by legal punishment. However, with their fast increasing number, the perception on drug addiction has been changing: drug problems can no longer be left unchecked as a personal matter and should be managed as a social problem. Against this backdrop, it has become more vital to provide rehabilitative education to prevent repeated crimes and assist drug offenders to return to society.

* Yearly number of drug offenders: '15 (11,916) → '16 (14,214) → '17 (14,123) → '18 (12,613) → '19 (16,044) → '20 (18,050)

2) Achievements

A) Introduction and Operation of a Mandatory Education System for Drug Offenders

The MFDS made it mandatory for drug offenders to be educated, to prevent a repeated offense, by amending the Narcotics Control Act in December 2019 and implemented the action in earnest (from Dec. 4, 2020) and prepared the educational sessions with KRW 650 million in budget.

Further, the Ministry developed education programs through outsourced institutions to ensure substantial educational content (Dec. 20, 2020), and built the foundation for quality education services to forestall repeat crimes: the manuals for instructor training and counseling and the software for rehabilitation education, counseling, and instructor management.

B) Establishment and Operation of an Addiction Rehabilitation Center in Yeongnam

Although there have been difficulties in offering recovery services to drug addicts living outside the metropolitan area due to distance, the Addiction Rehabilitation Center in the Yeongnam region (Gyeongsang-do) enabled the region to provide integrated rehabilitation services that encompass education, counseling, rehabilitation and social return. As a result, the MFDS is able to deliver practical support for drug addicts to return to society even after the end of mandatory education, in connection with individual recovery services of the center.

3) Implementation plan

An addiction rehabilitation center, which had only been operated in Seoul, was additionally established in Yeongnam in 2020, to facilitate accessibility of drug addicts. Nevertheless, the service is unavailable for drug addicts in Chungcheong and Honam (Jeolla-do), giving rise to the need for more centers. In 2022, the MFDS plans to actively construct centers in Chungcheong and Honam to resolve a gap between regions. Until addiction rehabilitation centers are installed, it will ease inconvenience of drug addicts there by providing them with counseling and education through 13 regional preventive counseling centers that act as rehabilitation centers.

Moreover, the Ministry will train and increase rehabilitation instructors to achieve the solid operation and educational effects of compulsory education for preventing repeat crimes.

C. Pursuing Advanced Research and Analysis on the Pattern of Using New·Illegal Narcotics

1) Background

New/illegal narcotics have been increasing fast in recent times along with their misuse and abuse. However, there is no accurate statistic data on the patterns of their use, i.e. substance types and used amounts, and such information is simply estimated through investigations, enforcements and detections, which limits the efforts to create preemptive safety control measures. Meanwhile, advanced regulators in Europe, etc. have constantly analyzed use patterns of illegal narcotics with a scientific technique (sewage epidemiology[3]) and harnessed the findings in making policy decisions. Agreeing on a necessity to establish preemptive countermeasures through the methodology, Korea introduced it in 2020 after preparations such as collecting and reviewing domestic and foreign data on the residual amount of drugs in living sewage from 2017.

2) Achievements

In an attempt for preemptive safety management policies, the MFDS secured KRW 1,176 million as a budget for 2020, and allocated the same budget to continue the project in 2021.

With respect to the 2020 project, the Ministry achieved results in analyzing the drug use behavior of the Korean people in daily life by completing the second sample analysis as of December 2020, and detecting 9 types of 21 analytical materials.

* Methamphetamine, amphetamine, ketamine, phendimetrazine, propofol metabolites, methylphenidate, phentermine, ketamine metabolites, methylphenidate metabolites.

3) Implementation plan

Following the 2020 pilot project titled "Investigative Study on the Use of New and Illegal Drugs," the MFDS plans to launch its main project with a budget for 2021. The key points of the 2020 pilot project: a) a study on monitoring of sewage epidemiology-based drug usage, b) a study on regional residential and floating population calculation techniques, and c) a study on analysis, evaluation, and utilization of monitoring results. To ensure consistency, the Ministry is set to perform a survey analysis for more precise monitoring, considering the characteristics of each region and time. In doing so, it will create a comprehensive safety map including analysis of new and illegal drug use patterns by region and time in Korea to assure precise drug safety management policies in future.

3 Sewage epidemiology: This method is collecting samples from sewage treatment plants and analyzing the type and amount of residual narcotics with professional equipment (LC-MS/MS and the like) and estimating the amount of used narcotics in proportion to the population considering the sewage inflow rate, the number of the population in the sewage collection area and human metabolic rate. It can be deployed as a method for monitoring and researching illegal narcotics.

6. Strengthening Safety Management of Narcotic Drugs

A. Implementation of a “Helper for Safe Use” System against Misuse and Abuse of Narcotics

1) Background

The MFDS amended Article 11 (Report of Handling Narcotics) of the「Narcotics Control Act」(May 18, 2015) for more exhaustive safety management of narcotics to address risks such as illegal leak and misuse and abuse of narcotics for medical use. After this system started operation, analysis results on their prescription and administration data revealed a number of abnormal cases of suspected misuse and abuse of narcotics. The Ministry plans to more actively address those cases by analyzing prescription data in the system and setting the criteria for misuse and abuse of narcotics.

2) Achievements

The MFDS first implemented a system named “Helper for Safe Use” concerning the cases suspected of misuse and abuse of narcotics based on analysis of prescription data of physicians. This system serves as a written warning system for physicians who may prescribe and administer narcotics wrongly or excessively beyond safety standards. Its procedure is as follows: the Ministry offers information and carries out follow-up observation in the first stage; if there is no change in prescription or administration, in the second stage, it checks submitted opinions after a written warning; if there is no change in prescription, it takes measures such as on-site investigation. In December 2020, the Ministry activated Helper for Safe Use for appetite suppressants and notified in writing (step 1) a total of 1,755 doctors who took prescriptions outside of safety standards of their possible violation and has tracked and managed the prescription details are after the written notice.

Image 3-1 **Procedure for the Helper for Safe Use for appetite suppressants**

(As of Feb. 1, 2021, Source: Narcotics Management Division)

3) Implementation plan

In 2021, targets for “Helper for Safe Use” will expand to zolpidem, propofol, narcotic painkillers and anti-anxiety drugs in addition to appetite suppressants. Currently, there are limitations in visiting and checking all medical institutes suspected of immoderate use of narcotics. Therefore, the MFDS anticipates that the “Helper for Safe Use system” will induce doctors to provide appropriate prescriptions with proactive warning and aggressive response to suspected cases.

B. Creation of an Autonomous Misuse Prevention Environment Based on Big Data

1) Background

After operation of the Narcotics Integrated Management System (NIMS), an annual average of 46,000 people report the used amount of 1.72 billion ea (tablet, vial). Since a single case of reported information contains 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.

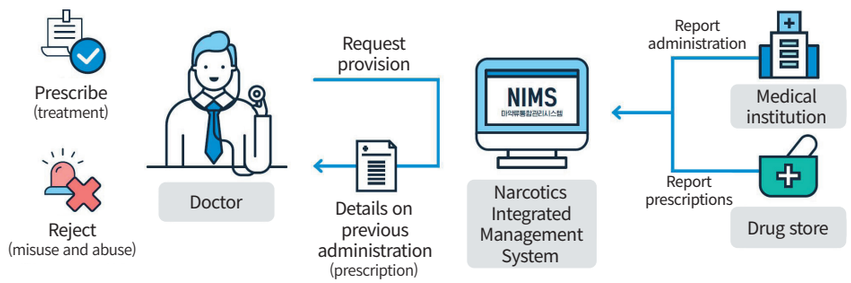
The MFDS is implementing policies using big data to realize safety management of narcotics. Using big data, policy authorities can exploit information from narcotics handlers like doctors and pharmacists and deliver related information to patients and handlers, and also develop, process, and share statistics with researchers or the public.

2) Achievements

Previously, if a patient does “medical shopping” at several medical institutions where medical narcotics are prescribed excessively or overlappingly, it was difficult for the doctor to confirm the details in advance and properly make prescriptions. To solve the problem, the MFDS is creating an autonomous environment for appropriate narcotics use by making doctors check their patients’ medical drug administration history before prescription and administration and allowing them not to prescribe and administer narcotics if they are afraid of misuse.

Image 3-2 Information Net for Preventing Medical Drug Shopping

(As of Feb. 1, 2021, Source: Narcotics Management Division)



Until now, it has been hard to exactly quantify the extent to which Koreans use medical narcotics. After the initiation of Mandatory Narcotics Handling Reporting System, all handling details are reported, making it possible to analyze various types of information. Analysis data to June 2020 showed that one out of 2.9 Koreans used narcotics for medical use and those in their 50s were ranked as the largest group to have used narcotics at 21.1%. The MFDS offered such analysis data to the public as press releases and card news. Especially, the MFDS analyzed prescription data on ADHD drugs, painkillers, anti-anxiety drugs, zolpidem, propofol and appetite suppressants, and provided the findings to individual doctors so that they could examine their prescriptions to moderately prescribe narcotic drugs for medical use and safely manage them.

In post-management, the MFDS selects hospitals and clinics suspected of illegal use and abuse, such as administration to the dead, false record on resident numbers, and medical drug use for purposes other than allowed use, by analyzing big data; it operates an efficient inspection system through joint intensive investigations by prosecutors and police and field response teams, too. In addition, the Ministry supports local offices and governments to directly check drug handling information through the reporting system such as the need for management of drug handlers by drug and type, and suspected misuse and abuse cases and to use the data in selecting monitoring targets and making a plan for surveillance.

3) Implementation plan

To ensure moderate use of narcotic drugs for medical use, the MFDS plans to expand a service with which doctors or patients can check administration histories for medical narcotics in the NIMS, from 3 types of propofol, zolpidem, and appetite suppressants to 49 types of drugs in 2021. 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 refrain from misuse and abuse by confirming administration data. Meanwhile, as this service makes it possible to check illegal cases of patient ID theft, the management

authorities can also capitalize on the data for post-management.

For the letters on safety use of narcotics, the Ministry also will provide letters on eight kinds of drug by mail, adding two types of hypnotics and anesthetics from the existing six types (zolpidem, propofol, appetite suppressants, ADHD treatments, painkillers and anti-anxiety drugs), and will also deliver online letters to all doctors hoping to receive them.

7. Support for Fast Approval and Commercialization of Medical Products including Combination Products

A. Enhancement of Efficiency and Consistency in Handling Civil Service about Medical Devices

1) Strengthening the Medical Product Approval and Evaluation System

A) Background

The MFDS disbanded the “Innovative Combination Product Support Unit” (Mar. 4, 2019) as a temporary arm, and established a dedicated division as a regular arm under the manager on Aug. 31, 2020, for more professional approval and evaluation of medical products and support of their rapid commercialization. With reorganization of the medical product license review system, the Ministry established two divisions, the “Approval Office” and the “High-Tech Product Approval Office,” and started carrying out licensing work that had been done by the National Institute of Food and Drug Safety Evaluation (NIFDS).

B) Achievements

The “Approval Office” is responsible for licensing drugs, including biopharmaceuticals and herbal medicines, and improving the approval and

evaluation system for medical products as a whole. The “High-Tech Product Approval Office” is responsible for licensing biopharmaceuticals including medical devices, combination products, and quasi-drugs. The NIFDS established the “Preliminary Consultation Division” and the “Fast Evaluation Division” to shorten the period of commercialization of medical products subject to rapid review and to expand treatment opportunities for safe and new medical products. The “Preliminary Consultation Division” conducts preliminary consultation from the development stage on the clinical protocol and license application for expedited review, and the “Fast Evaluation Division” conducts a quick review when a company applies for an item approval.

C) Implementation Plan

Through this reorganization, the MFDS will focus on establishing a general management system for medical products (medicine, bio, quasi-drugs, medical devices) approvals and on increasing the consistency of approval and evaluation. It also plans to establish a notice on prior consultation by integrating separate provisions for consistent operation of the Preliminary Review System.

2) Stabilization of an Applicant-Oriented Drug Approval System

A) Background

The MFDS runs the “Preliminary Review System”, the “System for Designating a Period for Supplementary Requests”, and the “System for Coordinating Supplementary Requests” to enhance the predictability and transparency of the affairs of approval and evaluation of medical products and to support the rapid commercialization of medical products.

B) Achievements

(1) Preliminary Review System

The Preliminary Review System is to quickly check whether submitted data meet relevant requirements and to notify the applicant of necessary data before official evaluation of civil petitions. The MFDS informs the applicant of the status of preliminary data by mobile text message within five days from the date of receipt of the petition.

The Preliminary Review System was introduced to improve the inadequate areas in the approval and evaluation process, which was conducted over three months (March-June 2019) since the establishment of the Innovative Combination Product Support Unit. It was firstly operated in the pharmaceutical area only, but the scope of its application has expanded from July 2019 to cover all medical products including quasi-drugs and medical devices.

In order to prepare a legal basis for the Preliminary Review System, the MFDS is implementing the system for medical devices in November 2019 while amending the “Regulation on Approval, Report, Evaluation, Etc. of Medical Devices.” In January 2020, the Preliminary Review System is expanded to all medical products such as medicines, medical devices, and quasi-drugs.

In addition, the MFDS operated the “Applicant Checklist” form in the electronic service counter for medicines to improve the operation of the Preliminary Review System so that the applicant could check submitted data. This provided convenience for civil petitioners by switching to entering data directly at the service counter without downloading relevant forms. Applicants can access the “Applicant Checklist” via Drug Safety Korea of the MFDS, and present a civil complaint and submit required documents, and enter the checklist preparer.

The expansion of the Preliminary Review System is expected to shorten the licensing period for medical products because efficient and rapid examination is possible.

(2) The System for Designating a Period for Supplementary Requests

The “System for Designating a Period for Supplementary Requests” has been in service since April 2019. This system requests an applicant to submit supplementary documents for the approval of the application, if required, within 2/3 (1/3 in case of medical devices) of the legal deadline even after the review process has started in earnest. In 2020, the cumulative compliance rate of medicines and quasi-drugs was 96% and that of medical devices 89%, exceeding the fast and supplementary compliance rate compared to the target in all medical products. It shows that the system resulted in the effective establishment of deadline for civil petitions about medical products and the prediction of the expected date of approval.

(3) The System for Coordinating Supplementary Requests

To hear diverse and objective opinions on primary supplementary requirements for item application, the MFDS operated a scheme to review and reply relating to the validity of supplementary requests through a third party the “Innovative Product Coordination Council.” In 2020, the MFDS held three council meetings, prepared a new manual on the coordination system in July, and updated related regulations in October. All this continued to increase the credibility of complaints.

(4) Official Communication Channel

The “official communication channel” is an official civil service consultation system related to approval to enhance responsibility by officially reflecting consultation results in the process of licensing medical products and raising work efficiency by minimize unannounced consultation.

In October 2019, the MFDS introduced a new “face-to-face evaluation” in the approval stage of the “Plan (Draft) to Expand Communication Channels with Medical Product License Applicants”; pushed for a revision of the notification system in April 2020 to introduce a face-to-face evaluation system and impose fees for approval and evaluation of medicines; and established an application and

history management function for “official communication channel” in the Drug Safety Korea. By doing so, the MFDS completed related system development. In August 2020, the MFDS enacted and distributed the “Official Communication Channel Operation Guidelines for Approval and Evaluation of Medical Products.” It mainly included the operation of the electronic civil service system for the channel, unification of the channel, and enhancement of consultation quality and accountability through a fee system.

The “official communication channel” is divided into the “Preliminary Review System” and the “Face-To-Face Evaluation System” according to the stage of medical product development. In the development stage, the MFDS uses the Preliminary Review System by adding a “prior meeting” to the existing “face-to-face meeting.” The new “Face-To-Face Evaluation System” in approval and evaluation stages are based on an “opening meeting”, a “complementary explanation meeting”, and an “additional complementary meeting.” The MFDS has been piloting new drugs since November 2020 and quasi-drugs containing new substances since March 2021, and plans to broaden the scope to newly developed medical devices and rare medical devices from September 2021.

(5) Operation of Internal/External Communication Channels for Medical Products

The MFDS operates internal and external communication channels to resolve difficulties related to approval and evaluation of medical products, through smooth communication between the government and industry, and to support rapid commercialization. As an internal communication channel, the Ministry is trying to establish a cooperative system and secure the expertise and consistency of those in charge of licensing medical products by holding nine meetings between the headquarters and local offices. As an external communication channel, the MFDS held seven meetings for public-private consultative group “Farm Together” in the pharmaceutical sector in 2020; six meetings for a public-private consultative body “Communication and Sharing (Ownership)” in the medical device sector; four meetings for the Council on the Improvement of the Drug Approval and Evaluation System; four meetings for the Council to Prepare Improvement Plans for Drug Substances subject to Registration.

C) Implementation Plan

(1) Expanding the Scope of Pilot Operation of “Official Communication Channels” and Establishing a Foundation to Settle Them

Nov. 2020, an “official communication channel” is being piloted for medicines (new drugs) and Mar. 2021, substance-containing quasi-drugs, and in September, the official channel function in the medical device electronic service system will be established. In addition, the MFDS will revise the Ordinance of the Prime Minister and related item licensing notice and fee regulations from January 2021 to establish the legal basis for official communication channels, and will impose fees and finalize detailed application targets and ranges for medicines, and begin full-scale implementation from June 2022.

(2) Facilitation of Improvement of Medical Product Approval and Evaluation Systems through More Internal and External Communication Channels

From 2021, the MFDS is planning to strengthen an innovative shared growth network between the government and industry by expanding public-private communication channels for medical products. Above all, the MFDS will lead continuous dialogue with the industry through non-contact communication methods to overcome difficulties in communication such as resolving pending issues and difficulties due to the suspension and delay of meetings, including limited face-to-face meetings due to COVID-19. In the past, a public-private consultative body “Communication and Sharing (Ownership)” gathered opinions from the industry through two associations – the Korea Medical Devices Industry Association and the Korea Medical Devices Industrial Cooperative Association. As the Act on In Vitro Diagnostic Medical Devices was enacted in May 2020,

however, the Communication and Sharing will strengthen communication with "in vitro medical device" makers by expanding communication channels to three associations and NIDS including the Korea In Vitro Diagnostics Association so as to listen to the voice of the scene.

B. Establishment of a Foundation to Standardize and Advance the Approval and Evaluation Standards for Medical Products

1) Support of Rapid Commercialization of Medicines and Introduction of Standard Forms

A) Background

In order to enhance transparency and completeness of medical products, the MFDS examined its guidelines and guidebooks in 2019. It legislated upwardly and enacted, revised, and abolished the guidelines to reflect examination results and the changes in the era of the Fourth Industrial Revolution. In addition, given the issuance method and forms of certificates are not standardized by medical product despite growing exports, the MFDS pushed for the reorganization of English certificate standards and the introduction of MedDRA for international harmonization of medicines.

B) Achievements

(1) Supporting Rapid Commercialization and Securing Transparency through Wider Disclosure of Drug Licensing Information

As a result of the full inspection of guidelines and guidebooks in 2019, the MFDS took measures for 221 out of 263 guides to be improved (114 one-time instructions, 149 guidelines, etc.), out of 783 guidelines in total. In July 2020, it prepared a sub-category system and category numbers to quickly classify sanitary pads among quasi-drugs and arranged a revision (draft) to the "Designation of the Medicine Scope" to overhaul item category numbers of licensed (declared) products.

In June 2020, the Ministry held a meeting of the cell therapy industry and the Central Pharmaceutical Affairs Review Committee on reauthorization of cell therapy in order to prepare a plan to reauthorize cell therapy under the Advanced Regenerative Bio Act; and established a plan to overhaul "blood product" approvals in December.

In the case of medical devices, the MFDS handled a total of 73 cases until December by operating a "Pre-Inquiry System" for minor changes in January 2020, and published a related casebook to support prompt commercialization for the medical device industry.

To provide more information on medical products, the Ministry published an approval report that had previously been limited to medicines and medical devices but came to include quasi-drugs. It also revised, in November 2020, the civil petition guide for improved new drugs and quasi-drugs.

To prepare a plan to standardize the approval and evaluation procedures for medicines, the MFDS clarified the procedures for handling civil complaints by establishing a single civil petition procedure for stability and improving the procedure for examining the quality of drug substances subject to registration. To classify medical products and create a safety management foundation for the entire life cycle, in February 2020, it formulated a roadmap of combination products for developing approval and evaluation guidelines (20 types); enacted the "Manual on Combination Medical Products and Their Classification Procedure"; published the "Casebook on the Classification of Combination Medical Products" and the "Collection of Overseas Post-Management Systems for Combination Medical Products"; and held a workshop for experts in an attempt to support rapid commercialization, including introduction of commercialization cases in major countries.

(2) Introduction of Standard Forms of English Certificates and the Disclosure of Forgery Identification Systems and Procedures

To introduce English certificate standard forms, the MFDS compared and reviewed certificates in each field with certificates from overseas regulators such as the WHO, and revised and distributed the English certificate issuance manual. It also disclosed and actively promoted standard forms and forgery identification systems and procedures to governments and public organizations related to medical products in top 25 exporting countries.

(3) Formal Introduction of MedDRA in Approvals for International Harmonization

To standardize and internationally harmonize the terms for drug approval, the MFDS officially introduced MedDRA for new applications from May 2020. In addition, it is pushing to revise regulations so that drug approval and evaluation personnel, who use the integrated drug information system, can first apply MedDRA when reviewing and writing permissions.

(4) Pilot Operation of the "DMF Pre-Registration System" to Link Quality Review of Drug Substances and Drug Products

In June 2020, the MFDS piloted the Drug Master File (DMF) Pre-Registration System (linking quality review of drug substances and drug products) to improve comprehensive quality control and evaluation efficiency between drug substances and drug products, and thus eased the registration requirements for drug substances subject to registration. In addition, it prepared and distributed detailed operation plans (procedures and Q&A), and improved the electronic civil service system for quality review. To establish a legal basis for the "Pre-Registration System for Drug Substances Subject to Registration," an administrative notice is underway on the revision of the "Regulation on the Registration of Drug Substances" and the enactment of the "Regulation on Pre-Review of Medical Products."

C) Implementation Plan

The MFDS plans to continually overhaul laws and guidelines to standardize and advance medical product approval and evaluation standards. It will contribute to improving public safety and reliability with quick permission of essential medical products such as COVID-19 treatments, diagnostic reagents and masks and come up with preemptive support policies for new innovative products. Besides, it will improve regulations for international harmony, such as enhancing efficiency by linking of examinations of drug substances and drug products and easing the requirements for drug substance data on the condition of submitting it at the time of license application.

C. Support for Rapid Commercialization of Combination Medical Products

1) Background

With the global rise in aging population and increased demand for consumer-tailored products, the global market for combination products of a new concept and form is on a steady increase, and is witnessing a competitive release of many medical products that cut across industries combined with the latest technologies.

The convergence of medicines and medical devices is becoming more complicated in relation to combination products inquired about by civil petitioners, and the coverage of combination products is expanding by supplementing shortcomings of existing products or combining conventional products. Therefore, it is necessary to preemptively offer various information on combination products and to properly classify, review and manage the products applied with new technologies.

2) Achievements

A) Delivering Information to Support Rapid Commercialization of Combination Medical Products and Secure Work Transparency

To ensure clarity, consistency and transparency in the process of classifying combination medical products, etc., the MFDS established standard classification procedures—"Combination Medical Products and Their Classification Procedures." Through this, the Ministry supported rapid commercialization and offered transparent administrative procedures by standardizing the consultation procedure between divisions, in terms of operating regulations and civil service for classifying combination products.

To provide clarity and predictability about the combination product classification conducted by researchers and developers and industries, and to support rapid product development, the MFDS prepared the "Classification Casebook of Combination Medical Products."

In an effort to assist with the industry in export and product development, the MFDS published the "Collection on the Post-Management of Combination Medical Products" after investigating regulations and data on distribution, sale, side effects, and recall of combination products.

B) Establishment of a Communication Venue for Combination Medical Products

In September and December 2020, the MFDS invited domestic and foreign experts on combination products to provide a communication venue for their developers and researchers. Although communication was made in a contactless online method because of COVID-19, the MFDS actively promoted it to the media by distributing press releases and requesting public relations cooperation from related agencies to induce participation of industries and others in need of export support.

In September, the Ministry created a section on convergence medical products at Global Bio Conference 2020 as an international conference to strengthen the global competitiveness of domestic combination products and share regulatory considerations and global trends. It was conducted online, attended by 4,259 people from 28 countries.

In December, the MFDS held an invitation training course (workshop) to support swift development of the domestic industry and its prompt entry into the market. To help the industry develop products, the non-face-to-face training course consisted of 10 professional classes, including approval procedures, domestic and foreign manufacturing and quality control trends, FDA review system, and patent protection. On the same day, real-time Q&A was arranged at the site to provide a place for communication between industry, academia, and related officials. 313 officials from 185 organizations, including 121 combination product firms and 12 medical institutions, participated in the course. The satisfaction rate of institutions, which need practical product development and export support such as companies and medical institutions, was 82.9%.

3) Implementation plan

To quickly classify combination medical products, the MFDS will continue to maintain online Q&A (electronic service system for combination products) while actively communicating with the industry by preparing an educational opportunity for domestic and foreign experts and providing information including FAQs on combination products and by supporting the development of combination products applied with various new technologies.

8. Establishment of a Public Health Crisis Response System

A. Enactment and Promulgation of the "Special Act on the Promotion of Development and Emergency Supply of Medical Products in Response to Public Health Crisis" (Act No. 17922, Mar. 9, 2021)

1) Background

In order to effectively respond to a public health crisis, it was necessary to lay the foundation for supporting the development of medical products and enabling emergency supply of goods. As various medical products* are intensively inputted at once in times of crisis, this special law was enacted in accordance with social demand for a quick and consistent response through a single legal system.

2) Achievements

A) Support for Developing Medical Products and Expedited Approval of Vaccines and Treatments

Based on the experience and the response system gained from responding to infectious diseases such as SARS and MERS, the MFDS supported and quickly approved the development of medical products to enable rapid diagnosis and prevent spread of COVID-19. This had secondary spread contained for a considerable period, and secured the time to support safe and rapid development and operate an approval procedure safely and quickly before vaccines and treatments were supplied. In addition, the MFDS promptly approved COVID-19 vaccines and treatments through prior consultation, expedited review, and conditional permission under the Special Act.

Table 3-1 Emergency Supply of Medical Products Related to COVID-19 under the Special Act

(As of Dec 31, 2020, Source: Pharmaceutical Policy Division)

No.	Date	Category	Description	Remarks
1	March 2021	Designating crisis-response medical products	Preventive medication for COVID-19 caused by SARS-CoV2 virus	- Designated No. 1 (AstraZeneca Korea COVID-19 Vaccine Inj.) - Designated No. 2 (Pfizer Korea, Comirnaty Inj) - Designated No. 3 (Janssen Korea, COVID-19 Vaccine Janssen Inj.) - Designated No. 4 (Green Cross Corp., Moderna COVID-19 Vaccine Inj.)
2	May 2021	Designating crisis-response medical products	Mask	
3	May 2021	Emergency Use Authorization (EUA)	COVAX-AstraZeneca COVID-19 vaccine	
4	May 2021	EUA	COVAX-AstraZeneca COVID-19 vaccine	

3) Improvement Plan

The MFDS is enacting the Enforcement Decree and Enforcement Rule of the Special Act on the Promotion of Development and Emergency Supply of Medical Products in Response to Public Health Crisis to prescribe matters delegated by the Special Act. After the enactment of sub-regulations, the MFDS plans to establish Korea as an advanced country in disease prevention and control by overhauling its organization, etc. and thus solidifying an institutional foundation to cope with both COVID-19 and emerging infectious diseases in the future.

Section 2

Advancing Safety Management of Biopharmaceuticals and Leading Innovative Growth of the Industry

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

A. Safety Management and Quality Management of Biopharmaceuticals

1) Background

The manufacturing process of biopharmaceuticals is not only complex owing to raw materials or materials derived from living things, but also difficult to maintain uniform quality and impossible to sterilize, making it more important to secure a more thoroughly sterile manufacturing process than synthetic (chemical) drugs. In this context, regulatory agencies and pharmaceutical companies around the world have continued to make efforts to produce safe and effective medicines with strict quality standards. In particular, the global community is also strengthening the mid- to long-term safety management of advanced biopharmaceuticals, such as stem cell and gene therapy drugs with little use experience, through follow-up studies

after release. Therefore, from 2020, Korea has implemented a safety management regulatory framework different from the existing Pharmaceutical Affairs Act by enforcing the Act on the Safety and Support of Advanced Regenerative Medicines and Advanced Biopharmaceuticals.

2) Achievements

A) Tougher GMP Management and Examination of Biopharmaceuticals

The MFDS enacted the “GMP for Biological Products, Etc.” (2001) and introduced preliminary GMP by item (2003) to secure quality of biopharmaceuticals at decent levels. The MFDS has also been operating revised measures including an improvement to allow manufacturers to apply for preliminary examination on GMP status assessment even before license application by creating GMP guidelines and manuals for manufacturing and quality control of biopharmaceuticals by reflecting their characteristics.

In 2014, Korea joined the PIC/S[4] with 49 member countries including the U.S., Japan, and Europe. Accordingly, the MFDS amended regulations to ensure that details on pharmaceutical GMP meet PIC/S rules, and implemented overseas manufacturer registration system (Dec. 12, 2019) to strengthen foreign factory management for imports. Like this, the MFDS has pursued both international harmony in the biopharmaceutical sector and better manufacturing and quality control.

B) Improvement of the Lot Release System

In June 2012, the MFDS reformed the national examination system for biological products, which had been in place from 1953, to form the “Lot Release System.” In 2014, it also revised the notice on the Regulation for the Procedure and Method to Designate and Approve the Lot Release Pharmaceutical Products, from the negative

4 Pharmaceutical Inspection Co-operation Scheme (PIC/S): An international organization joined by 49 countries, including the United States and Europe, to harmonize pharmaceutical GMP and improve quality of inspection systems

method (exempting some items according to the results after examining all) to a positive one (designating important examination items by risk stage). In 2015, the Ministry created specific standards for risk assessment to comprehensively assess and determine the risk of the factors affecting drug quality. In 2016, the MFDS amended the National Lot Release System by revising the "Detailed Guidelines for Evaluating Hazardous Stages for Differentiating Inspection Items for Lot Release Pharmaceutical Products." This way, it has been pushing for improving the system.

C) Setup of a Ground for Safe Use of Biopharmaceuticals over the Entire Life Cycle and Technical Support for the WHO's Pre-Qualification (PQ)

For prompt information sharing and consistent response to serious cases of adverse events after vaccination, a cooperation system was established among related ministries (institutions) (2013) and based on it, information on adverse events is shared every quarter. The MFDS works closely with the Korea Institute of Drug Safety & Risk Management and the Korea Centers for Disease Control and Prevention (KCDC) to establish an integrated management system for the vaccine's adverse events, and publishes and distributes safety instructions for vaccines every year.

In addition, the MFDS continues to produce and distribute self-injection instructions of biopharmaceuticals and related videos to support safe biopharmaceutical use because there are more permission and use of biopharmaceuticals injected by patients on their own without help of medical personnel.

To sharpen the competitive edge of domestic biopharmaceutical makers, the MFDS supports them to acquire PQ of the WHO, which can be a steppingstone for domestic vaccines to advance into the global market. To that end, the MFDS and the WHO signed a PQ cooperation agreement for vaccines in December 2016, and has yielded results such as reducing the WHO PQ certification period by more than 6 months by assisting with the "One-to-One Customized Expert Council" by company, etc.

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 programs. It also came up with the Roadmap to Introduce QbD and the Procedure for Developing QbD Application Models. The MFDS developed QbD models for genetic recombination, vaccine APIs and cell therapy products, and published guidebooks and guidelines for industry application.

E) Improved Safety Management of Blood Products including GMP Introduction

The MFDS established the guidelines for blood product GMP reflecting their characteristics (small volume manufacturing, simple process, etc.) (April 2014). Besides, it promoted legislation of blood product GMP for harmonization with international regulations and safety management, and instituted the "Blood Product GMP" (Jan. 4, 2017) and has implemented it since February 11, 2019. The MFDS prepared the "Blood Product GMP Manual" (June 2017) and "Evaluation Guide for Blood Product GMP" (June 2017) for relevant industries and evaluators to stably settle the new GMP. Further, with the Ministry of Health and Welfare, which had previously conducted blood safety monitoring for all blood collection centers, the Ministry conducted pilot evaluations and on-site education, and has developed and provided online education programs for blood product GMP workers since 2020.

F) Establishment of a Safety Management System for Advanced Biopharmaceutical Materials and the Enhancement of Safety Management after Marketing

Under the Act on the Safety and Support for Advanced Regenerative Medicine and Advanced Biopharmaceuticals enforced in August 2020, a safety management system has been established for human cells, etc. (cells/tissue of humans or animals, animal organs), which are raw materials of advanced biopharmaceuticals such as cell and gene therapy products. This secured the quality and safety of high-tech biopharmaceuticals.

Pursuant to the Advanced Regenerative Bio Act, follow-up studies of stem cell treatments and genetic treatments became mandatory to check adverse events for a certain period of time after administration, and sub-regulations were established to prescribe the study procedures and methods. Moreover, the Korea Institute of Drug Safety & Risk Management was designated as an "regulatory affairs center" to support and manage safety control of advanced biopharmaceuticals (September 2020).

G) Enhancement of Joint Responses to Distribution and Quality Issues of Influenza Vaccines

Meanwhile, in the wake of room temperature exposure and white particles of influenza vaccines during their distribution for national vaccination between September and October 2020, the MFDS is working to strengthen the vaccine management system with the KCDC. On top of it, it is push ahead with improvement measures to ensure that safe and effective vaccines can be supplied in a timely manner: upgrading the vaccine management system and solidifying verification at the lot release approval stage.

3) Implementation plan

For biopharmaceutical quality and safety management, the MFDS has been performing projects such as inspection on risk analysis bases, WLA listing, and QbD model introduction with the aim of providing the world's highest quality biopharmaceuticals and strengthening pharmacovigilance and international regulatory harmonization for safe biopharmaceutical use. It plans to establish a related computer network so that the follow-up study system, which is mandatory pursuant to the Advanced Regenerative Bio Act, can be operated efficiently.

B. Advanced Safety Management and Quality Management of Human Tissue

1) Background

Due to the aging society and rapid development of medical technology, the demand for human tissue has been growing in Korea every year. However, such demand cannot be fully met by domestic donors, and therefore, about 80% of the total demand is fulfilled by imported tissue. Human tissue requires special attention to safety management, such as quality, as it remains in the human body for a very long time. Since the enactment of the Safety, Management, Etc. of Human Tissue Act in 2005, the MFDS has established a safety management system such as mandatory confirmation of donors' medical history and drug administration history, compulsory attachment of Unique Device Identifications (UDIs) and bar codes to all human tissue labels, registration in the integrated safety management network for human tissue, and preparation of Good Tissue Practice (GTP).[5]

2) Achievements

A) Building Safety Management Capacity by Training Employees of Tissue Banks

In order to support workers in small and non-profit human tissue organizations, the MFDS is actively striving to bolster safety management of human tissue by providing their training from 2014 and revising related laws and manuals to establish and settle management standards fit for GTP, etc.

B) Enhanced Processing of Human Tissue Safety Information

To manage human tissues more safely, the MFDS enacted the "Guidelines

5 Good Tissue Practice: Quality control standards for all tissue banks for donation, collection, storage, handling, processing, preservation, and distribution of excellent and safe human tissues

for Processing Human Tissue Safety Information" in 2016 and "Instructions on Processing Human Tissue Safety Information" in 2020 to quickly and efficiently take follow-up action on domestic and foreign information. Through this, it is expected that public damage can be minimized by taking prompt measures for safety information on human tissues.

3) Implementation plan

The MFDS is training more workers since 2014 to strengthen the capacity of employees at tissue banks, while promoting non-contact online education to prevent the spread of COVID-19 in 2021. In addition, the Ministry will improve the HUman TIssue Safety management System (HUTIS), which is operated to strengthen the human tissue tracking system from 2015, to enable rapid and accurate tracking.

2. Provision of Medicinal Herbs Trusted by the Public and Safety Management of Natural Medicine

A. Establishment of a Foundation for Manufacturing and Supplying Medicinal Herbs Trusted by the Public

1) Background

As the population ages and resulting chronic diseases become rampant, the public pays more attention to herbal medicine. Thus, there is growing social demand for quality control of medicinal herbs used for drugs (hereafter "medicinal herbs"). In response, the MFDS has made efforts to obtain trust from consumers by strictly managing their quality and safety.

Especially, the MFDS prepared a legal basis for the "Good Manufacturing Practice (GMP) for Medicinal Herbs" and introduced it in 2012. Since 2015, when GMP was made mandatory for all manufacturers, the MFDS has worked on building a systematic manufacturing environment ranging from raw materials to final products. It also carries out customs inspection on medicinal herbs for every import, and has controlled medicinal herbs from 2008 through measures, e.g. inspection on overseas manufacturers when approving their products, in order to manage ever-growing imported medicines.

2) Achievements

The MFDS enhanced the quality assurance and safety management of medicinal herbs by appropriately controlling support and monitoring & inspection of manufacturing companies.

First, to stabilize the "GMP for Medicinal Herbs" mandated in 2015, the MFDS held policy seminars for relevant organizations and companies to provide education on manufacturing and quality control and to share and promote information on GMP policies. Additionally, to reduce the burden of quality test costs imposed on small manufacturing companies, the MFDS continues to run an open laboratory. It was expanded and relocated in December 2019, and supported pilot tests for 1,058 cases of 22 firms in 2020. The Ministry has established and operated an online application system since 2020 to further the use of the open laboratory. 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 154 in 2020.

Besides, the MFDS has endeavored to secure safe imported medicinal herbs by tightening customs inspection such as random monitoring and cross-checking at sensory evaluation sites, which are conducted by testing and inspection agencies, and by piloting contactless inspections on overseas manufacturers to prevent the spread of COVID-19.

In addition, to distribute herbal medicines and standards that consumers can

trust and to advance their standards, the Ministry conducted a review of the item standards in the official compendium. For rational resolution of pending issues in the field of natural medicine, it also held a consultative body for the development of the natural medicine industry and a briefing session on civil complaints to promote communication and cooperation at home and abroad.

3) Implementation plan

In 2021, the MFDS will keep reinforcing the project that has been in place since 2015, with the safety management of herbal medicine and the like as a priority goal. It will monitor and cross-check customs inspection of imported medicinal herbs, and operate regular inspections of overseas manufacturing plants in non-contact mode considering COVID-19.

Moreover, the Ministry will expand the scope of quality management education for medicinal herbs, to go for qualitative growth of the manufacturers and improve their competitiveness and thereby to restore consumer confidence in Korean herbal medicines.

Apart from it, the MFDS will carry out research projects to scientifically and rationally improve standards and specifications for herbal medicine, and based on the outcome, will revise the “Korean Pharmacopoeia” and the “Korean Herbal Pharmacopoeia.”

3. Strengthening Competitiveness of the Cosmetics Industry through Safety Management

A. Creation of a Safe and Proper Environment for Using Cosmetic Products

1) Establishment of Regulations for Safety Standards on Cosmetics

Since the Cosmetics Act was fully revised (on Feb. 5, 2012), to boost the cosmetics industry by developing new raw materials and align domestic regulations with the international level, the system for managing cosmetic ingredients was modified to the “Negative List Method.” It notifies the industry of raw materials that cannot be used in cosmetics and allows the others to be used under corporate responsibility.

The MFDS continues to revise the standards for cosmetics materials that cannot be used and that require restrictions on use, reflecting domestic and foreign harmful cases and risk assessment results relating to the materials at issue.

2) Decision on Companies that Conform to the Cosmetic Good Manufacturing Practices (CGMP)

Since March 2011, the MFDS began inspecting and evaluating cosmetic manufacturers and awarding CGMP certification to them. With 12 businesses certified in 2020, a total of 165 companies (as of the end of December 2020) are registered as CGMP-compliant firms.

To make sure that domestic cosmetics have a competitive edge in the global market and cosmetics of good quality are supplied to the domestic market, there should be more CGMP-compliant firms. In this context, the MFDS plans to support higher quality control standards for the industry by expanding customized consulting and education for CGMP applicants.

3) Strengthening Safety Management of Cosmetics that Are Used by Infants or Children

As the age of using cosmetics gradually lowers and the cosmetics labelled or advertised for children increases, the MFDS enhanced the safety of cosmetics for infants or children. As part of such a move, from January 2020, the MFDS required cosmetics vendors to prepare and store data that can prove safety for each product indicating or advertising that infants or children may use.

The Ministry tried to secure safety of cosmetics for infants and children and to minimize consumer concerns, through briefing sessions and guidelines for operators and consumer education and promotion, and will continue education on how to use cosmetics safely for elementary, middle and high school students so as to induce proper understanding and use of cosmetics.

B. Promoting Development of Cosmetics and Managing Their Safety by Reflecting Consumer Trends

1) Full Implementation of the Personalized Cosmetics System

The Personalized Cosmetics System allows cosmetics to be immediately mixed and divided into small packages in order to meet consumer preference or skin condition. This system became effective on Mar. 14, 2020.

The personalized cosmetics sale business is run under a reporting system. As of the end of 2020, 118 businesses were reported, and 3,694 professional managers were produced through three national qualification tests in 2020 by operating a preparation manager system.

In 2021, the MFDS will continue working with the industry to make the personalized cosmetics system more stable and more vigorously promote it to consumers.

2) Introduction of a Certification System for Natural and Organic Cosmetics

The MFDS established a definition of natural cosmetics in the revised Cosmetics Act, which took effect on Mar. 14, 2019, and introduced a certification system to encourage the industry's development of natural and organic cosmetics and provide more accurate information to consumers.

As of the end of 2020, three institutions were designated, and the Ministry will advance the standards by comprehensively reviewing the status of foreign countries and opinions of consumers and the industry, and prepare a civil petition guide for labelling and advertising standards.

C. Strengthening Safety Management of Cosmetics on the Market

1) Monitoring Cosmetics

To establish an environment that allows manufacturing and circulation of safe cosmetics, the MFDS formulates a master plan for manufacturing and distribution management by setting monitoring directions every year, and then conveys the plan to each local office and local government for follow-up management. In 2020, it emphasized self-inspection of cosmetics vendors and manufacturers, and conducted joint planned monitoring about whether the cosmetics that contained restricted ingredients complied with the standard.

In 2021, the MFDS will intensively examine cosmetics to ensure public trust, by means of checking the adequacy of cosmetics manufacturing and quality control and by jointly monitoring on whether the manufacturers comply with the labeling obligation.

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 "Quality Monitoring", which is part of the "Basic Plan for the Management of Manufacturing and Distribution." The MFDS crafts and controls the Basic Plan for Quality Monitoring while its regional offices and local governments periodically collect and test cosmetic products.

In 2021, the Ministry plans to collect and inspect suspected quality control items such as commonly used women's products, which have recently attracted social attention, and will continuedly gather domestic and foreign harmful information in real time to block unsafe cosmetics from the market.

D. International Cooperation and Technical Support to Make Cosmetics More Competitive

1) Accession to the International Cooperation on Cosmetics Regulation (ICCR)

The International Cooperation on Cosmetics Regulation (ICCR) is a voluntary international consultative body organized in 2007. It consisted of cosmetics regulators and industry associations of the European Community (EC), U.S. (FDA), Japan (Ministry of Health, Labor and Welfare (MHLW)/Pharmaceuticals and Medical Devices Agency (PMDA)), Canada (Health Canada (HC)) and Brazil (Brazilian Health Surveillance Agency (ANVISA), joined in 2014). And its aim is to minimize trade barriers in cosmetics and harmonize regulations on consumer protection.

Since attending the 2012 annual meeting, the MFDS has actively proposed domestic opinions by participating in annual meetings and expert working groups from 2016, and joined the ICCR with Taiwan in December 2020 on the back of unanimous support at the 14th annual meeting.

As a regular member, the Ministry will actively attend the periodical steering committee, consumer communication, integrated strategy expert groups for microbiome and safety evaluation, and strive to help Korean standards lead the world by serving as the 16th chair.

2) Strengthening Cooperation between Countries to Remove Non-Tariff Barriers

To break down non-tariff barriers, the MFDS hosts the One Asia Cosmetics & Beauty Forum and conducts official development assistance (ODA) projects every year to understand cosmetics regulations in major exporting countries and introduce domestic regulations.

Through the One Asia Cosmetics & Beauty Forum, the Ministry introduced the latest cosmetics regulations and market approaches of each country through presentations of regulators and marketers from major exporting countries, and held online business consultations for ASEAN countries so as to support export contracts.

In addition, it presented overall regulations on cosmetics sold online and supported stronger management capabilities together with the regulators from Laos, Malaysia, Myanmar, Vietnam, Indonesia and the Philippines.

3) Operation of the Global Regulatory Harmonization Support Center for Cosmetics

To tackle changes in the cosmetics system environment at home and abroad, the MFDS opened the website for the Global Regulatory Harmonization Support Center for Cosmetics in November 2020. The center was intended to meet the demand of the cosmetics industry – various education programs, latest information on cosmetics regulations, etc. –, globalize the industry, revitalize the personalized cosmetics system, and educate new business operators.

The Ministry will operate a real-time interactive chatbot service from March 2021 to enhance understanding of the cosmetics industry concerning related systems

and will provide education on domestic and foreign institutions and deliver information and practical training on domestic and foreign regulations.

4. Quasi-Drug Safety Management Trusted by the Public

A. Reinforcement of Safety Management for Quasi-Drugs

1) Background

Quasi-drugs are commonly used household products that are closely related to people's daily life. Their examples are health masks, sanitary pads, toothpaste, and mosquito repellents. Consumers are highly interested in their safety, and social impact of illegal products such as false/exaggerative advertising and defective products is significant. In response, the MFDS is trying to supply safe quasi-drugs and establish a foundation for their safe use culture where people feel relieved by strengthening management of quasi-drugs, including verifying their safety and improving relevant systems rationally.

2) Achievements

A) Comprehensive and Efficient Safety Verification and Management of Quasi-Drugs

According to repeated safety issues, which have been triggered by unintentionally mixed materials, the MFDS verifies safety of about 10 item groups every four years regarding quasi-drug hazards (the mid- to long-term plan was established in January 2018). In 2020, it worked out a plan for safety verification of quasi-drugs (January), and carried out information surveys and exploratory and periodic monitoring by item group/ingredient.

(1) (Information Survey) The MFDS performed a survey on consumers (about 7,000) of five item groups including mouth washers: how much consumers used each item group, how they used it, and whether they experienced adverse reactions. Based on it, the Ministry collected and sorted out the ingredients in question and safety information by item group and found post-management subjects.

(2) (Exploratory monitoring) The MFDS validated analysis methods for seven harmful substances for each item group and dosage form including toothpaste, and conducted exposure and risk assessments on 22 components in 11 item groups including anti-odorants, to secure safety.

(3) (Regular monitoring) As a result of analysis of 60 types of Volatile Organic Compounds (VOCs) in 385 sanitary pads on the market, the MFDS confirmed that they did not pose a risk to the human body. It blocked the distribution of nonconforming products by way of monitoring the quality of 575 products, including medical masks, and their regular and special collection tests.

B) Improvement of the Safety Management System for Quasi-Drugs and Minimization of Blind Spots

As the development and use of filters, main raw material of masks, became more active, the MFDS established quality standards to strengthen safety management of filters (including replacements).

The MFDS implemented a preliminary examination system to inform civil petitioners of necessary data before the official examination began, for the purpose of prompt permission and efficient examination of quasi-drugs.

In addition, as the demand for light masks that reflects seasonal (summer) and contextual characteristics increased in the COVID-19 situation, the Ministry newly designated and managed anti-droplet masks as quasi-drugs. The masks can replace medical masks, and are light and breathable.

C) Creating a Safe Use Culture of Quasi-Drugs by Providing More Consumer Information

The MFDS actively offered the right method of selecting and using disease prevention and control products such as masks and hand sanitizers for COVID-19 response. What's more, it produced and distributed correct usage information leaflets for menstrual products to provide more consumer information, and established standard recommendations and introduced standard forms to enhance the readability of labeling for oral products (toothpaste, mouth washers) and the delivery of accurate information.

3) Implementation plan

As safety controversy over harmful ingredients arises every year in daily necessities such as sanitary pads, the MFDS plans to establish a mid- to long-term safety management system that takes into account preventive verification. To this end, it plans to design a circular safety verification system with a 4-5 year cycle for the entire group of quasi-drugs, actively collect clue information, and continuously promote customized safety verification sequentially.

The MFDS will also introduce GMP for quasi-drugs to supply excellent products and strengthen precautionary safety management. In 2021, it will prepare related regulations such as GMP review guidelines and phase in the GMP by conducting trial operations on contact lens management products (2 locations) and menstrual products (5 locations).

5. Support for Biopharmaceuticals, Etc. Going Global and Strengthening Global Cooperation

A. Support for Biopharmaceuticals, Etc. Going Global

1) Background

Biopharmaceuticals such as vaccines, plasma-derived products, recombinant DNA-derived products, cell culture drugs, gene and cell therapy drugs have recently received more interest in the customized treatment area, and biologics has been actively developed. Hence, their share in the overall pharmaceutical market is on the rise.

Korean biopharmaceuticals likely grow to global products and their domestic market is worth 2,600,200,000,000 won (about 2.6 trillion), accounting for about 10.7% of the 24.31 trillion won market. Biopharmaceuticals take up eight of the world's top 10 drugs in sales in 2019, and the patents for a number of blockbuster biopharmaceuticals are expected to expire around 2020. Now that the development of innovative new drugs slows, competition in the biosimilar market is also accelerating worldwide through strategic partnerships and pursuit of licensing and merger with biopharmaceutical companies.

In Korea, multiple pipelines have been formed in the areas with comparative advantages in international competitiveness, such as vaccines, biosimilars, and stem cell treatments, which supports the aforementioned outlook.

If new technologies such as genetic scissors are commercialized along with advanced DNA and life sciences, the global pharmaceutical market is predicted to undergo reorganization around biopharmaceuticals.

2) Achievements

The MFDS is strengthening cooperation with international regulators such

as WHO and APEC. It is notably to establish a high-tech biopharmaceutical safety management system, expand customized support to strengthen global competitiveness of domestic vaccines, pursue WHO Pre-qualification (PQ)[6], support entry of Korean biopharmaceuticals into the world market by providing domestic and foreign regulatory information, consulting service, etc.

In 2020, the MFDS enacted 1) the Enforcement Decree of the Act on the Safety and Support of Advanced Regenerative Medicines and Advanced Biopharmaceuticals, and the Rule on the Safety and Support of Advanced Biopharmaceuticals, 2) item approval and evaluation regulations for high-tech biopharmaceuticals at the time of examination by determining the evaluation criteria and quality evaluation data, and 3) regulations on approval, safety, etc. of advanced biopharmaceuticals such as human cells, etc. that prescribe the matters necessary for permitting advanced biopharmaceuticals such as human cells.

The MFDS held a "Global Bio Conference" to link international workshops organized by the IPRP and the AHC to international events. In doing so, the Ministry set the stage for knowledge sharing for Korea to realize its vision of the world's leading biopharmaceutical powerhouse and supported global growth in the biopharmaceutical sector.

In addition, the MFDS developed a plan to support global vaccine commercialization, strengthening the WHO PQ assistance and the international cooperation system to sell cell lines, support customized technologies and systems, and boost export.

The MFDS operates an industry-academia-government consultative body to expand domestic self-sufficiency capabilities for essential preventive vaccines, which rely mainly on import, to support the commercialization of vaccines and the construction of production facilities so that people can be fully supplied with vaccines in time.

6 WHO PQ (Prequalification): A system through which the WHO evaluates quality and safety/effectiveness of products to internationally procure medicine to developing countries. PQ exerts a global impact. (As of now, 22 products (package units) from 4 companies received PQ).

To quickly approve biopharmaceuticals, it has preemptively prepared approval and evaluation standards following Europe, and is actively working with international organizations such as the WHO and regulators from other countries to enter the global market.

Besides, since 2014, the MFDS has continued to implement a project to build a bio-IT platform, a customized export support program for biopharmaceuticals, to provide regulatory and industrial information on overseas licenses to the industry.

3) Implementation plan

The MFDS plans to provide consulting service to the biopharmaceutical industry which desires to go global. It will also publish "Global Entry Strategy Information" that describes domestic and foreign licensing systems and regulatory and industrial information and distribute it to biopharmaceutical institutions to help Korean products to make inroads into foreign markets.

The Ministry plans to quickly find and reasonably overhaul necessary or unnecessary regulations to promote commercialization, such as continuously operating public-private commercialization consultative bodies by item and preparing commercialization guidelines in a timely manner.

The MFDS actively responds to the era of sophisticated bio-technology by arranging a ground to support advanced biomedicine from R&D to commercialization. In order to systematically and efficiently manage cutting-edge biopharmaceuticals that reflect the latest technical trends, the MFDS enacted and started to enforce (August 2020) the Act on the Safety and Support of Advanced Regenerative Medicines and Advanced Biopharmaceuticals including advanced tissue engineering, cell and genetic therapy products, etc. The Ministry will try to implement the law stably.

The Ministry will facilitate vaccine development by establishing cell lines essential for vaccine production and selling them to companies; operate the Global Vaccine

Commercialization Group (consultative body) that supports vaccine production technology and offer a regulatory information to support national vaccine commercialization; and establish a vaccine safety technology center and thus run commissioned testing and inspection labs to operate clinical sample analysis and self-quality tests in a reliable and stable way.

The MFDS will establish a system necessary for safe and high-quality biopharmaceuticals from R&D and commercialization to global market entry; establish and promote a comprehensive customized support plan by constructing organic cooperation through information sharing between the government, industry, academia and research institutes, and by doing so expand an industrial base for domestically developed biopharmaceuticals; and secure international competitiveness so that they can grow into global products in the future. Like these, the MFDS will do its best to provide priority support and unsparing efforts to help the nation's biopharmaceutical industry become a leader in the Fourth Industrial Revolution.

B. Acquiring Global Competitiveness through International Cooperation

1) Background

The bio industry is converging with various industries such as medicine, chemistry, electronics, energy, agriculture and food through integrated biotechnology technologies. With respect to the global biopharmaceutical market, the U.S. accounts for the largest share of more than 61% whereas Korea represents only 0.7%. So, the Ministry is preparing support plans for institutions, technology, infrastructure and global expansion for Korea to be globally competitive through international cooperation.

2) Achievements

A) Advanced 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 WHO Collaborating Centre 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 regulatory agencies' capacity building including operating education programs and 4) disseminating the WHO's international standards to the West Pacific and other areas. After the designation, the MFDS offered technical advice for developing 14 WHO international guidelines (2020) 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 testing 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 control standards for vaccines. Furthermore, until 2019, the MFDS carried out training programs 13 times and 140 trainees from 29 countries like Iran, Vietnam, and Laos completed the training (10 people from 5 countries in 2019).

In April 2015, the Ministry began ODA projects by signing a donor agreement with the Western Pacific Regional Office. The projects will strengthen Korea's international status and lead to cooperation in responding to health crises such as infectious diseases. In November 2020, the MFDS conducted a 2015-20 self-evaluation of the West Pacific developing country's biopharmaceutical and licensed technology support projects through the six OECD DAC evaluation indicators and literature reviews and surveys. It helped the MFDS examine the performance of relevant projects, and as a result, their appropriateness and sustainability were

confirmed with the rating of "Excellent."

(2) International Pharmaceutical Regulators Programme (IPRP)

Since November 2013, the MFDS has been the chair of the "Biosimilar Working Group" at the IPRP, leading the biosimilar sector based on information exchange on regulatory issues and international discussions on collaboration among regulators. It also assists with international harmonization to expand national presence in markets of the U.S. and the EU.

As chair of the International Pharmaceutical Regulators Forum (IPRF), the predecessor of the IPRP, the Ministry has actively shared biosimilar regulation information of the U.S. and Europe through face-to-face meetings and teleconferences, and kept leading activities in the working group for cell and gene therapy products.

(3) Asia-Pacific Economic Cooperation (APEC)

The MFDS was selected as "Champion Country" for the Biopharmaceutical Products Roadmap at the APEC Senior Officials Meeting in September 2011. The roadmap was finally approved by the APEC Regulatory Harmonization Steering Committee (RHSC) in February 2013 and the MFDS held an international workshop organized by the AHC. In February 2016, the APEC RHSC approved the MFDS' pilot operation of the Center of Excellence (CoE) for biopharmaceuticals. So, the Ministry operates a pilot program for APEC regulators. In August 2019, it held a workshop under the auspices of the AHC on the achievement of the Biopharmaceutical 2020 roadmap and future planning, and measured the regulatory harmonization performance through surveys on key indicators for APEC member countries.

(4) Bilateral Cooperation

Except for activities in international organizations and global conferences, the MFDS sought for bilateral cooperation for close and direct exchanges with countries.

As a result, it established a partnership with the German Paul-Ehrlich Institute (PEI) in October 2013 and a future confidentiality agreement with the U.S. FDA.

The Ministry maintains partnership with trading partner regulators. In 2015, it signed agreements for Regulatory Collaboration (RC) with the Health Canada (HC) Biologics and Genetic Therapies Directorate (BGTD) and the Japanese Ministry of Health, Labor and Welfare and a RC MOU with the Vietnamese Ministry of Health. In 2016, it signed an MOU on information exchange with the Peruvian Ministerio de Salud (Ministry of Health) and the Argentine Alimentos y Tecnologia Medica (Food and Drug Administration), and the UK National Institute of Biological Standard and Control (NIBSC).

B) Building an Expert Network and Professional Capacity

The MFDS continuously hold international forums and workshops to strengthen professional capabilities of high-tech biopharmaceuticals. After 2015, it integrated them into the "Global Bio Conference," which is held every June to establish itself as a representative international bio event involving about 3,000 people every year from government agencies, industries, academia, and the media.

3) Implementation plan

The MFDS plans to expand international cooperation activities such as multilateral and bilateral cooperation to expand biopharmaceutical export and lead international standards with the goal of becoming one of the world's top seven pharmaceutical powers in 2021.

A) Pursuit of Becoming a Hub for Multilateral Cooperation

(1) World Health Organization (WHO)

Official Development Assistance (ODA) for "Technical Support for Biopharmaceutical Evaluation and Authorization in Developing Countries in the

Western Pacific Region" was updated in April 2021 (6th year) at the request of the WHO Western Pacific Regional Office. Regarding this, the MFDS plans to sign a Donor Agreement (DA) with the Western Pacific Regional Office and continue to provide education, technical advice, and equipment. In addition, as the WHO GLO International Education and Training Center, it will operate applicable training on GMP and lot release approval/tests and inspections through practical learning and case studies to deliver knowledge and technology appropriate to participating states. All this intends to strengthen, expand and maintain vaccine quality regulatory functions in developing and middle-income countries.

(2) International Pharmaceutical Regulators Programme (IPRP)

The MFDS will play an international leader in the biosimilar field by continuing activities as a biosimilar working group member in 2021 and preparing a clinical evaluation manual. It will also continue to exchange views with cell and gene therapy product working groups.

(3) Asia-Pacific Economic Cooperation (APEC)

In 2021, the MFDS will share findings on key biopharmaceutical performance indicators for APEC member states, develop 2030 visions and action plans, and conduct formal training at Northeastern University, Duke-NUS in Singapore and Kobe University in Japan, which are accredited professional educational and training institutions. The AHC and Peru's National Institute of Health will co-host the "Biomedicine Public-Private Dialogue."

B) Further Bilateral Cooperation

In future, the MFDS plans to expand collaboration with Paul Erlich Institut (PEI) and the Health Canada (HC) Biologics and Genetic Therapies Directorate (BGTD). For the WHO, the Ministry will actively attend related expert meetings (Expert Committee on Biological Standardization (ECBS)) to play a leading role in harmonizing international regulations such as establishing and amending guidelines and exploring international joint research opportunities.

C) Setting the Stage for Regulatory Harmonization

To support global expansion of biopharmaceuticals, the MFDS will invite experts from home and abroad to hold the "2021 Global Bio Conference" on September 13-15, 2021. It will maximize synergy through shared expertise and experience such as latest international trends, prospects, and recent regulatory issues, and thus serve as a venue for realizing the vision of a pharmaceutical powerhouse.

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. In particular, the spread of the new COVID-19 infectious disease highlighted the importance of developing platform-based vaccines (nucleic-acid vaccines, etc.) and antibody treatments combined with cutting-edge technologies. On the other hand, for an early end to new infectious diseases, cooperation among the industry, government, and academia is needed to minimize trial and error of developers.

The mechanism of advanced biopharmaceuticals (genetic therapy, cell therapy, tissue engineering drugs) is complex and thus their features are difficult to determine. In addition, there are no uniform criteria for approving and evaluating biopharmaceuticals across the world due to a lack of approval and clinical experiences. Against this backdrop, it is all the more important to establish the

standards for their approval and evaluation earlier than other countries, in securing safe advanced biopharmaceuticals based on new concepts and quickly approving them. The portion of biopharmaceuticals is increasing in the global pharmaceutical market; vaccines to prevent new infectious diseases are of greater significance; and more domestically developed medicines like biosimilars, etc. are entering overseas markets. Hence, building an internationally harmonized biopharmaceutical approval and evaluation system in line with such a growth trend is the very core of stronger competitiveness.

For biosimilars, 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 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.

B. Advancement of Approval & Evaluation of Herbal Medicinal Products

With the increasing demand for stronger control of herbal medicinal preparations manufacturing including quality, etc., regulations are getting stricter. Meanwhile, due to the rising interest in developing herbal medicinal preparations, there has been an increase in formulation changes of pharmaceuticals for herbal medicine health insurance. Further, the number of clinical trials with herbal medicinal products is growing. 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 2020, the MFDS prepared regulations on herbal medicine products and guides for the public, e.g., a revision (draft) of the official compendium, and a “Casebook on the API Chemical Profile of Herbal Medicine Products.” It held civil service briefings, meetings, and counsel meetings to share regulatory changes and review directions. In addition, the Ministry held a briefing session on the approval of clinical protocols to revitalize clinical studies, and implemented various measures to enhance the quality of approval and evaluation and commercialization by conducting tailored 1:1 consultations on clinical R&D tasks of the Ministry of Health and Welfare. Especially, in an attempt to support speedy commercialization of COVID-19 treatments, the MFDS operated a custom counseling program for the entire product development process and finally approved a clinical protocol for one item.

The MFDS plans to create a reasonable regulatory environment for a predictable and transparent evaluation system, improve standards, present evaluation guidelines, and update product information. Also, it will promote consulting to facilitate bilateral communication with the industry and clinical trials with an aim of supporting expedited commercialization of herbal medicine products including COVID-19 treatments.

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

In order to raise objectivity and efficiency of evaluations for newly added functional cosmetics and support the development of safe and quality functional cosmetics, the MFDS set the "Product Standard and Testing Method" in the standards and testing methods for functional cosmetics. It will advance the evaluation system according to changing circumstances by continuously revising the regulations on functional cosmetics evaluation. Furthermore, the MFDS will hold briefings to promote better understanding of new systems and thus support the development of new products, and continue to carry out public campaigns on the safe use of cosmetics.

Section 3

Establishing a Medical Device Safety Management System that Leads Industry 4.0

1. Construction of Innovative Growth Foundation for Medical Devices and Establishment of Their Life Cycle Safety Management System

A. Background

The medical device industry has great potential to develop into one of promising industries in the future. It is because its demand is expected to increase thanks to technological development, extended life, and a growing elderly population. Along with the recent progress in high-tech technologies, it is urgent to promote the development of innovative medical devices and In Vitro Diagnostic Devices (IVDDs) while establishing a system to build a permission and management system suitable for their characteristics. In addition, medical devices for rare and intractable disease patients should be supplied timely to support the vulnerable and eliminate unchecked safety areas. Moreover, the world shifts to integrated safety management that controls stage-specific information from UDI-based approval to distribution

and use. In this vein, it is necessary to minimize damage from a harmful medical device by spreading safety information quickly and to recover it fast by tracking distribution and inventory information.

B. Achievements

According to the enactment of the Act on Nurturing the Medical Devices Industry and Supporting Innovative Medical Devices (Apr. 30, 2019), the MFDS dedicated itself to preparing sub-regulations and civil petition guides to prescribe details on the designation of innovative medical devices, their approval and evaluation exemptions, standardization procedures and methods for innovative medical device technology and to promoting new systems.

Additionally, the Ministry designated eight products, including “computer aided diagnosis software” that analyzes eye-fundus images, as innovative medical devices, and allowed them to be promptly approved through special support in approval and evaluation and others.

In order to stabilize the supply system of medical devices requiring rare and emergency introduction, it designated six more devices from a year earlier, and allocated an additional budget of 500 million won to supply 1,743 devices to 40 or so medical institutions. What’s more, the MFDS was committed to registering rare and intractable disease patients for National Health Insurance care benefits to prevent them from giving up surgery and treatment due to economic burdens such as high medical expenses.

In addition, the MFDS established an integrated information system that comprehensively controls information on medical devices with attached UDIs throughout their entire cycle, and mandated reporting of supply details starting from Class 4 medical devices (Jul. 1,2020).

C. Implementation Plan

In order to promote commercialization of innovative medical devices, the MFDS plans to enhance special support for approval and evaluation, and designate and operate related institutions to systematically collect and provide information on innovative devices and train professionals. Further, in the case of rare and emergency medical devices, the Ministry will increase supply benefits by increasing the number of pre-purchase items and quantities, and expand collaboration with related ministries by enforcing “mandatory reporting of supply interruption” (Oct. 14, 2021) to enable rapid response to supply instability or interruption. In addition, for an integrated information system based on UDIs, the MFDS will develop additional functions such as introducing a certification system to report supply histories using the integrated information system. It also plans to enlarge the scope of compulsory UDI labelling and registration and provide education on related content.

2. Strengthening Consumer-Centered Medical Device Safety Management

A. Background

In Korea, as a result of the aging population and paradigm shift to “quality of life”, the medical industry and the medical device industry are witnessing steady growth. Accordingly, it is more crucial than ever to provide accurate information on medical devices and manage their safety including quality. Therefore, the MFDS is working on safety management policies for medical devices through monitoring, quality inspection, advertising management, etc.

B. Achievements

The MFDS modified its strategy, which had been concentrated on post-monitoring to resolve complaints, to preemptively address risk factors and prevent problems from having greater impact. Towards this, the Ministry analyzed hazard data and, based on it, carried out planned and special oversight of 11 areas in safety blind spots like high-risk implantable devices, etc. and frequent mixing with foreign substances. Further, the Ministry inspected the status of low-power external defibrillators and automatic blood pressure meters which the vulnerable utilized commonly at culture facilities, etc. and took corrective action against nonconforming products. This way, the Ministry forestalled possible harm to users.

The MFDS verified the quality of medical devices directly linked to public health: items related to human transplant, the vulnerable, frequent mixing with foreign substances, and social issues. As a result, it was found that the rate of nonconforming products remained less than 10% (6.2% in 2018 → 7.5% in 2019 → 5.3% in 2020). Based on the result, the Ministry took corrective and preventive measures through technical support for 42 companies that failed to meet relevant quality standards, thereby preventing damage to consumers.

Besides, in cooperation with the Cyber Investigation Bureau, the MFDS monitored illegal advertisements like false/exaggerative ads and actively took follow-up action like shutting off websites so that consumers could buy proper medical devices. It performed planned inspections of medical device free trial centers to prevent damage to seniors and homemakers due to false/exaggerative ads or rip-offs, building an environment where the users could reasonably buy products.

The MFDS also tried to improve the operation level of GMP by domestic manufacturers. To that end, it adopted the latest international GMP standards, and published guides and provided online training for domestic manufacturers to apply the standards, and issued the guidelines for operating clean rooms at manufacturing plants.

C. Implementation Plan

In 2021, the MFDS will conduct intensive management, including choosing data-oriented management targets, to prevent potential risk factors and block the spread of problems to distribute safe medical devices. In line with the post-COVID-19 era, it will manage safety by converting some inspections to non-contact ones, as well.

In addition, to inspect the quality of medical devices in the post-COVID-19 era, the Ministry will make consumers more confident of medical devices by gathering and inspecting high-risk implantable products, holiday preparation products, and medical devices at social issue.

Moreover, to forestall high-priced purchases of vulnerable consumers such as seniors and housewives, the MFDS will examine free trial rooms for medical devices on a frequent basis and keep monitoring online illegal advertisements and take follow-up action.

Finally, for mutual recognition of medical device GMP between countries, the MFDS plans to promote official accession to the IMDRF Medical Device Single Audit Program and continue technical support to reinforce quality control capabilities of domestic manufacturers.

3. Establishment of a Safety Evaluation System for Medical Devices

A. Background

Korea has seen more uses of medical devices. The reasons are new infectious diseases such as COVID-19, the increased demand for chronic disease treatment that stems from the aging population, and the social needs for health such as disease prevention that arises from higher income levels. As a result, safety

management of medical devices—collecting and analyzing their adverse events, tracking implantable products, and reevaluating products on the market—is ever more crucial.

B. Achievements

In order to facilitate reporting on the side effects of medical devices and establish an advanced side effect management system, the MFDS has been running "Medical Device Safety Information Monitoring Centers" since 2011. In 2020, it operated 124 small- and medium-sized partner hospitals through monitoring centers at 17 general hospitals by region.

As the MFDS encouraged monitoring centers, partner hospitals and medical devices manufacturers and importers to report adverse events, it gathered a total of 53,904 cases a year. By analyzing and evaluating the adverse events, it provided safe utilization tips to users and strengthened cautions for use and ensured that medical device manufacturers could exploit adverse event data in improving products through corrective and preventive measures, etc. Such efforts helped consumers use medical devices in a safe manner.

In addition, as for medical devices that might cause fatal harm to the human body due to side effects or defects, the Ministry designated them as tracking targets to trace all distribution stages from manufacturing to use. In 2017, it improved its system to allow the records of medical institutions to be submitted and managed through a computer system. In 2020, the MFDS built a "Patient Safety Information Verification System" that enables the patients using implantable devices to personally check product and safety information.

Together with it, in 2020, the MFDS regularly reevaluated the safety and validity of licensed (certified) or reported medical devices. As part of the action, it assessed safety information such as adverse events after release and reflected cautions for use in approval matters. This evaluation was made on products of class 3 & 4, which were approved in 2014; and life-friendly products of class 2, most of which failed to meet the quality criteria. The Ministry is also seeking to secure the safety of IVDDs: it announced reevaluation of the products whose category changed from medicine and industrial products to IVDDs (class 3).

C. Implementation Plan

According to changes in the policy environment, such as increased side effects of implantable medical devices and patient-centered safety management, the MFDS will more strictly control adverse events by speeding up reporting, analysis, and evaluation of adverse events, internationally harmonizing domestic adverse event UDIs and establishing an active system for collecting side effect information. Furthermore, the Ministry will push for the introduction of a damage compensation system, including regular reporting of implantable medical devices; the mandatory purchase of liability insurance to compensate victims; and preparation of a dispute mediation agency. Moreover, it will keep managing safety of medical devices by reassessing products that are under high social interest or feared to cause consumer damage.

4. Advancement of Medical Device Approval and Evaluation

A. Support for Innovative Growth in Medical Devices

1) Preparation of a Plan to Approve and Evaluate for Software-Based "Digital Therapy Devices"

As digital-based medical devices (software) progress toward treatment beyond diagnosis of disease, it is necessary to prepare measures to approve and evaluate digital-based software medical devices.

The MFDS presented the definitions and the criteria of digital therapy devices and how to fill in the principle of action, purpose, performance, and test specifications in technical document applications, as well as the requirements and scope of data on the principle of action, performance, and clinical trials. This aimed to make the public enjoy convenience and offer transparency in approval and evaluation affairs by setting forth those conditions to enterprises or civil petitioners.

2) Establishment of a Safety Management System for Innovative Medical Device Software and Innovative Medical Devices

The "Act on Promotion of the Innovative Medical Device Industry and Support of Innovative Medical Devices" was implemented on May 1, 2020, for special exemptions in approving innovative medical device software. Therefore, it was necessary to establish a full cycle safety management system by regularly controlling the risk, purpose of use, and post-marketing status of innovative medical devices and their software.

In response, the MFDS laid out a manual about details (drafts) including targets and methods for simplifying the approval and evaluation of innovative medical device software under special exemptions and about the review of post-marketing survey materials; and offered the guidelines for significant changes and phase-specific evaluation of innovative medical devices. By presenting them to businesses or civil petitioners, the Ministry intended to deliver public convenience and transparency in approval and evaluation affairs.

B. Strengthened Entire Cycle Safety Management of Medical Products

1) Development of Review/Approval Guidelines to Prepare for Effectuation of the Act on In Vitro Diagnostic Medical Devices

With the effectuation of the revised In Vitro Diagnostic Medical Devices Act (May 1, 2020), the range of the act extended from in vitro diagnostic reagents to equipment and software, and the relevant approval regulations were revised accordingly. In addition, advanced IVDD technology led to various IVDDs, making it necessary to revise the existing guideline as it was improper to apply.

Thus, the MFDS deleted overlapping parts from the approval and evaluation guidelines and planned to refine the guideline on in vitro diagnosis (IVD) to reflect requirements of relevant approval regulations. In 2020, the Ministry first amended the guideline to make it align with revised regulations including the approval regulation guidebook. It is planning to merge or abolish 13 guidelines for reagents for high-risk infectious agents and develop the guidelines for the usability evaluation of personal IVD reagents in 2021.

2) Strengthened Patient Safety Management with Enhancement of the Vascular Stent Evaluation System

While the development of various vascular stents has been accelerated due to the increasing number of vascular diseases, stents for blood vessels are currently categorized into only six types, causing difficulties in precise classification. Therefore, the MFDS formed a consultative body of experts from medical device manufacturing/import companies, testing and inspection agencies, and relevant institutes and to prepare a revised public notice (draft) that divides vascular stents into 13 types. Based on the more detailed classification, the Ministry came up with the "Guidelines for Approval and Evaluation regarding Vascular Stents for

Vascular Diseases Including an Aneurysm" as well as test methods and standards reflecting characteristics of a product in order to create a reasonable review system and support approval regarding newly established categories. The Ministry also held training and briefing sessions for better utilization of the guidelines. It will continue its efforts to build an evaluation system such as constant development of theguidelines for an intensified entire cycle safety management of implementable medical devices (IMDs).

3) Development of an Approval System to Strengthen Safety Management of Medical Devices for Orthopedic Operations

As the necessity for stricter safety management of medical devices for orthopedic operations has increased due to side effects, the MFDS formed a consultative group that consists of experts from the industry, academia, medical institutes, and testing and inspection agencies; gathered opinions from cooperating organizations; and published the guidelines for the global level of evaluation items and test methods and essential performance evaluation plans. Intending to achieve better safety and promotion of the industry, the Ministry will publish the "Guidelines for Approval and Evaluation regarding Anchor-Type Orthopedic Bone Screw (for civil petitioners)" and "Guidelines for Approval and Evaluation regarding Non-Biodegradable Surgical Staples and Staple Appliers."

4) Reinforced Approval and Evaluation System for Innovative Dental Medical Devices

With the recent development of 3D printing technologies in the dental clinic area, there are increasing cases of manufacturing tailor-made dental products based on the information of the patient's body such as the status of the patient's gums and teeth implant obtained from medical imaging technology such as CT and dental scanning. As a result, it became necessary to preemptively prepare guidelines to boost relevant industries. Thus, the Ministry published the approval and evaluation guidelines regarding 3D printing dentures (denture materials) and 3D printing ceramic dental materials (crown and bridge materials for dental use) in November 2020, thereby contributing to the promotion of the industry.

C. Capacity Building for Approval and Evaluation and Enhanced Communication with Public

1) Capacity Building of Key Talents Using On-Site Learning in the Era of Fourth Industrial Revolution

For swift commercialization of innovative medical devices with key technology of the Fourth Industrial Revolution, it is necessary to provide tailor-made training for experts according to the cycle of medical device development, from development to approval. Therefore, the MFDS has been carrying out the "Capacity Building Project for Key Talents" since 2015 to strengthen the capacity of the industry, reviewers, and approvers. The program is focused on the researcher–oriented curriculum and practice-oriented curriculum for reviewers and approvers. The training of researchers in 2020 had 9 courses such as "Basic Curriculum for Licensing of Industry 4.0 Medical Devices." It was conducted 12 times in total, and 415 trainees completed the course. As for the reviewer and approver training, 9 courses including "Clinical Practice Training for Medical Devices" were provided in 14 sessions with the completion of 267 trainees. In 2021, the MFDS will develop online training content for reviewers and approvers according to their work experience and expand contactless online training in order to overcome the difficulties from limited offline training opportunities that are caused by social distancing to prevent the spread of COVID-19. In addition, the Ministry will lead the advancement of the expertise of reviewers, approvers, and the industry related to IVDDs by developing expert training courses.

D. Support for Innovative Growth of Medical Device Industry and Expansion of International Cooperation

1) Development of AI-Based Evaluation Technologies for Medical Devices through Inter-Ministerial Cooperation Projects

The MFDS has been carrying out the “Project for Expedited Commercialization of Newly Developed Medical Devices through Inter-Ministerial Cooperation” since 2015. It is to help prompt approval for high-tech/newly develop medical on the verge of commercialization among government-funded projects. To do so, it has provided support for test method development, evaluation of safety/performance, and preemptive development of clinical protocols. The Ministry has developed guidelines for 28 evaluation techniques. In 2020, in particular, it supported quick approval by developing evaluation techniques for “Dr. Answer,” an AI medical device. In 2021, it is planning to develop safety/performance evaluation methods, ways to design clinical trials, and evaluation standards for effectiveness in accordance with the technical characteristics of each product. By doing so, it will promote prompt commercialization of digital care devices that are supported by the Ministry of Trade, Industry and Energy. The MFDS will constantly provide fast and predictable approval support for various products developed domestically.

2) Establishment of Infrastructure to Support the IMDRF Chair Country

Korea has been participating in the efforts of the International Medical Device Regulators Forum (IMDRF) for regulatory harmonization since 2014. With the recognition of its contribution, it officially joined the IMDFR as a tenth-member country in 2017. It also made a meaningful achievement, in the 15th IMDRF general assembly held in 2019, of becoming a chair country of 2021. The MFDS made a preemptive suggestion to form the Artificial Intelligence Medical Device Working Group (AIMD WG) for harmonization of international regulations on AI-based medical devices that lead digital health in the era of the Fourth Industrial Revolution. The member countries gave their full approval for it. Further, Korea was selected as the first chair of the AIMD WG, leading the harmonization of international AI medical device regulations. In addition, it made an active contribution to international efforts for regulation harmonization via the international approval and evaluation document WG, personalized medical device WG, excellent evaluation standard WG, cyber security WG, medical device clinical test WG, and IVDD classification WG. At the same time, it also shared information on the medical devices for disease control and prevention with the WHO and IMDFR member countries to strengthen the cooperation system. The MFDS plans to discuss how to carry out joint cooperation in a way the IMDFR, a key player of international health, can make a contribution to better global health and draft specific details for implementation. To this end, the Ministry is mapping out ways to share necessity of cooperation under the international health crisis as the chair of the 2021 IMDRF general assembly and to make a fruitful achievement such as realizing a close cooperation system by playing a leading role.

3) Preemptive Support for Commercialization of Innovative Medical Devices with Novel Materials

Recently, there are active R&D regarding 3D printing artificial joints using cobalt-chrome alloy for orthopedic implants. Accordingly, it became necessary to draft a approval and evaluation guidelines for artificial joints that propose evaluation items and considers characteristics of the product to support prompt approval and ensure safety/performance. Thus, the MFDS published the “Guidelines for Approval and Evaluation for Cobalt-Chrome Alloy Artificial Joints Using 3D Printers (guidelines for civil petitioners)” that include corrosiveness testing and performance evaluation in consideration of possible corrosion in a body in order to contribute to the

promotion of the industry via rapid approval and evaluation while securing safety.

Furthermore, following the research to use human-derived materials including human waste fat as raw materials for medical devices, the interest is increasing in every social sphere. As a result, the revised Waste Control Act (draft) was proposed to enable the industry to recycle waste fat, which used to be controlled as waste, as raw materials for medical devices. With regard to it, “Approval and Evaluation Plans for Medical Devices Using Human Derived Materials” were prepared to make sure consumers can safely use medical devices using human-derived materials (i.e. collagen) and support the industry’s development efforts. Major content is as follows: 1) Virus inactivation during the manufacturing process, 2) Safety and performance evaluation, 3) Suitability of the donor, and 4) Guaranteed traceability.

chapter 4

Risk Prevention

Section 1

Establishment of Consumer-Oriented, Preemptive Risk Prevention and Foundation for Crisis Responses

1. Establishment of a Foundation for a Crisis Response System to Prevent Safety Incidents

In preparation against an emergency that may threaten public health or cause uneasiness because of a food and drug safety incident, it is necessary to refine emergency manuals in normal times and carry out systematic and repetitive education/training to enhance the capacity of working-level staff for swift and preemptive responses and countermeasures.

Beginning with the establishment of the manual for food and drug safety in 2009 that defines the emergency protocol for each sector of food and drug, the MFDS also set the manuals for medical devices (2011) and cosmetics (2012). Furthermore, since 2019, it has drawn up and implemented the “Emergency Protocols for Major Food and Drug Safety Incidents,” which was revised in accordance with the national risk management system following the basic guidelines for national crisis management.

The Ministry also published the “Manual for Crisis Management Practice in Case

of Radiation Leakage of a Neighboring Country” (2012), “Manual for Crisis Response Practice for Nuclear Safety (Nuclear Leakage)” (2015), and “Manual for Crisis Management Practice against Infectious Diseases” (2015). On top of it, in 2020, it revised its practice manual according to the amended standards manual.

In the year 2020, in particular, the MFDS established a patient-centered crisis response organization to prepare for a crisis causing patient incidents while developing its work flowcharts for each of the 10 types of incidents for a prompt response.

In order to strengthen its crisis response capacity, the Ministry has been constantly performed relevant training and drills. As part of such efforts, it conducted training for crises related to areas of hygiene products and infectious diseases in 2020.

For its members to be able to follow the manual for food/drug crisis response on the site, the MFDS will not save its efforts to improve its crisis manuals and provide site-oriented drills to intensify initial response ability, thereby advancing the crisis response system and capacity of its staff. In addition, for swift crisis response in case of food/drug accidents, it plans to build a systematic mutual cooperation system among relevant ministries and institutes and keep advancing its rapid response system against new types of crisis to minimize damage to the public with the prompt implementation of countermeasures and securing public safety and trust.

2. Preliminary Survey on Food and Drug Risk Factors for Risk Prevention

A. Preventive Risk Management

The MFDS is collecting risk information via various channels such as domestic & foreign government institutes, international organizations, and the media to secure the safety of products, including domestically distributed foods, that may harm people. In case that necessary measures should be taken with regard to domestic

distribution – when collected information identifies that a product should be under urgent management or possible to harm human bodies, or has nonconforming factors –, the Ministry reviews ways for its management and take action such as prohibition of manufacturing/sale/distribution to prevent food safety.

For harmful substances with no domestic standards or in uncontrolled areas, the MFDS has been collecting and inspecting food and pharmaceuticals through preliminary surveys since 2006 to formulate safety management measures. Depending on the survey results, the Ministry assesses potentially hazardous foods to check if they are harmful to humans and set standards and specifications and takes action by recommending suspension of manufacturing/sale or reduction of such items.

In 2020, the MFDS reported 652 cases of collection and inspection from three categories of food and hygiene products: hydrogen cyanide in cassava and processed foods containing cassava, ochratoxin A in food ingredients for both food and drugs (25 types), and fluorescent whitening agents in wet towels categorized as hygiene products. Based on the preliminary survey results, the Ministry checked the safety level of relevant products and is underway to set the standards for wet towels.

In 2021, the MFDS will create standards for management, and its efforts will include about 500 preliminary surveys and the establishment of standards.

B. Establishment of Basis for Managing Harmful Substances in Tobacco

Tobacco smoke contains thousands of harmful substances such as carcinogens and various chemicals added to Tobacco in the manufacturing process. However, information on harmful substances contained in manufacturing ingredients and smoke is insufficient.

Especially, it has become more important to come up with plans to manage e-cigarettes as many people died from severe lung damage caused by e-liquid in succession in the U.S. in 2019.

Korea ratified the "Framework Convention on Tobacco Control (FCTC)"[1] in May 2005 and has been developing various policies. However, it has not introduced regulatory policies to analyze and control or disclose tobacco ingredients yet and is still in the discussion concerning the introduction and amendment of relevant laws.

The MFDS has been developing methods for tobacco ingredient analysis and investigating and analyzing overseas regulatory cases since 2013 as a base study to analyze and disclose harmful substances of tobacco. Based on this, the Ministry announced the share of harmful substances present in regular cigarettes and e-liquid in 2017, and the harmful content of heat-not-burn (HNB) tobacco in 2018.

Besides, in 2019, the MFDS analyzed e-liquid in domestic products to find if it contained any of the substances that caused severe lung damage related to e-liquid in the U.S. (seven ingredients including those derived from hemp [tetrahydrocannabinol] and vitamin E acetate) and announced the results. The Ministry also analyzed and disclosed the content of harmful substances in e-liquid (seven ingredients including vitamin E acetate, propylene glycol, and glycerin) in 2020. The US Centers for Disease Control and Prevention (CDC) pointed out vitamin E acetate as a substance that might be a major reason for serious lung damage risks. The Ministry confirmed that it was not detected in the smoke of e-cigarettes sold in Korea, but three flavoring substances (diacetyl, acetoin, and 2,3-pentanedione) that might cause lung diseases were found in some of the products.

To tackle the issue, the MFDS operated a response team on e-cigarettes in cooperation with relevant ministries such as the Ministry of Economy and Finance (MOEF), the Ministry of Health and Welfare (MOHW), and the Korea Disease Control and Prevention Agency (KCDC). The MFDS analyzed harmful substances and shared the results with the KCDC. The agency used them when studying the

1 It is the first international treaty in health area adopted by unanimous consent by the WHO in May 2003, and ratified by 181 countries as of January 2020. It contains price and non-price measures and institutional strategies to reduce the demand and supply of tobacco.

harmfulness of the substances per content.

Additionally, it developed a method to distinguish natural nicotine from synthetic nicotine to find out e-liquid falsely labeled as synthetic nicotine by discerning natural/synthetic one.

The MFDS is also planning to enact and revise relevant laws cooperating with other ministries so that it is solely in charge of the affairs related to management of harmful substances such as submission/disclosure of tobacco materials. To this end, the Ministry is jointly working with the MOEF, which is in charge of the revision of the Tobacco Business Act. The Revised Tobacco Business Act (Kim Su-heung, representative proposer, of the Strategy and Finance Committee) and the Tobacco Hazard Management Bill (Choi Hye-young, representative proposer, of the Health and Welfare Committee) were also proposed on Jul. 14, 2020 and on Jul. 17, 2020, respectively, and are currently under discussion at the National Assembly.

The MFDS has been conducting base studies to control harmful substances including developing analysis methods for tobacco substances. Between 2021 and 2023, the Ministry will compare and analyze 44 harmful substances from the smoke of regular tobaccos and HNB tobaccos sold in Korea in order to obtain the baseline data in preparation for the introduction of analysis/introduction regulations on harmful substances in tobaccos. As for liquid e-cigarette (e-liquid), it will design an analysis method for heavy metals and additives such as flavoring substances.

Further, the Ministry is going to have close coordination with the National Assembly and related ministries to enact and revise the relevant law to make it mandatory for tobacco sellers to submit information on tobacco ingredients as well as to review and announce the submitted information to the public in order to enact and amend related laws and respond to the emergence of new types of cigarettes that may threaten people's health. The MFDS will expand its international cooperation activities to conform with international regulations through the implementation of the FCTC of the WHO.

3. Establishment of the Roadmap for Research & Development on Food and Drug Safety Technology

The Act on the Promotion of Technology for Ensuring the Safety, Food, Drugs, Etc. consists of 18 articles that stipulate the obligation to devise master plans for the promotion of safety technology and formulate the grounds for awarding financial contributions, and a system to promote safety technology. The act was passed by the National Assembly on May 18, 2015 (Act No. 13333) and effectuated on Nov. 19.

Following the enactment and enforcement of the Act, the First Master Plan of the MFDS for the Promotion of Safety Technology for Food, Drugs, Etc. (2016-2020) was established and implemented from April 2016 to 2020. In 2020, the Ministry established the Second Master Plan for the Promotion of Safety Technology for Food, Drugs, Etc. (2021-2025). The second master plan will be implemented between 2021 to 2025, and the MFDS is setting its R&D directions for food and drug safety technology by developing annual action plans according to the master plan.

In addition, the MFDS refined the Regulations for the Operation of Research and Development of Safety Technology for Food, Drugs, Etc. (MFDS Instruction No. 183, Dec. 29, 2019) to enhance the efficiency of R&D project operation/management and convenience of researchers by categorizing the projects into self-, contract, contribution, and joint R&D projects based on the operation/management characteristics.

The Ministry is planning to further cooperate with science and technology-related ministries to commercialize excellent achievements of national R&D by enacting and effectuating the Guidelines for the Ministerial Relay for National R&D Achievement (public notice) (February 2021). It will also continue to establish and carry out R&D projects for the development and promotion of food and drug safety technology.

4. Strengthening of the Cooperation System on Food and Drug Safety Issues between the MFDS and Korea Consumer Agency

As consumers' interest in health-related food, pharmaceuticals, cosmetics, and medical devices has increased rapidly, various organizations including the Korea Consumer Agency (KCA) and consumer groups are strengthening efforts to implement consumer safety campaigns and provide damage relief services.

In particular, the KCA directly collects and analyzes data related to consumer complaints and risk data and announces information on the safety of a product to the public after conducting research and study, if needed, through various media and other means.

In this regard, there is a need to form a close cooperative relationship between the KCA and the MFDS, which has unique expertise and policies on the safety of food and drugs. This would allow both of them to provide accurate information on relevant products and to carry out joint research and study when necessary.

In 2009, the MFDS signed an MOU with the KCA and has continued to work together by sharing consumer injury information and carrying out joint research and investigation on the safety of food and drugs.

Particularly, with a view to preventing the release of inaccurate information and resulting confusion, the MOU was renewed in 2015, and it was mutually agreed to hold a consultation meeting prior to public announcements related to food and drug safety. In 2019, the two organizations provided information to the public through 21 press releases from the KCA with mutual consultation and worked together to improve relevant regulations by reviewing 17 policy proposals.

The MFDS and the KCA also set up a system for joint project planning and investigation/announcement on agendas of consumer interest, established a communication channel for mutual cooperation, and held regular meetings to build and maintain a constructive, cooperative relationship.

In 2021, the Ministry will keep operating the close cooperation system with the KCA including prior consultation for public announcement, joint survey and research, exchange of hazard information and hosting meetings.

5. Prevention of Consumer Damage by Blocking False/Exaggerative Online Advertisements

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

1) Continuous Growth of Online Markets and Changing Environments

With advancements in technology, the modes of product advertisement and sale are shifting fast from offline to online (Internet/mobile). As the scale of online markets is expanding at a rapid pace lately, the portion of food and beverages and cosmetics controlled by the MFDS has also increased. Recently, the online advertising industry is actively using advanced digital technologies, and, therefore, it is necessary to reform the online monitoring system.

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

Given the characteristics of online markets such as anonymity, contactless transactions, borderless functions, and convenient market entry, illegal activities are hard to specify and regulatory restrictions are seldom effective. This generates serious social issues about false/exaggerative advertisements and rampant illegal activities, such as unlawful product distribution, in the online markets.

Especially, government monitoring and management are necessary for boundary

products (industrial products) that claim medical effects without verification of safety since they are in the blind spot of government control.

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

1) Contribution to a Safe Purchase Environment by Conducting Focused Investigations on Products of Consumers' Interest

In 2019, the MFDS held an idea contest and analyzed the Public Communication Bureau's survey result on the eradication of false/exaggerative online advertisements. Based on the obtained information, the MFDS elicited items to be reviewed, selected online priority review areas for 2020 through discussion with consumer groups, and performed related work.

Based on this, the MFDS carried out 40 inspections on false/exaggerative online advertisements and unlawful distribution of krill oil, protective products to prevent COVID-19 infection, and products advertised by influencers.

The major cases were: prevention of possible spread of damage via swift inspection of hydrogen peroxide that caused serious harm to consumers such as hemoptysis and announcement of the result; on-site inspection and administrative accusation of famous social media influencers and companies with intentional and frequent violation cases; and 5 inspections on unfair advertising for protective products such as masks and hand sanitizers to help people overcome the COVID-19 outbreaks, detecting 2,800 violation cases.

Additionally, the MFDS regularly announced review results and disclosed identified firms and product names through 36 times of press releases, providing information to protect consumers from false/exaggerative advertisements.

2) Prevention of Consumer Damage by Establishing a Constant Online Monitoring System

The operation mechanism of the Cyber Investigation Bureau is as follows: it selects monitoring targets and devises a monitoring plan through civil reports submitted via e-People, 1399, and social issues and then searches and monitors open markets, individually operated shopping malls, and posts on the portals and reviews illegality of the outcome.

If a violation of law is confirmed, the Bureau requests the Korea Broadcasting Commission or portal operators to close the relevant website. Case by case, the process may include accusation, request for investigation, and on-site investigation.

The Bureau took action including shutting down 96,597 websites in 2020 through constant online monitoring with regard to false/exaggerative online advertisements and unlawful distribution.

3) Prompt Shutoff of Illegal Websites Based on Stronger Private/Public Cooperation and Establishment of a Channel for Reporting Illegal Distribution

The MFDS crafted operator-centered measures to promote the government's policy against illegal distribution and to guide and induce online sellers and distributors to adopt legally acceptable practices voluntarily. As part of such efforts, the Ministry signed MOUs with 35 organizations including the Online Distribution Association, TV Homeshopping Association, and T Commerce Association and their members in 2019. The MFDS requested MOU partners including portal operators to shut off websites facilitating false/exaggerative advertisements and unlawful distribution.

Additionally, the MFDS opened a channel for reporting illegal online distribution on its website (from March 2019) and has been offering guidelines and information.

4) Provision of an Opportunity for Recognizing False/Exaggerative Advertisements by Scientifically Verifying Products that Claim Medical Effectiveness

Since the MFDS was aware of the need to set up an objective verification system regarding unverified medical efficacy/effectiveness to prevent consumers from being cheated by false/exaggerative advertisements, it organized the "Private Advertisement Verification Group" where experts examine ads objectively/scientifically. The group comprised a total of 43 private sector experts such as medical doctors/professors/journalists/those from consumer groups & industries. The main targets of examination were food and cosmetics advertisements claiming scientifically unverified cure/prevention of disease, health improvement, diet value, or addition of natural/organic ingredients. The Ministry ensured fairness and reliability of the verification policy and protected consumers' right to know by having experts in the relevant fields verify their content through thesis analysis and data survey and announced the results 10 times.

5) Expansion of a Culture to Forge Public Consensus on Eradicating Illegal Online Distribution of Food and Drugs

To further eradicate false/exaggerative advertisements and illegal distribution, the MFDS held contests on ideas, UCCs, and webtoons for the public to involve. They were promoted via portal banners of social media such as YouTube and Facebook, IPTVs for viewers who want health-related information, and subways/traditional markets.

C. Plan to Eradicate False/Exaggerative Online Advertisements and Unlawful Distribution

1) Reinforcement of Consumer-Centered Online Monitoring Capability

With more online shopping markets, false/exaggerative advertisements and illegal distribution continue to come up by means such as changing the website address regularly, despite constant crackdowns. Therefore, the MFDS intends to identify and carry out planned inspections of repeatedly violating goods, items of public interest, products at issue from the standpoint of the media/National Assembly. The Ministry will also strictly implement post-management of targeted products through regular/repeated monitoring.

2) Provision of Consumer-Friendly Information and Stronger Cooperation with the Industry

So far, the MFDS has delivered information only in the form of news or reports by announcing results of its planned crackdowns and verification results of the Private Advertisement Verification Group on false/exaggerative online advertisements. However, the MFDS now plans to stage an online campaign in cooperation with YouTubers and portal operators.

The Ministry plans to establish a regular monitoring system by operating online monitoring civil groups while expanding civil advertisement verification groups to reinforce objective and specialized verification of products that claim to have a positive effect on health.

3) Strengthened Online Safety Management for Food and Drugs in Cooperation with Relevant Institutes

The MFDS will cooperate with central administrative agencies, local governments, and associations; build an effective system on wrongful online advertising via consultative bodies; and reinforce its role as a control tower of online safety management for food and drugs. In addition, the Ministry will make an environment to strengthen voluntary management by providing information that can be used by civil servants in charge of false and exaggerative advertisements and sellers.

Section 2

Building Consumer Trust through Reinforced People-Friendly Communication on Food and Drugs

1. Enhancing Two-way Communication by Identifying Consumer Needs

The MFDS has striven to identify, reinforce, and improve weak areas in food and drug policies by establishing a two-way communication channel with people from all levels of society in order to listen to various opinions and encourage the public to engage in policy making.

In this regard, the MFDS formed a communication group consisting of 1,000 people aged 19 or above to identify consumers' complaints and concerns on food and drug safety, and analyzed consumer consultation cases and media reports to find consumer needs. In cooperation with relevant divisions, the Ministry took action on such needs. These measures included: instruction and supervision, status surveys, institutional improvement and provision of life-friendly information.

Apart from this, 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 strengthen public trust in the government. This forum serves as a venue where consumers, civic groups, industry, academia, related agencies, and ordinary people participate and present their opinions.

By establishing a bilateral communication channel that directly collects and feedbacks public opinions via various channels with consumers and civic groups, the Ministry discovered information related to daily life and quickly produced and distributed consumer newsletters that include correct information by time and issue.

The MFDS will preemptively identify and respond to concerns by enhancing a two-way communication channel that conveys inputs from/to the public through a precautionary communication system. This would help to reassure the public and communicate with them about safe management of food and drugs.

2. Disseminating Food and Drug Safety Culture Based on Communication Tailored to Targets

The MFDS operates diverse participatory programs so as to communicate with people of various classes ranging from youths to seniors, and in turn, enable them to have firsthand experience of food and drug policy.

The MFDS runs a program called “Food and Drug Young Leader” for teenagers. It is a food and drug online/offline promotional program in which participants can take part in producing UCC and logo songs, social media publicity, and street campaigns on communication subjects.

Furthermore, the MFDS operates “Food and Drugs Avengers,” a social communicator initiative for MFDS internal experts and the general public, and pursues open communication reflecting fresh ideas from the public about food and drug safety policy and life-friendly information.

Additionally, in order to assist vulnerable groups such as elderly people who have difficulties distinguishing and acquiring correct information via broadcast or online channels, the MFDS conducts a program that connects face-to-face education and non-contact education through life-care managers (teamed up with the Ministry of Health and Welfare) to prevent damage from wrong use of food and pharmaceuticals and false/exaggerative advertisements. In 2020, the MFDS visited welfare centers, senior-citizen centers, public health centers, etc. in seven cities and provinces (Gyeonggi, Gangwon, Chungnam, Gyeongnam, Gyeongbuk, Jeonnam, and Jeonbuk), and carried out food and drug safety education sessions for a total of 7,541 elderly people.

In the future, the MFDS plans to listen to the public voice on food and drug safety first; promote communication tailored to average people by establishing a systematic strategy based on national awareness; and take the lead in improving public awareness of safety and spreading safety culture.

Section 3

Expansion of Sharing, Disclosure, and Use of Food and Medical Product Safety Information

1. Collecting, Analyzing, and Utilizing Information on Food and Medical Product Safety

Trade volumes have been expanding between countries which are stimulated by more Free Trade Agreements (FTAs), and customs clearance agents and personal direct purchases from overseas have been increasing. Thus, stricter safety management of food and drugs is getting more essential. To respond to this, the MFDS established a methodical system for preventing hazard accidents through prompt and accurate collection, analysis, and sharing of information 24/7 on the safety of domestic and foreign foods and medical products.

The MFDS monitors 200 food-related websites of 29 countries and 165 medical product-related websites of 23 countries to collect data on hazards, and runs the Overseas Information Reporter System utilizing Korean expatriates, who engage in applicable fields, to gather local information.

The MFDS collected 49,591 cases of risk information in 2020 and took preemptive

safety management actions such as stricter inspection and temporary suspension of distribution and sale on 612 cases. In addition, it gathered a total of 1,634 pieces of local information through overseas reporters. Among them, in-depth information of 181 pieces was used as policy references for relevant departments.

Along with this, the MFDS operated “Room for Cautions to Overseas Korean Travelers” for consumers who travel abroad, offering information on 90 cases in 2019. The Ministry delivered information on 585 cases through “Room for Cautions about Overseas Direct Purchase” on the Food Safety Korea website, to assure the safety of consumers who purchase food and medicine directly from abroad.

For companies exporting food and medical products overseas, the Ministry offered a total of 127 pieces of information, including regulatory information by country, through the MFDS website “Export Support Room.”

It plans to proactively promote safety management by continuously operating the information collection system for foods and medical products and regularly collecting, analyzing, and sharing risk information on the goods that are left unchecked.

2. Pan-Governmental Linkage and Integration of Food Safety Information and Advancement of Food Administration

The number of potential risk factors that affect food safety is on the rise: climate change, environmental pollution, change in the food industry, and growing trade between countries. In addition, the public is more concerned about health, nutrition and safety associated with food. Moreover, there is increasing demand for creative, big data-based innovation, to solve food safety problems and issues and help consumers make the right decision. It is expected that science & technology originating from the Fourth Industrial Revolution would help to meet the challenges.

The MFDS held pan-ministry integrated network operation meetings twice a year to link, integrate, and utilize food safety information scattered among ministries, such as the Ministry of Agriculture, Food and Rural Affairs, the Ministry of Oceans and Fisheries; expanded information-linked institutes of the integrated network to 30 agencies to disclose this information for the benefit of the public; and increased the variety of information to be connected and shared from 159 to 234 types, enhancing the availability of information on food safety.

In response to the prolonged COVID-19 and changes in dietary habits, the MFDS further linked restaurant sanitation information to the delivery apps with a growing market, allowing consumers to check administrative measures for delivery restaurants before ordering food. It also provided the "Word Cloud" service that visually expresses popular search terms in the Food Safety Korea, Korea's representative portal in food safety, and the "Tree Map" service that shows the most frequented menus, helping visitors of 25.27 million as of 2020 to grasp issues and key information at a glance.

Moreover, the MFDS operated an application "Food Safety Information in My Hand" to help people view anytime and anywhere information on matters such as administrative actions taken against their community restaurants and food makers, their sanitation grade system, and participants of the sodium-reduction drive. In addition, people could report fraudulent and defective foods more conveniently through the improved consumer reporting function.

The Ministry established a cooperative system with the private sector such as startup companies, and held consultations with "private experts in the food information industry" to further activate the use of food safety information. As a result of proactively listening to and responding to user opinions, the opening and utilization of public information increased 65% from a year ago to 3.05 million cases.

The MFDS plans to expand the food safety environment by actively disclosing public data and expanding links with the private sector, such as delivery apps, and vitalizing the private use of public data through contests so that anyone can employ food safety information. Further, it intends to implement a scientific food administration system by improving public services, including convenience functions for consumers and operators and industrial support services, and the administrative system for each step such as production stage.

Section 4

Enhancing International Competitiveness through Advancement of Testing and Inspection Agencies

1. Advancement of Testing and Inspection Agencies Management System in the Food and Drug Area

The MFDS promoted the reliability and enhance inspection quality of testing and inspection agencies by enacting the Act on Testing and Inspection in the Food and Drug Industry in 2013 (enforced on Jul. 31, 2014). The Ministry also instituted the enforcement decree and enforcement rule of the same act, and the Regulation on the Evaluation of Testing and Inspection Agencies in the Food and Drug Industry, in 2014.

Among testing and inspection agencies, there are statutory inspection agencies designated according to the ordinance of the Prime Minister, private inspection agencies designated by the Minister of the MFDS, as well as foreign testing and inspection laboratories located in overseas countries. These agencies are also classified by category: food, livestock, medicine, cosmetics, medical devices and hygiene products.

Any entity that wants to submit an application 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 regulations. The applicant shall be evaluated through submitted documents and on-site inspection and designated as a testing/inspection agency if the specified requirements are met.

The table below shows the status of testing/inspection agencies designated by the MFDS as of the end of December 2020.

Table 4-1 Status of Testing/Inspection Agencies by Categories

(As of Dec. 31, 2020, Unit: case, Source: Laboratory Audit and Policy Division)

Category	Total	Domestic Institutions		Foreign Statutory Institutions
		Statutory Institutions	Private Institutions	
Food	163	25	78 (P 15, C 63)	60
Livestock	80	26	54 (Import 4, C 50)	-
Medicine	47	24	23 (Medicine 19, medicinal herb 3, Medicine/herbal medicine 1)	-
Cosmetics	41	24	17	-
Medical devices	14	1	13	-
Hygiene products	36	24	12	-

※ P: Professional food testing and inspection agency
C: Commissioned self-quality testing and inspection agency

In particular, for the purpose of managing the inspection capacity of testing and inspection agencies, we provide unknown standard samples to testing / inspection institutions every year and carry out proficiency evaluations to evaluate the accuracy and accuracy of tests to improve the inspection quality of testing / inspection institutions. To ensure that it complies with the quality control standards of testing and inspection agencies such as operating system suitability, it is evaluated annually.

2. Strengthening the International Competitiveness of Testing and Inspection and Ensuring the Quality of Inspection

In 2018, the MFDS established a system to designate and operate national standard experiments in order to secure the international public credibility of national testing and testing capabilities in the food and pharmaceutical fields and to guide the testing and testing capabilities of private testing and testing institutions. It operates. The national standard experiment develops, provides, and verifies the official test method through the scientific support for the test · test, and when a social problem occurs and the test · test result is the final judgment at the time of controversy, the formula at the time of drug safety accident Crisis response test · inspection, test · inspection International cooperation, etc. It operates 16 experiments (26 items) in 2020, and strives to improve its international competitiveness by strengthening and expanding the continuous national standard clinical tests.

In response to the emergence of new trade agreements and the strengthening of norms requiring testing and inspection to be carried out at an international level, the evaluation system of national testing and inspection agencies should be harmonized with international standards, and the evaluation items of international standards The quality control standard evaluation system of the testing and inspection organization is being improved and promoted by reflecting all of the above. In order to secure the international public credibility of proficiency evaluation operated at the MFDS, we are promoting a consulting business for accreditation of internationally recognized proficiency evaluation institution in 2020, and designated as an internationally recognized proficiency evaluation institution this year (Accreditation ISO 17043).

MFDS have established an organic cooperative relationship between the City and Road Health and Environment Research Institute and private testing and inspection institutions to promptly respond to food and drug accidents. Every year, we hold test / inspection policy briefings, periodic private test / test representative round-table

conferences, food · pharmaceuticals · medical devices · cosmetics test · inspection institution business manager meetings, etc. The direction of the above is shared, and the difficulties in the field are converged and reflected in the policy.

In order to respond to the rapid increase in mask demand due to COVID-19 at the beginning of 2020, we will operate a hot-line with a mask inspection organization to listen to, resolve and support real-time complaints, and the mask inspection report issuance period will be from 45 days to 2 The number of days can be shortened significantly, and as a result, it can greatly contribute to the stable supply and demand of masks. In addition, although it was predicted that the mask manufacturing and supply would be hindered due to the shortage of mask filters at that time, the situation of production discontinuation could be made in advance by promptly issuing an inspection report for item approval of masks to which the new filter is applied. To prevent it, we actively assisted in promptly permitting the splash blocking mask (KF-AD). In order to improve the inspection quality of testing and inspection institutions in the future and strengthen the international competitiveness of testing and inspection, we plan to continuously communicate and cooperate with testing and inspection institutions and local governments.

Section 5

Establishment of a Safety Management System for Hygiene Products

1. Establishing a Foundation for Safety Management of Hygiene Products

A. Improvement of the Hygiene Products Safety Management System

The Public Health Act, which managed hygiene products such as detergents, wet wipes for restaurants, etc. that are closely related to daily lives of the public, was terminated in 1999 and the Public Health Control Act was enacted in its place.

However, the new law regulated only businesses such as lodging, hair design, bath and laundry related to public health concerns, not hygiene goods. In accordance with the Addendum to the Public Health Control Act, hygiene products were to be governed by the (former) Public Health Act until the enactment or amendment of the new law.

Yet, as there had been no regulatory action for 18 years since then, unreasonable cases appeared; there were blind spots and unnecessary regulatory application far

from reality because of a lack of legislation under changing circumstances.

In order to manufacture disposable water cups, printing machines and wax coating machines were required in the past since they themselves conducted paper coating and printing. But the operators still had to install more expensive equipment than they needed, though materials that were printed and coated beforehand were in common use.

In addition, one who wanted to declare sanitary imports must visit the competent government office at least twice, and the officials handled complaints manually. Besides, the Ministry of Health and Welfare, three local FDS Offices, and local governments controlled hygiene products together, which hindered effective safety management of life-friendly hygiene products.

Therefore, the Ministry enacted and implemented the Cleansing and Hygiene Products Control Act, to reorganize the safety management system by unifying the management bodies to the MFDS and to strengthen the safety management of hygiene products by preparing realistic management standards. As a result, the Cleansing and Hygiene Products Control Act was enacted and enforced.

The MFDS endeavored to enact separate legislation for hygiene products to improve national health by upgrading their management and improving the sanitary level. It enacted and promulgated the Cleansing and Hygiene Products Control Act in 2017 and established its subordinate regulations in 2018: the Enforcement Decree of Cleansing and Hygiene Products Control Act and the Enforcement Rules of Cleansing and Hygiene Products Control Act. Also, the Ministry instituted the Standards and Specifications for Hygiene Products, the Labeling Standards for Hygiene Products, the Regulation on the Inspection of Imported Hygiene Products, the Regulation on the Designation and Operation of Hygiene Education Institutions for Hygiene Products, and the Regulation on the Operation of Consumer Hygiene Watchdog System for Sanitary Goods, which were enforced with effect from Apr. 19, 2018.

According to the Cleansing and Hygiene Products Control Act, the MFDS

required operators, who manufacture and import hygiene products or sanitize wet towels, to report their business about the hygiene product manufacturing industry, the hygiene product import industry, and the wet towel sanitization industry, respectively. On top of it, the Ministry enhanced safety management for manufacturing and import so that people can use hygiene products safely by reporting the items, which contain ingredients at risk of exposure, to the competent authorities and by ensuring that imported hygiene products go through the MFDS before customs clearance or importation into Korea.

On the other hand, the MFDS reasonably improved the facility standards and inspection cycles to ease the burden on operators, and computerized business reports, item manufacturing reports, and import reports for more convenient civil services.

In 2019, the Ministry reasonably improved regulations to prevent unnecessary facility investments by permitting the same operator to use the same lab when he or she does business in the different industry as well as in the manufacture industry of food, livestock, health functional food, medicine, quasi-drugs, and cosmetics. In the past, only if the same operator who engaged in the same industry in different locations, he or she could use the same lab.

In 2020, the MFDS alleviated the burden of reporting by enabling operators to report at any time, which is different from the past restriction of 30 days prior to the date of business suspension, closure, or resumption. There was another improvement, too. Previously, product descriptions were labeled and advertised only when they were certified and guaranteed by central or local administrative agencies, local governments, or public institutions. However, under new statutes (amended the enforcement rule, Jul. 22, 2020), the content certified by foreign government agencies can now be labeled and advertised.

Meanwhile, the Ministry sought to strengthen sanctions against habitual and persistent violators by establishing standards to differentiate fines on the number of repeated violations (amended the enforcement decree, Mar. 24, 2020).

The Ministry has hygiene product operators (hygiene product and hygiene wet towel manufacturing business) periodically inspect their own quality and manufacture and distribute only products that meet the Standards and Specifications for Hygiene Products. This is a new obligation for the operators after the Cleansing and Hygiene Products Control Act (Apr. 19, 2018), requiring wet towels to be examined more than once a month; the items subject to reporting such as cleaning agents to be inspected more than once every three months; and other items to be inspected more than once every six months. In 2020, the MFDS enacted the Designation of Self-Quality Inspection Items and Details of Hygiene Products was as its notification (Jun. 2, 2020) to make the system more effective, such as adjusting inspection items. As a result, the operators can conduct tests centered on harmful ingredients and microorganisms.

For hygiene products, the amount of the content shall be marked, and the allowable shortage amount have been set in the Labeling Standards for Hygiene Products according to each labelling method (length, weight, etc.). In particular, items such as toilet paper should not lack in actual content compared to those labelled by the manufacturer. So, with the revision of the Labeling Standards for Hygiene Products (Sep. 2, 2020), the MFDS introduced width and length tolerances for hygiene products (disposable toilet paper, disposable dishcloths, disposable paper napkins, etc.). In future, it will also consider industrial conditions including small business sizes and support the development of the hygiene product industry by improving regulations rationally to enhance the effectiveness of safety management.

In 2021, the MFDS plans to clarify the scope of management of hygiene products and redefine their definitions by considering the purpose of use, human contact methods, and risks. In addition, it will reorganize the item designation method to quickly adopt items that need to be managed.

In addition, the Ministry will preemptively block the distribution and sale of hygiene products by providing grounds to dispose of risky products as well as

non-conforming products, and reinforce pre- and post-safety management by designating tattoo dyes, which is now controlled under the Ministry of Environment, as hygiene products.

B. Management of the Standards and Specifications for Hygiene Products

Most of 19 hygiene products under the Cleansing and Hygiene Products Control Act have not been controlled in safety or never been re-evaluated in public health for a long time. Therefore, safety standards and specifications for hygiene products should be refined in line with the latest science and technology, consumer and business requirements, and recent changes in living conditions such as consumption trends.

With the development of science and technology, various materials (raw materials) are used to make hygiene products, and convenient products that combine hygiene products, electrical goods and household goods are being developed. To safely manage emerging new products, their standards and specifications need to be modified.

Environmental problems caused by plastic waste are emerging as a global issue. Now that the use of disposable hygiene products translates to environmental waste, the MFDS has pushed to convert their materials (plastic, synthetic fiber, etc.). For example, the Ministry prepared the standards, specifications, and test methods (April 2020) to control the safety of hygiene products made of natural materials: disposable straws using reeds, bamboo, etc., disposable diapers using natural absorbers, and disposable dishcloths using plant fibers.

In addition, new hygiene products with practical and convenient functions are emerging according to advanced science and technology and consumer needs for convenience. For instance, a product has been released to remotely notify nurses of the time of diaper replacement for seniors or patients using diapers in nursing homes by attaching a urine detection sensor to regular disposable diapers. Thus, the Ministry created the criteria to manage them (September 2019).

There is an increasing need for safety management of household chemical products after the humidifier disinfectant incident in Korea. Accordingly, the MFDS enacted and distributed (July 2020) the “Guidelines for Applicants for Using Cleaner Ingredients” to improve safety management of cleaning agents that use chemicals as major raw materials. This enables manufacturers and importers of cleaning agents to preliminarily judge the safety, etc. of ingredients (raw materials) they want to use newly in cleaning agents.

To help people use safer products, the Ministry revised the Standards and Specifications for Hygiene Products, and arranged a direction for the standards and standards for safe and proper hygiene products through debates and discussions with experts in various fields.

The MFDS will assure the safety of raw materials used in cleaning agents, rinsing supplements, kitchen towels, and wet towels closely related to national food consumption, so that safer hygiene products can be provided to the public. It will also include the items, which have similar levels of raw materials and manufacturing processes and safety management to those of hygiene products, into the items subject to the Cleansing and Hygiene Products Control Act. By doing so, the MFDS will efficiently manage them.

Further, to solve the growing environmental pollution problem attributed to increasing disposable products, the Ministry plans to revise their standards and specifications so that eco-friendly materials such as natural materials and biodegradable materials can be used to manufacture disposable hygiene products.

Moreover, it will continue to carry out research to strengthen the safety management of chemicals in hygiene products, revising the Standards and Specifications for Hygiene Products so that the goods can be safely managed from raw materials to final products.

2. Safety Management of Distributed Hygiene Products

A. Safety Management of Domestically Distributed Hygiene Products

The MFDS integrated hygiene products, food appliances, industrial products, or non-legally-governed items into one management system, the Cleansing and Hygiene Products Control Act, and has implemented it for more than three years. This unified management system is in need to provide a foundation for people to use products with confidence by raising the level of safety management of hygiene products that directly contact with the human body.

Recently, people more prefer disposable products that are inevitably used personally, so safety management in false/exaggerative online advertising is more important. In addition, not only safety management but also industrial (manufacturing) foundation are desperately required, to take into account industrial conditions such as the small size of sanitary goods companies and to raise safety management effectiveness by improving unreasonable standards.

Hygiene product manufacturers shall report their business in compliance with the facilities standard, etc., and observe the obligation on reporting the items that are feared to expose chemicals, and other obligations on labelling standards, self-quality inspections, production performance reporting, etc.

After hygiene products increased to 19 items, the overall industrial status was surveyed based on the previous year's production performance. It was reported in 2020 by hygiene product manufacturers and hygienic wet towel processing operators. The production performance is a combination of the manufacturing, processing, and portioning results of hygiene products and the sanitization results of wet towels used by food service providers. The findings of the 2020 survey showed that the performance in 2019 was worth about KRW 2.02 trillion. The scale is estimated to account for 0.42% of gross domestic product (GDP) and 0.11% of GDP with about KRW 2 trillion in manufacturing hygiene products and about KRW 20 billion in sanitization respectively. Among made-in-Korea products, top items in distribution and sales were toilet paper, disposable diapers, cleaning agents, disposable cups, and disposable towels.

Hygiene products are closely associated with people's lives, such as disposable cups, which leads to a greater need for safety. In this vein, it is essential to build their safety management foundation. Since 2018, the MFDS has examined hygiene products, and guiding and inspecting the hygiene product manufacturing industry and hygienic wet towel sanitization businesses. In doing so, the Ministry is raising the level of hygiene product safety management to forge a basis for people to use the products with confidence. In particular, it has established a safety management plan, and the local FDA Offices and Si/Do (city, county, district) have mapped out and implemented detailed plans in accordance with the Ministry's guidelines.

After the first nationwide joint crackdown in 2019, the MFDS selected products with multiple records of nonconformities—wet towels, cleaning agents and wet wipes used by food service providers—, intentional and habitual violators, and products at issue. And it made enforcement more effective by notifying operators of the crackdown plan in advance so that they could autonomously raise their sanitation level and by making the media report uncovered violations.

In 2020, the Ministry inspected along with local governments the disposable products that were in increasing use due to changes in consumption patterns. As a result, it investigated 703 hygiene product manufacturers and wet towel sanitization companies and detected 15 companies, and found 4 out of 397 products to be inadequate.

Apart from the joint crackdown, the MFDS conducted five planned crackdowns in 2020, focusing on risk and consumer deception activities targeting nonconformities, social issue items, and commonly used items. It supervised and inspected a total of 2,007 sales offices and detected 57 nonconformities. The nonconformity rate was 2.8%, which continued to decline since the enforcement of the Cleansing and Hygiene Products Control Act (April 19,2018). In addition, the

MFDS collected and inspected 3,995 hygiene products, and seized and discarded 9 nonconforming products. The nonconformity rate plummeted from the previous year to 0.2%. This is an improvement in the record in the previous year which originated from the detection of prohibited ingredients in imported cleaners. It seems that risk monitoring and the safety management crisis response system played an important role in such an achievement. Besides, safety management of hygiene products during distribution appears to be more stable in 2020 than the previous year, with nonconformities in guidance, inspection, collection, and testing on the decrease.

Wet towels are used in handwashing, etc. in food service stores. They are processed and packaged in sanitary ways, such as washing, sterilizing, and disinfection. In that wet towels were relevant to many cases of nonconformity and careless use in 2019, safety management during 2020 was concentrated on wet towel sanitation operators and food service providers as actually users. The MFDS prepared safety management rules and treatment guidelines for operators in the wet towel sanitization industry, and produced educational and promotional materials for consumers and food service workers to properly use wet towels. Additionally, the Ministry provided those materials to the Korea Wet Towel Industry Association and the Korea Foodservice Industry Association and tried to minimize the production and distribution of nonconforming products through education and promotion tailored to actual operators and users.

The hygiene product labeling system is operated as a notice under Article 11 of the Cleansing and Hygiene Products Control Act, providing accurate information for consumers to establish exact standards for product selection and serving as a ground to prevent consumer damage. From April 19, 2020, hygiene products shall not conform to previous governing laws such as the Public Health Control Act, the Food Sanitation Act, the Electrical Appliances and Consumer Products Safety Control Act, or the Special Act on the Safety of Children's Products. They shall be labeled pursuant to the Sanitary Products Management Act.

As the consumption pattern of hygiene products changes including their growing sales amount via communication media like the Internet and TV, the MFDS planned in 2020 to prevent consumer damage caused by false or exaggerative advertisements and confirm compliance with labeling matters about hygiene products. To that end, with local FDS Offices and 17 Si/Do (city, county, district), it intensively examined their labeling and advertising through the Internet (portal companies, open markets, etc.), broadcast (including home shopping) and newspapers in the second half of 2020. In future, the Ministry plans to make sure that more accurate and correct information can be provided to consumers. For this, it will check labels and advertisements that are likely to cause raw materials, components, effects, etc. to differ from the facts or be exaggerated and that may incur consumer deception, misunderstanding or confusion; and awards, letters of appreciation, certification, guarantee, recommendation, etc. that differ from the facts or have been exaggerated.

What's more, in order to reflect social needs for stronger consumer rights and safe use, the MFDS required firms to mark allergens among flavor components in hygiene products (Labeling Standards for Hygiene Products, amended on Sep. 2, 2020). Conventionally, fragrances used in manufacturing could be labeled as "such and such scent," with no obligation to mark detailed composition of allergens. However, the new mandatory labeling scheme allowed consumers to receive specific information to safely use sanitary products. From July 2022, a business operator that manufactures and imports hygiene products shall comply with relevant labeling obligations.

For hygiene product safety management, the MFDS plans to improve the efficiency of on-site inspections by expanding non-contact inspections in response to environmental changes such as COVID-19. Further, it will intensively crack down, from the manufacturing stage to the distribution stage, on the products used by vulnerable groups such as children and the elderly and the hygiene products that are repeatedly non-conformant every year. It will continue to guide and check false

labels by reflecting consumption trends such as increasing online distribution and sale as well. The Ministry is set to increase the effectiveness of safety management by regularly announcing inspection results and delivering specific information on violations, such as disclosing detected companies and products. In addition, it plans to strengthen standards for consumer safety and right to know, while actively improving unreasonable regulations to revitalize the hygiene product industry, which will improve the manufacturing environment and ensure consumers can purchase hygiene products with confidence.

B. Safety Management of Imported Hygiene Products

In 2020, the number of imports and the import volume from 36 countries (based on manufacturing countries) including China and Japan stood at 13,613 and 100,000 tons, respectively, up 30% and 49% from 2018. According to the status of import by country, China, Japan, Indonesia, Taiwan, and the U.S. are in order of large to small, and 81% of hygiene products are imported from the top five. Most of the nonconforming items are disposable cotton swabs from China, and it is time to control safety in customs clearance. Besides, public anxiety over imported hygiene products is still high due to the 2019 import cleaner incident triggered by isothiazolinones (CMIT/MIT), making it more important than ever to strengthen customs clearance inspection of imported products.

As customs clearance inspection (continuous inspection) was conducted in accordance with risk information, there were disruption of goods supply and overload of local FDS inspection institutions. So, the MFDS reviewed the possibility of improvement for the “Intelligent Imported Food Integration System,” and established an efficient inspection system (interim system) and conducted its pilot operation.

The MFDS analyzed data on the countries, items and manufacturers with a history of nonconformity and the cheap products priced not more than 70% of the average reported value, and applied different random sampling rates. It selected core inspection items for detailed inspection on risk information and concerns. The MFDS selected and operated items with a high risk information generation ratio or a high risk as “targets for ordered inspection” (the country bears the burden of inspection costs) based on risk information at the customs clearance stage. Among them, it enhanced the safety management of import cleaning agents by ordering simultaneous analysis tests even on rinse supplements and wet tissues for food service establishments, regarding the isothiazolinone family, including benzisothiazolinone (BIT) in the same family of methylchloroisothiazolinone (CMIT) and methylisothiazolinone (MIT), which are prohibited from using imported cleaning agents. The Ministry took preliminary action on safety management in advance in anticipation of an increasing import of eco-friendly disposable straws made of natural plants (reeds, etc.) according to the Ministry of Environment’s plan to reduce disposable products. Moreover, it acquired the safety of imported sanitary products by establishing an online pre-registration system for foreign manufacturers to prevent harm from hygiene products which were imported every year.

Considering the importance and level of risk information, it applied both the existing inspection method and intermittent inspection method to solve difficulties such as disruption of supply and demand of operators by distributing the workload of local office inspection agencies and pursuing seamless work. In addition, it secured the safety and quality control of imported hygiene products through intermittent inspections (pilot operation).

In order to establish a safety management system for the pre-import, customs, and distribution stages and realize a scientific and efficient inspection of imported hygiene products, the MFDS will automate the review of import declarations of imported hygiene products using the Intelligent Imported Food Integration System; streamline the customs inspection of imported products by analyzing accumulated information on hygiene product inspections and hazardous information; and realize intensive inspection of imported hygiene products with concern about risk.

Intermittent inspection will apply to hygiene products with a high nonconformity rate at the import stage. The MFDS will analyze and improve deficiencies after its trial operation and expand the number of items in subsequent test operation to enhance the sense of responsibility of operators and prevent recurrence of nonconformities. It will thereby create an environment for importing superior products.

chapter 5

Research and Development for Food and Drug Safety

Section 1

Research and Development that are Directly Linked to Safe Life of the Public

1. Research and Development Programs on Technology for Ensuring the Safety of Food, Drugs, etc.

A. Securing Safety Technology for Food, Drugs, Etc. that the Public Can Trust

For the research and development projects on technology for food and drug safety (hereinafter referred to as “R&D projects”), the MFDS have established and systematically implemented the Master Plan for Promoting Safety Technology for Food, Drugs, Etc. in accordance with Article 5 of the Act on the Promotion of Technology for Ensuring the Safety of Food, Drugs, Etc. The plan reflects progress directions and objectives, strategies for developing key technologies, and mid- to long-term investment directions to promote safety technology for food, drugs, etc. in Korea.

The purpose of the MFDS R&D projects is to develop scientific safety technology for food and drugs in a way of protecting the public so that they can enjoy safe and healthy lives. With the 2020 R&D budget of KRW 96.4 billion won, the MFDS

conducted seven specific R&D projects in the following areas: safety management of food, etc.; safety management of drugs, etc.; safety management of medical devices, etc.; R&D on safety evaluation technology; advancement of safety technology; safety management of agro-livestock and fishery products; and research on promoting private food & drug safety technology. Major R&D sizes continued to grow, reaching a total of 113.6 billion won (compound annual growth rate (CAGR) of 8.5% over the past five years), for 10 projects including three new ones – regulatory affairs talent project, project for assessing the foundation for next-generation medical products, and smart food safety management project. The details are shown in Table 5-1.

Table 5-1 Financial Operation of Key R&D Projects over the Recent Five Years

(As of Dec 31, 2020, Unit: 100 million won, Source: Research Planning and Management Division)

Classification	2017	2018	2019	2020	2021	CAGR (%)
Total	818.6	830.7	858.1	963.9	1,135.6	8.5
Safety management of food, etc.	280.8	298.0	310.2	318.0	338.7	4.8
Safety management of drugs, etc.	240.9	232.2	237.6	271.3	257.5	1.7
Safety management of medical devices, etc.	85.2	77.5	80.7	82.2	114.8	7.7
R&D on safety evaluation technology	125.3	133.4	135.8	182.8	190.3	11.0
Advancement of safety technology	34.4	32.4	31.4	16.5	9	-28.5
Safety management of agro-livestock and fishery products	52.0	57.2	62.4	91.1	104.4	19.0
Research on promoting private food & drug safety technology	-	-	-	2.0	20	900
Foundation for next-generation medical products	-	-	-	-	51.3	-
Regulatory affairs talent project	-	-	-	-	31	-
Smart food safety management	-	-	-	-	18.6	-

In regard to the R&D outcomes in 2019, under the category of safety management of food, etc., the MFDS invested KRW 31 billion and implemented 100 R&D projects to develop 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, development of technologies for reduction of harmful substances, and prevention of the causes of food poisoning. Further, in order to prepare a scientific basis for establishing safety management policies for pharmaceuticals and develop technologies for screening and evaluation to help rapid commercialization of pharmaceuticals, the MFDS invested KRW 23.8 billion and carried out 105 projects, improving the pharmaceutical safety system. For safety management of medical devices, etc., the MFDS invested KRW 8.1 billion and performed 41 projects focusing on the safety of medical devices and development of 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 13.5 billion and carried out 65 projects. The goal of these projects was to establish a scientific foundation for safety management policies governing food, drugs, etc. through base technologies for safety prediction and evaluation. These technologies would cover areas such as toxicity, pharmacology, clinical study, and advanced analysis, laboratory animals, and alternative tests. For the advancement of safety technology, the MFDS invested KRW 3.1 billion and conducted 6 projects. These were to build a base and a support system for companies in the private sector so that they can improve their capabilities regarding safety technologies. The Ministry intended to help them pursue private-led technical development rather than those led by the government by linking technical development, assistance for commercialization, and reinforcement of professional capability for food and drug safety. For safety management of agro-livestock and fishery products, the MFDS invested KRW 6.3 billion and carried out 16 projects to develop scientific inspection technologies, come up with measures for safety management of hazardous elements and set up a preventive safety management system.

The MFDS plans to expand priority investment in sectors that are deeply related to people's daily lives, and prepare a scientific basis to respond to low birth rates, aging society, and new and environmentally hazardous substances. 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 and screening policies to reinforce the international competitiveness of industries such as pharmaceuticals and cosmetics; and implement R&D projects with a view to pioneering technologies and preoccupying markets for leading the 4th Industrial Revolution.

2. Impartial Research Management and Provision of Services for Researchers

A. Systematic Evaluation of Research Tasks and Securing Transparency in R&D Costs

R&D work of the MFDS, which manages the safety of food, medicine, cosmetics and medical devices, is centered around securing scientific grounds such as setting related policies, standards, and specifications. Since 2016, the Ministry has also performed R&D tasks to enhance private food and drug safety technology. To establish transparent and impartial management of R&D tasks, it controls a series of processes, from planning, notification, selection and final evaluation to performance management, through a research performance management system. Research funds consist of 1) testing research funds for in-house studies, 2) outsourced R&D funds, and 3) grants based on the Act on the Promotion of Technology for Ensuring the Safety of Food, Drugs, etc. The MFDS also provides various services such as briefing sessions and brochures in order to help with administrative work of researchers so that they can concentrate on their work.

In 2020, a total of 213 new R&D tasks were selected through 22 sessions of evaluation. These included 56 in-house tasks, 138 outsourced tasks, and 19

funded tasks. In the case of outsourced R&D tasks, the Ministry introduced a price evaluation system based on the bidding price of a price proposal (March 2016) according to "Contract Standards by Negotiation," a contract regulation of the Ministry of Strategy and Finance. This system allows R&D plans to become substantive and enables researchers to estimate appropriate funds. Final evaluations or interim (annual) evaluations were performed for 223 tasks over 16 sessions.

The outsourced R&D projects in 2020 totaled 221 with 138 new tasks (26.3 billion won) and 83 continuing tasks (26.7 billion won), down from the previous year, but the total research costs increased to 53 billion won (※ 224 tasks conducted in 2019 and 51.88 billion won).

In addition, the MFDS selected 22 funded R&D tasks in 2016-19 and 28 tasks in 2020 by adding 19 tasks, with the contribution budget secured under of the Act on the Promotion of Technology for Ensuring the Safety of Food, Drugs, Etc. which was enacted in 2015.

In order to systematically and transparently manage R&D costs for services and funded R&D tasks, it introduced the research fund card system since 2003 and commissioned the research fund management system (July 2017). In addition, to improve user convenience and transparency of research fund execution, the MFDS has established and operated the Ez Food and Drug Research Fund Management System (January 2019) with advanced functions such as approving a plan before use and retrieving real-time usage histories. Since January 2020, the Ministry has been managed the fund for funded R&D tasks through the pan-ministry integrated research fund management system (Ezbaro) to enhance researcher convenience.

To ensure transparency and impartiality in executing R&D budgets, the MFDS entrusted account settlement to an external accounting corporation. It has designated an accounting corporation from 2018 in order to operate a preliminary consulting system for research funds so that outsourced R&D institutions can observe rules from the start of projects. The Ministry has also updated and distributed the "Guidelines for Standard Account Settlement for MFDS R&D Tasks" in consultation with the accounting corporation after publishing its first edition (August 2018).

Further, the MFDS is committed to facilitating successful research activities by sharing the changes every year. For this, it has been continuously revising and distributing the "R&D Guide for Researchers" after publishing its first edition (March 2018). It explains how to use, manage and settle the R&D budget to help researchers who involve MFDS R&D tasks.

Moreover, the MFDS held a briefing session (outsourced: September 2019, funded: October 2019) for research directors and related personnel in charge of MFDS R&D tasks on the use (settlement) of R&D budget. It published and disseminated the "R&D Cost Execution and Settlement Guide for Researchers" by organizing settlement procedures and answers to FAQs so that researchers can always refer to it in executing and settling R&D costs.

The MFDS will pursue transparent evaluation of R&D tasks and strive to create a researcher-oriented R&D environment to facilitate excellent outcomes by revising guidelines and regulations. For this, it will reflect pan-government standardization regulations, etc. which prescribe changes in procedures, forms, etc. under the enactment of the National R&D Innovation Act.

Further, the MFDS will hold a "R&D cost execution and settlement briefing" for research directors and institutes and publish a revised "R&D Cost Execution and Settlement Guide for Researchers." In particular, it plans to encourage researchers to execute and settle R&D costs correctly and create an environment to manage R&D funds transparently and reliably by producing and distributing video education materials that summarize answers to FAQs.

3. Performance Management for Effective Research and Development Tasks

A. Efforts to Create Excellent Performance and Promote and Spread It

The MFDS pushes for national R&D projects in accordance with related laws such as the Act on the Promotion of Technology for Ensuring the Safety of Food, Drugs, Etc. and the Framework Act on Science and Technology, and ensures the results are widely utilized. It also uses the standards, specifications, guidelines, and test methods, which are the R&D results, to establish safety management policies for food and medicine. In addition, the Ministry has established detailed project performance targets and indicators depending on project features pursuant to the Act on the Performance Evaluation and Management of National Research and Development Projects, Etc. In the case of tasks, it collects, verifies, and analyzes the results of each task according to the "MFDS Standard Performance Indicators" from planning to performance evaluation.

The MFDS set R&D project performance indicators by program (connection rate with food and drug safety policy) and for a unit project "Food and Drug Safety R&D" (elicitation of food and drug safety standards, SCI thesis index). The results for each indicator exceeded its target by more than 100% in 2020, and the performance by indicator has improved over the recent three years (2018-2020). In case of the thesis index, however, the performance dropped in 2019 compared to 2018 (67.9). Still, the figure increased between 2019 (67.3) and 2020 (67.5) and remains 1.9% higher than the average government R&D thesis index (66.25).

The MFDS undergoes a (self/higher-level) mid-term evaluation for specific projects. In 2020, it received "Excellent" rating for "R&D on Safety Evaluation Technology, etc." and "Normal" for "Advancement of Safety Management" in a higher-level evaluation conducted by the Ministry of Science and ICT (MSIT).

In addition, the MFDS achieved a feat: its two project results were selected among Korea's excellent 100 national R&D projects every year by the MSIT. Their titles were "Further Building and Utilizing Integrated Food Poisoning Bacteria Database" and "Scientific Assessment to Designate Narcotics and Development of the Fast Prediction and Assessment Method." Besides, "Strengthening a High-Tech Analysis System that Can Respond Quickly, Accurately, and Preemptively to Illegal Foods" was selected as an excellent R&D achievement in the field of disaster safety and won the Ministry of the Interior and Safety award.

To provide and utilize specific information of MFDS research achievements, the MFDS published source books on three research results, including the R&D Activity Survey and Analysis Report. It produced 30 videos that introduce research results about food and medicine safety technology (on-site coverage, Q&A, etc.), which are difficult for the general public to understand, and promote them online (MFDS YouTube channel) to promote public interest and to be useful in universities, enterprises, research institutes, etc.

In 2021, the MFDS will conduct self-evaluations for specific projects of "Safety Management of Food, Etc." and "Safety Management of Medical Devices, Etc." by comprehensively analyzing outcomes for the last three years (2018-2020) and evaluating their achievement levels of performance goals and indicators and their performance excellence. To periodically manage research performance in accordance with the innovated performance evaluation system of the MSIT, it is to draw up a strategic plan based on business planning for such detailed projects as safety management of medical devices, etc., safety management of agro-livestock and fishery products, smart food safety management, foundation for next-generation medical products, and regulatory affairs talent project.

In an attempt to shift to a system that deploys actual performance with higher efficiency in performance management and less burden of evaluation, the MFDS will change the current uniform follow-up evaluation to follow-up investigation that examines and verifies performance considering task characteristics.

In addition, the MFDS will publish the "MFDS R&D Investigation & Analysis

Report," which analyzes the R&D performance of the last five years (2016-2020), and the "Collection of Excellent Performance Cases", which presents cases of excellent performance selected from each area, such as food, pharmaceuticals, etc. The Ministry will continue its effort to strengthen public relations and raise awareness of its R&D projects by providing opportunities for the MFDS, related agencies, and food and drug researchers to share information and promote research results, including the "2021 MFDS R&D Project Performance Competition."

Section 2

Expanding Risk Assessment for Scientific Food Safety Management

1. Enhancement of the Risk Assessment System with Expanded Domestic and International Cooperation

The MFDS carried out integrated risk assessments of 60 substances that were exposed to the human body simultaneously through various products or whose impact on human health was newly reported. In 2019, the Ministry completed integrated risk assessments of 14 harmful substances of step 1 (three types of bisphenol, seven types of phthalate, four types of paraben) to draw up and release a report in order to publicize the assessment results. It also conducted the same assessments of 33 harmful substances of step 2 (five heavy metals, 28 types of dioxins). Furthermore, the MFDS closely cooperated with the Ministry of Environment (ME), the Ministry of Trade, Industry and Energy (MOTIE), the Ministry of Oceans and Fisheries (MOF), and the Rural Development Administration (RDA) by holding working-level meetings, etc. The collaboration led to the establishment of the domestic Health based Guidance Value (HbGV) for six harmful substances including PFC and formaldehyde. The HbGV was provided to relevant government entities such as the ME to facilitate harmful substance management.

The MFDS will continue to carry out integrated risk assessments and review the appropriateness of integrated risk assessments of new drug candidates to draw up the second roadmap for integrated risk assessments. It will also keep cooperating with other ministries.

The MFDS advanced the Monitoring Information Management System/Monitoring Database and Assessment Program (MIMS/MAP), which has been run since 2009, by standardizing the codes used by the Korean National Health and Nutrition Survey and the Korean Food Code. On top of it, it expanded and revised the MIMS/MAP, which was centered around exposure assessment, into the integrated system to manage human health risk assessment for the one-stop processing of four steps (hazard identification/characterization, exposure assessment, and risk characterization). For international exchange on risk assessment techniques, in 2021, the MFDS will renew its MOUs with foreign institutes specialized in risk assessments including the German Federal Institute for Risk Assessment (BfR) and the French Agency for Food, Environmental and Occupational Health and Safety (ANSES). It will also jointly host a contactless international symposium on the risk assessment with the BfR and ANSES to advance its expertise and credibility on the international stage. As for microplastics, the MFDS released the results of relevant research conducted since 2017 including the studies on the level of microplastic contamination of marine products and the change in the amount of microplastics contained after sediment removal. The press release was made in March 2020 to actively communicate with people. The Ministry will continue related research in 2021 such as the development of analytical methods, expansion of monitoring, and development of assessment techniques to measure body exposure.

Since the late 1990s, the MFDS has been participating in the OECD's efforts to develop international standard tests to detect endocrine disrupting chemicals among chemical substances. Further, for the first time in Korea, the Ministry's testing method to identify androgen disrupting chemicals using prostate cancer lines was selected as the OECD Test Guideline 458 in June 2020. The testing method

was developed in Korea and was selected as one of the OECD test guideline projects in 2015 for the first time in Korea.

2. Strengthened Safety Management System for Residues in Agricultural/Livestock/Marine Products

A. Scientific Risk Assessment for Safety Management of Residues

There are pesticides and veterinary drugs used intentionally to boost the productivity of agricultural/livestock/marine products. For them, the MFDS sets and controls the Maximum Residue Limits (MRLs) taking consumer safety into consideration. To establish the MRLs, it is necessary to first conduct a series of scientific risk assessments of comparing the food intake obtained from the Korean National Health and Nutrition Survey with the toxicological safety standards; and then sets the MRLs if there is no risk.

In 2020, the MFDS did 1,336 risk assessments of 181 pesticides including flumequine as necessary to newly create and expand standards for pesticides in agricultural products. The Ministry also conducted risk assessments of 28 pesticides including metrafenone to set standards for 110 livestock products. In addition, it established 33 MRLs via risk assessments of 11 veterinary drugs such as lincomycin. For the safety management of new pesticides, the MFDS reviewed toxicity data of two types of substances including prothioconazole, set the safety factor and the Acceptable Daily Intake (ADI), and wrote the safety assessment report. When it comes to the safety management of agricultural products at the production stage, the MFDS announced the MRLs of 40 pesticides in six agricultural products such as strawberry at the production stage and distributed press releases to share the information with the public. As the Codex Committee on Pesticide Residue meeting was canceled because of COVID-19 in 2020, the Ministry is going to establish the

international standards for cypermethrin and other substances in ginseng in 2021. Also, it will develop a risk assessment system that is most appropriate for Korea to enhance the exposure assessment method and develop a summary report on the safety assessment of each pesticide to publish it on the Ministry webpage.

B. Establishment of an International-Level Residual Substance Test Method and Surveys on Residue Status

The MFDS has been developing testing methods and carrying out risk assessments in accordance with the verification process suggested by the Codex Alimentarius Commission (CAC) to ensure international equivalence and reliability.

For rapid testing of residues in food, the Ministry expanded the subjects of the simultaneous testing from 473 items to 511 items for pesticides in agricultural products, 99 items to 168 items for veterinary drugs in livestock products, and 62 items to 168 items for veterinary drugs in marine products. The MFDS developed nine test methods for newly registered pesticides in agricultural products including afidopyropen and test methods for two unregistered veterinary drugs such as lubabegron. As a result of a survey on the residue status of pesticides and 683 veterinary drugs in 1,146 agricultural/livestock/marine products using multiresidue methods, the Ministry reported 405 detection cases. Among those cases, two exceeded the MRLs, and the Ministry requested the local government in charge to take an administrative measure such as postponing shipment. Furthermore, it included the detection results into the guidelines for the food safety management so that local FDS Offices as well as local governments can use them for safety management of domestically distributed agricultural/livestock/marine products.

In addition, the MFDS promptly prepared testing methods and monitored food accidents and risk information regarding ethoxyquin in krill oil products, ethylene oxide in sesame, and THC and CBD in hemp seeds and hemp seed oil while preventing the distribution of nonconformities by collecting/disposing of them as a whole. At the same time, the Ministry implemented the Inspection Order System so that importers are allowed to bring food into Korea only when they prove the safety of the food, thereby enhancing the safety management of imported food.

C. Support and Capacity Building of Domestic Inspection Agencies for More Reliable Residue Analysis

With the full implementation of the agricultural products Positive List System (PLS) (Jan. 1, 2019), new items have been added to the list of inspection items for pesticides in imported/domestic agricultural products, and the demand on the reference standards has increased accordingly. Thus, swift and efficient inspection support is required. It is also needed to provide training on testing method theories and practices to enhance inspection capacity regarding the testing method to be revised.

In 2020, the MFDS provided support to 30 entities such as local health and environment institutes, veterinary service laboratories, and local FDS Offices regarding 4,562 pesticide cases and 400 veterinary drug cases. The Ministry held 10 times of testing method practice training sessions including analysis of veterinary drugs in livestock/marine products and pesticides in livestock products as well. In 2021, the MFDS will constantly provide training on the testing methods to be revised and support to inspection agencies by giving mixed liquid of reference standards, which consist of subject materials of the simultaneous testing for residues (pesticides and veterinary drugs).

3. Strengthened Scientific Basis for Reducing Hazardous Contaminants in Food

A. Reinforcement of Rapid Response System for Safety Management of Hazardous Contaminants in Food

The possibility of human exposure to hazardous contaminants (heavy metals, persistent organic pollutants, fungal toxins, etc.) in food is increasing due to environmental contamination and changes in eating habits. As a result, the interest and concerns regarding food-related accidents/incidents as well as domestic and foreign hazardous contaminants in food are growing among consumers. Accordingly, to properly manage human exposure to hazardous contaminants caused by food intake, the MFDS will investigate the exposure to hazardous contaminants, conduct their risk assessments, and establish an objective and standardized risk assessment system, thereby laying a foundation for safety management of hazardous contaminants.

To this end, the Ministry will acquire ISO/IEC 17025, an international standard for heavy metal (lead) testing, as it did for dioxins, and strengthen its testing capacity by participating in the international proficiency assessment program with regard to heavy metals, phytotoxins, mycotoxins, dioxins, and shellfish toxins. Further, to produce reliable testing data, the Ministry plans to write the “Manual for Development and Verification of Testing Method” that can be applied to the tests for hazardous contaminants in food. Based on it, the MFDS will create testing methods for five new harmful heavy metals (thallium, chrome, nickel, antimony, and valium), mycotoxins (altenaria and five types of trichothecenes), marine biotoxins (five types of azaphylic acid, pectenotoxin, and yesotoxin), phytotoxins (tropane alkaloid), and radioactive beta-nuclide (technetium) while improving the testing method by reviewing the testing applicability following the expansion of the range of application of mycotoxin standards.

In addition, to secure the scientific grounds to reassess heavy metal standards, the Ministry will carry out heavy metal risk assessments to see changes in the exposure amount based on different dietary habits and environments. On top of it, the MFDS will conduct status surveys on hazardous contaminants such as natural toxins and toxic metals in food for their safety management so that it can obtain scientific basic data for risk assessments.

B. Strengthened Proactive Safety Management of Hazardous Contaminants for Future Response

Global warming is causing an increase in new natural toxins including marine biotoxins while the rapid industrialization of neighboring countries and the development of analysis technology are leading to the emergence of new risk factors such as environmental pollutants. At the same time, diversification of importing countries and increased import volume expand vulnerability factors in terms of safety. As a result, there is an increasing demand for new food safety management. In addition, there are accidents related to harmful substances in the industries at home and abroad and leakage of harmful chemical substances in the process of transport by ship or vehicles. Thus, it is required to develop a testing method for prompt response in preparation for a possible food contamination caused by such accidents.

To prevent food poisoning from the crossbreed pufferfish that has emerged following the habitat change because of global warming, the MFDS plans to develop molecular biological identification technology and establish a scientific basis for the preemptive safety management of marine biotoxins by surveying the content of tetrodotoxins by part. Furthermore, it will develop a simultaneous testing method for diarrheal shellfish poisons to monitor and assess the risks of shellfishes and tunicates. In addition, the Ministry will design rapid detection methods for paralytic shellfish poisons to enhance the convenience and speed of the safety management tests. As for shellfish poisons controlled in foreign countries, but not

in Korea, the Ministry will come up with a new testing method to be utilized for safety management policies including the standard establishment in order to carry out status surveys and risk assessments. To conduct such surveys, the MFDS will obtain essential reference standards of marine biotoxins. As for those not produced or sold, the Ministry will secure species that produce the required biotoxins and foster embryoid technology. The MFDS plans to develop testing methods for new microtoxins as well as those not controlled domestically, lay foundations for the preventive safety management via status surveys, and ensure the safety of food ingredients by constantly reviewing toxicity information and reevaluating the safety. These efforts will help the Ministry to prepare the revised standards (draft) for using food ingredients.

Meanwhile, the MFDS expects that it is possible to prevent the distribution of contaminated foods via swift food contamination inspection in case of an incident by developing testing methods for chemical substances (benzyl chloride, acrylic acid, propylene oxide, carbon disulfide) in preparation for possible harmful substance leakage at home and abroad.

C. Reinforced Safe Food Intake Base for Reducing Hazardous Contaminants

Currently, the safety management of hazardous substances in food is established and managed through the criteria for each food type, but there is a limit in the management of total exposure. Therefore, to manage exposure reduction and support businesses with practical reduction techniques, it is required to develop and distribute reduction techniques by stages of the food supply chain and provide cooking and eating guidance.

For this, the MFDS plans to provide information highly relevant to people's lives to create an environment safe from harmful substances. The information will include how to discern pufferfishes to respond to the emergence of crossbreed pufferfishes

and how to make Meju, a dried fermented soybean brick, and Doenjang, a soybean paste, that are free from mycotoxin risks.

4. Strengthened Future-Oriented Microorganism Analysis Technology and Scientific Research for Policy Support

Major developed countries have built a more precise contamination source identification and tracking system regarding food poisoning thanks to various analysis technology based on food poisoning genome information, and Korea needs to introduce such advanced technology. At the same time, it has become crucial to stably preserve the strain resources and accumulate analysis information in order to use the technology for not only food safety management but also research on foodborne pathogens. There are continued reports on emerging and variant pathogens including viruses due to climate change and the destruction of the environment. On top of it, bacteria with antimicrobial resistance (AMR) have also increased. Thus, it is necessary to take countermeasures. The microorganism risk assessments are required as a scientific basis to establish national food safety management standards and measures. To carry out the assessments, it is important to obtain the contamination level monitoring information; study relevant fields including developing an anticipation model of growth and death by food/temperature; and publicize the information to the public. Also, there is a growing necessity to improve testing methods including reinforcement of detecting technology for safety management regarding microorganisms in food as well as early detection and spread prevention of food poisoning.

In 2020, the MFDS established the "Network on Food Poisoning Genomes" to build an up-to-date system to identify the cause of food poisoning. The Ministry created 30 analysis programs in total including the cause identification, follow-up inspection, characteristics analysis, and lactic acid bacteria analysis together with a system to

use the programs on an online basis. The MFDS built the system to automatically collect genome data and the databased on the whole genome sequence of foodborne pathogens (5,550 pieces of domestic information, 550,000 pieces of foreign information) including E. coli. To systematically use the strain resources, the MFDS has made the strains, separated from various projects, into resources of the resource center. As of 2020, the Ministry obtained and managed 13,560 strains. Also, it secured a legal basis to manage strain resources by making the center designated as the "Bank for Foodborne Pathogens" pursuant to the Act on the Promotion of Collection, Management, and Utilization of Pathogen Resources.

The MFDS made efforts to standardize the method for ministries to detect the hepatitis A virus genome and has been constantly monitoring the hepatitis A/E viruses in underground water used for food (around 300 times a year). It also selected microorganisms with potential risks and possibility of emerging in Korea, prepared 42 testing methods, and carried out pilot surveys regarding the distributed food and environment. For 2,000 agricultural/livestock/fishery products, the MFDS conducted status surveys on the bacteria with AMR. At the same time, it contributed to the international coordination via participation in the activities of the Ad Hoc Codex Intergovernmental Task Force on Antimicrobial Resistance.

The MFDS performed 27 risk assessments throughout all the stages from production to consumption according to the mid to long-term roadmap for the microorganism risk assessment and prepared plans to reduce risk factors at each phase. In addition, the Ministry released 10 reports on the results of risk assessments including the assessment of listeria monocytogenes in agriculture/livestock/marine products. Furthermore, it proposed to improve the standards for clostridium perfringens in 10 types of foods such as Kimchi and pickled foods.

As for the accredited microorganism testing methods, the MFDS came up with a revision of four detailed items of testing methods for microorganisms such as listeria monocytogenes and the number of bacteria and fungi. At the same time, the Ministry introduced molecular biological testing for campylobacter and EHEC using

real-time PCR. It developed and improved 32 testing methods to identify the cause of food poisoning including vibrio cholera O1, O139 genetic testing and testing to find the causative virus of food poisoning. It also prepared the standard genetic testing method for the hepatitis A virus for all the ministries.

By operating the "Ministerial Consultative Body on the Genetic Information of Foodborne Pathogens," the MFDS will strengthen its research cooperation to make full use of the genetic information of microorganisms. Not only that, the Ministry will both internally and externally share microorganism resources of the foodborne pathogen resource center for research purposes. The Ministry will not spare its efforts to confirm the effectiveness of disinfectants against coronaviruses in the environment and on the food surface and to study the level of contamination of water for foods (underground water) regarding two new viruses. The range of microorganisms with possible risks will be expanded. As for the surveys on the status of AMR regarding agricultural/livestock/marine products at the distribution stage and research on how to reduce AMR, the MFDS will carry them out as planned. The Ministry will also make a plan to systematically strengthen the national microorganism safety management in the mid to long-term to prepare for new risk factors. Its plan includes the improvement of the testing methods of the "Food Safety Standards and Specifications" including campylobacter testing while studying on simultaneous analysis among the testing methods to identify the causative agents of food poisoning. On top of it, the Ministry will commercialize and demonstrate testing kits on the site for salmonella serotype and microorganisms that are indicators of fecal contamination.

5. Strengthened Foundations for Safety Management of Food Additives, Utensils/Containers/Packaging, and Hygiene Products

Since the emergence of COVID-19, there is a rising trend of increased contactless consumption of foods such as HMR (Home Meal Replacement), changes in dietary life, and widened use of disinfectants and detergents for utensils and other items at group meal facilities and home. The MFDS assessed cytotoxicity in food additives (12 kinds including seed malts) to secure the safety of food additives made with substances originating from nature (animals, plants, etc.); carried out exposure assessments of disinfectants (13 kinds including chlorine dioxide) used by group meal service facilities and businesses in the food industry for utensils and other items; and confirmed the safety.

In addition, to evaluate exposure of substances derived from utensils/containers/packaging, the Ministry carried out status surveys and exposure assessments of 27 substances such as volatile substances and additives in utensils/containers/packaging made of ABS (Acrylonitrile-butadiene-styrene copolymer), glass, or other materials. As a result, it was confirmed that they are at a safe level. The MFDS created the foundation for safety management via status surveys on contaminants (lead, etc.) and additives that are not allowed (color additives, preservative agents) to use for hygiene products including detergents and rinse as well as food residues (fat, starch, protein, etc.) left after dishwashing. It also developed training materials to analyze and reduce microorganism risk factors in wet towels and utilized them on the ground. For the safety management of food additives, the Ministry developed 28 testing methods including those for color additives.

At the same time, it laid the foundation for preemptive safety management by developing detection methods for food additives that can create nano substances in the process of manufacturing (titanium dioxide, etc.). To make sure it can promptly respond to risk information, the Ministry additionally developed testing methods for residual solvents (five kinds including hexane) and Sudan pigments in fish oil (krill oil) and chloric acid in catfish. Concerning strengthened safety management of utensils/containers/ packaging and prevention of related accidents, the MFDS developed and improved testing methods for seven substances such as migrants (antibacterial agents), sulfur dioxide, bisphenol A, and other relevant substances in utensils/containers/packaging. As for hygiene products, the Ministry prepared the following: tests for PCB (polychlorinated biphenyl) and heavy metals in hygiene products and formaldehyde, simplified detecting methods for food residues (fat, starch, protein) left after dishwashing, simultaneous analysis for three isothiazolinone substances including BIT (benzisothiazolinone) in detergents and other hygiene products. On top of it, the Ministry made efforts for sharing information highly relevant to people's lives. It distributed press releases on food additives (caffeine, disinfectants for utensils and other items) and promotion materials (card news, video clips, etc.) that would be helpful to people's dietary lives as well as card new containing information to help the correct understanding of "food utensils·containers and packages" such as convenience food packaging (instant cup noodle), it was promoted using press releases and SNS such as Facebook.

The MFDS will continue to reinforce scientific safety foundations through constant safety assessments, testing method development, and status surveys for food additives, utensils/containers/packaging, and hygiene products closely related to people's dietary lives.

6. Establishment of a Basis for Safety Management of Nutrition and Dietary Life and Health Functional Foods

A. Construction of a Base System for Nutrition and Dietary Life Safety Policies

The MFDS plans to analyze 108 kinds of nutrients such as sodium, sugar, vitamins, and minerals in 200 items including the HMR and meal kits to continue its efforts to establish the national food nutrient DB by reflecting changing dietary patterns due to COVID-19. Further, it intends to develop nutrition labeling guidelines (draft) incorporating the characteristics of prepared food of restaurants to enhance the reliability of the labeling while analyzing the content of food without labeling of nutrients that may be harmful as part of its efforts to provide a scientific basis for the reduction policy management of nutrients such as sugar, sodium, and trans-fat.

On one hand, the MFDS will continue to provide technical support to restaurants and manufacturing businesses including HMR manufacturers so that they can reduce sodium and sugar. On the other hand, it will keep sharing information on the nutrient content comparison and analysis of distributed products together with the status of sugar/sodium reduction to enable consumers to choose both safe and nutritious food. In addition, following the plan to safely control children's dietary lives and the pan-ministry implementation plan to improve student health, the MFDS will make its best efforts to analyze the amount of sodium and sugar intake, as they are nutrients with possible health risks, and share tips on how to live a healthy dietary life considering social changes including COVID-19.

B. Advancement of Test Methods for Nutrients and Index Components of Health Functional Foods

As diverse types of food and health functional food are developed, it is constantly required to actively improve their test methods through comparative reviews with the latest overseas methods, to manage food safety. In particular, it is necessary to prepare standardized testing methods that can be apply to products (formulation) containing compound ingredients when it comes to the items subject to a change in the notification among individually approved functional materials. Further, with the implementation of unction labeling of general foods, businesses need support to boost the development of their products by devising testing methods for functional ingredients in general foods. It is also desired to operate a national standard laboratory that meets international standards to guarantee the reliability of testing results of sodium, which is one of the nutrients with possible health risks.

For effective quality management of health functional foods, the MFDS is planning not only to develop standardized testing methods for index (functional) components to notify individually approved functional materials (four kinds: gallic acid from puer tea extract, chlorogenic acid from green coffee bean extract, xylooligosaccharide, and 3-carene, limonene, and terpinolene from pine needle distillation concentrate) but also to write officially accredited guidelines to advance testing and inspection techniques for health functional food. In addition, the Ministry will develop the following tests methods: tests for functional ingredients of foods subject to functionality labeling including the preconditioning/equipment analysis condition and validation to guarantee the specificity and accuracy of the contained functional ingredients (two kinds: corosolic acid in banaba leaf extract, total monacolin K in red yeast rice); and standardized testing methods that can provide precise nutrition labeling of sugar alcohol added to diet foods, sugar substitute foods, and low-calorie foods.

7. Strengthened Scientific Surveillance System for Adulterated Foods

A. Eradication of Defective and Adulterated Food Using Gene Technology

Due to insufficient marine products supply against consumption, low-price products are indiscriminately imported, and there are frequent cases of deceiving consumers for unfair profits such as selling red pepper powder mixed with seasoned red pepper sauce. Thus, in efficiently inspecting currently distributed agricultural and marine products, it is necessary to prepare a scientific method to distinguish species and build a database on morphological, genetic data. To this end, the MFDS designed a method to determine authenticity based on the specific sequence of species including frequently consumed marine products and the agricultural products for both food and drugs. In addition, the Ministry also designed a rapid detection method for on-site inspection. Further, it obtained the standard DNA barcodes of frequently consumed species and surveyed the status of ingredients of domestically distributed products. In the coming years, the MFDS will identify species-specific DNA barcodes of agricultural and marine products; build a DNA information bank to determine the authenticity of food ingredients using the Next Generation Sequencing (NGS); and expand the development of scientific ways to check the authenticity of food ingredients that are difficult to be distinguished with naked eyes because they are morphologically similar or have gone through simple process procedures (cutting, grinding, etc.).

B. Development of Scientific Site Surveillance Technology to Eradicate Defective and Adulterated Foods

As the standard of living and the public interest in health have increased, more people are directly purchasing and consuming overseas health functional food whose safety is unclear, resulting in increased consumer damage. Thus, it is imperative to survey the status and develop an analytical method to scientifically identify defective substances for the safety management of food that people directly order from foreign countries. Accordingly, the MFDS established simultaneous tests of multiresidue concerning 62 substances for effective and rapid analysis of defective substances such as those prohibited for food and pharmaceutical ingredients. It also completed the status survey of defective substances in 600 foods (claiming to be effective for sexual dysfunction, weight loss, muscle strengthening, nerve stabilization, etc.) directly purchased from overseas for personal use. For products found to contain defective substances, it requested the Korea Customs Service, etc. to shut off their online sales and block them at the customs clearance. The Ministry will continue to share the information on the defective substance detection, research status, and the reference standards of defective substances with relevant organizations, thereby reinforcing the food safety management to prevent food with defective substances from being distributed.

C. Establishment of an Analysis System to Identify the Cause of Foreign Substances

It is necessary to develop technology to control foreign substances in food and a way to increase the rate of identifying the cause of adulteration in order to remove people's distrust in food safety and make them feel some improvement. Therefore, the MFDS prepared an identification procedure to check whether foreign substances found in food are mold, using the morphological, physicochemical characteristics of mold. It also formulated a testing method to find out whether the detected foreign substances are frequently occurred mold based on genetic testing. The Ministry will analyze the impact of testing conditions for reliable results and establish analytical methods and identification procedures for each foreign

substance. And it will develop and commercialize automatic technology to filter and control foreign substances with help of up-to-date technology to prevent mixture of foreign substances during manufacturing, distribution and storage of food.

D. Assessment of Total Exposure of Harmful Substances to the Human Body and Development of Their Reduction Technology

For the safety management of harmful chemical substances unintentionally produced in the process of food manufacturing, cooking and processing, it is required to survey the amount of exposure after actual cooking and intaking and minimize the produced amount. For this, the MFDS assessed the exposure amount of harmful substances created in the manufacturing process of marine products (49 kinds including 3-MCPD, furan, and acrylamide) via the Total Diet Study that considers the intake in the actual dietary lives (2018-20). In addition, as part of basic research to set domestic management standards, the Ministry carried out surveys on the contamination level and risk assessments of glycidyl esters and total 3-MCPD in food containing fat such as confectionery and bread. To reduce harmful substances produced in the manufacturing process, the Ministry inspected the amount of substances (acrylamide and benzopyrene) created following the use of new cooking tools including air fryers and surveyed the amount of esters derived from fatty acid based on how to cook edible oil to publicize the correct way to use cooking oil. Regarding unintentional harmful substances, it recommends keeping the minimum level according to the international principle of ALARA (As Low As Reasonably Achievable). The MFDS will, therefore, constantly prepare baseline data for food safety management through reduction plans for harmful substances created from cooking and improved relevant testing methods.

Section 3

Testing and Research for Safety Management of Medical Products and Support for Their Commercialization

1. Advancement of the Foundation for Quality Management of Medical Products

An official compendium for each field of medical products provides a minimum quality standard for drugs and quasi-drugs on the market. The compendium includes the Korean Pharmacopoeia, one of the representative official compendiums, the Korean Quasi-drug Codex, the Korean Functional Cosmetics Codex, and the Korean Herbal Pharmacopoeia, and the Medical Device Standard. The standards and specifications presented in the official compendium should be continuously improved to make reasonable standard proposals that consider the introduction of new technology following scientific development, a rapid reflection of international harmonization, and conditions of the pharmaceutical industry. For this, the Ministry prepared revised regulations and standard specifications as follows: 95 regulation revisions (drafts) on drugs, four on biomedicines, 78 on herbal medicines, and two on medical devices; and standard specification revisions (drafts)

for quasi-drugs and hygiene products including the testing method for phthalates in disposable diapers. The mentioned revisions (drafts) were published as the “Korean Pharmacopoeia Forum,” gathering opinions from in and outside to make a more site-oriented pharmacopeia.

A reference standard, which is a reference material used for testing and inspection of pharmaceuticals, is directly linked to the quality of medical products and public health. The MFDS has steadily secured and distributed the reference standards for medical products, starting with reference standards for chemical drugs since 1991. The MFDS now provides 668 reference standards in total, including 239 kinds of chemical medicines, 31 kinds of biopharmaceuticals, 360 kinds of herbal medicine, 37 kinds of IVDDs, and one quasi-drug. In addition, to secure quality reliability, the MFDS regularly conducts stability tests on its reference standards. It also published and distributed the “2020 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-site demand surveys.

Also, to secure the quality of distributed drugs, the MFDS conducted testing and inspection of 2,104 chemical drugs, 26 biopharmaceuticals, 365 herbal medicines, and 123 cosmetics and quasi-drugs. At the same time, the Ministry monitored 12 kinds of polychlorinated biphenyls and assessed risks of 29 dioxins in 126 items of sanitary pads and panty liners. Since obtaining the certificate as an internationally accredited testing organization (ISO 17025) in 2004 to guarantee the objectivity and reliability of testing and inspection, the MFDS has expanded its accredited fields and acquired accreditation for 52 test items. The Ministry will also continue to expand the pool of accreditation test items and enhance the reliability and capability of testing and inspection through the designation of the national standard laboratory.

2. Research on Safety Management of Drugs

The MFDS made 95 revisions (drafts) in the Korean Pharmacopoeia considering changes in the regulatory environment such as swiftly revising testing methods of hand sanitizers for disease control and prevention, and proposing alternative tests in response to the changing domestic supply and demand of explosive reagents. In the process, the Ministry actively reflected voices from the field collected via e-People. Furthermore, the MFDS wrote and provided a sourcebook on general testing methods, including the microorganism limit test, and listened to the voice of the industry on difficulties and opinions regarding quality management. For a stable supply of frequently used, nationally designated essential pharmaceuticals, the Ministry produced and established reference standards that will be the basis of drug testing & inspection. It also tested the safety of 80 reference standards for sale to stably manage the quality. In order to achieve an international level of quality management, the MFDS has constantly cooperated with the WHO, the United States Pharmacopeial Convention (USP), and the European Directorate for the Quality of Medicines and Health Care (EDQM).

The MFDS promptly developed three detection testing methods following the detection of unintentional foreign substances in drugs and monitored 2,104 lots of distributed drugs. In addition, the Ministry continued to provide training on testing methods and consult on the analytical methods developed by the industry as part of its support for safe drug distribution and quality management.

On top of it, the MFDS drafted the Mid- to Long-Term Roadmap for the “Safety Management of Drugs, Etc.” (2021 - 25) based on opinions from industries and academia related to medical products to set the major direction of R&D to prepare for the future. At the same time, it provided information on the latest regulations of three regulatory bodies in major developed countries (FDA, EMA, and PMDA) and the industry trend on a quarterly basis, thereby contributing to determining the way forward regarding drug safety policies and research. The MFDS will continue

to put research efforts for following subjects: safety management in relation to unresolved medical demand issues; preemptive R&D of approval and evaluation technology to facilitate the development and commercialization of new technology; and the development of technology for safety/quality management that meets global standards throughout their lifecycle from manufacturing and distribution to use. Through this, the MFDS will pursue consistency in approval and evaluation assessments of drugs and studies to attain their scientific basis.

3. Research on Prevention and Safety Control of Biological Products and Infectious Disease

To support the commercialization of vaccines and respond to new and mutated infectious diseases, the MFDS conducted research to develop a vaccine quality test method and to establish reference materials. This led to the development of test methods and reference materials for assessing the immunogenicity of vaccines including those for typhoid fever. In addition, the Ministry carried out R&D on the development of test methods for quality assessment to support the national lot release of biological products including major domestic vaccines and manufactured and established reference standards for biopharmaceuticals. According to recent changes in the research trend, it also studied safety management of biological products based on new platforms and advanced technology to develop tests while creating guidelines (draft) for approval and evaluation. Based on such achievements, the MFDS will contribute to support for major Korean vaccine commercialization and preemptive safety management in preparation for the inflow and spread of emerging and variant viruses.

In 2021, the MFDS will assist with the commercialization of major domestic vaccine products, establish tests to evaluate the immunogenicity of dysentery, norovirus, and SFTS to deal with emerging/variant infectious diseases, and develop reference materials or veterinary models. The Ministry also intends to contribute to the advancement of quality management for biological products by manufacturing and standardizing national reference standards of biopharmaceuticals as well as by developing and standardizing quality management testing methods. Following the recent trend in vaccine development, the MFDS will conduct assessment research on the safety and efficacy of vaccines using new platforms and find ways for the safety management of biological products including vaccines using advanced technology. Marking the fourth anniversary of the “Inter-Ministerial R&D on Infectious Disease in Relation to Disease Prevention and Control” in 2021, it will continue its research efforts to create an integrated reporting system for adverse events following vaccine inoculation to make a contribution to the establishment of a national disease prevention and control system at the pan-ministry level. In addition, the Ministry will also keep communicating with other foreign organizations including the WHO.

4. Research on High-Tech Biopharmaceutical Regulatory Affairs

In order to tackle the issue of unmet medical demands regarding incurable diseases, the development of biologics based on advanced and innovative technology has been accelerated globally. Domestically, research to commercialize the advanced biopharmaceuticals and lead the market is actively conducted according to the enforcement of the Act on the Safety of and Support for Advanced Regenerative Medicine and Advanced Biopharmaceuticals (August 2020). Advanced biopharmaceuticals include cell therapy, gene therapy, tissue engineering products, and combination products combined with them. Due to their characteristics, it is difficult to apply existing quality and safety assessments. Hence, it is required to manage the entire life cycle safety from drug substances to drug products

and before and after being available in the market. For this, relevant policies, regulations, and safety assessments should be prepared accordingly. Against the backdrop, the Ministry focused on preemptive research on regulatory affairs.

The MFDS wrote four proposals including the “Monograph on Infliximab Concentrate” for international harmonization and advancement of the biopharmaceutical part of the Korean Pharmacopoeia and incorporated them in the standards and specifications. In addition, the Ministry provided standard quality tests for 28 biopharmaceuticals such as tests for quality management of CAR-T cell immunotherapy and stem cell-derived extracellular vesicles. It shared the test methods with domestic researchers and contributed to creating the basis for scientific approval and evaluation. As for regulatory affairs for the long-term follow-up of gene medicines after they are available in the market, it designed an algorithm for the cause-and-effect relationship of the drug and adverse event and a template to record patient cases via actual case studies. The Ministry also made efforts to provide technical support for reasonable policies and management by developing research guidelines (draft), using real-world data and evidence, for the safety management after biopharmaceuticals are released in the market. In order to secure the quality and safety assessment technology reflecting the characteristics of advanced biopharmaceuticals based on new technology such as stem cells, gene editing, and 3D-bioprinting, the MFDS conducted quality and safety assessment research with regard to advanced biopharmaceuticals using future technologies –next generation sequencing (NGS), technology for precision analysis of trace elements, “in silico” assessment modeling through big data, and AI. On top of it, the Ministry held the “Conference on Regulatory Affairs of Advanced Biopharmaceuticals” and the “Workshop on the Development of Advanced Biopharmaceuticals and Analysis Technology” involving experts from the industry/academia/research institutes of the biopharmaceutical sector to share the latest development status and provide analysis practice training on the up-to-date analysis technology, thereby strengthening the regulatory affairs analysis capacity and private-public communication. By doing so, it provided development trends for the latest analytical technologies and practical analysis training. Furthermore, the Ministry published a sourcebook on the technology development and regulatory trend on the CAR-T cell immuno-oncology therapy and 3D bioprinting items. It will continue to contribute to developing the advanced bio-industry and public health with constant efforts to facilitate the life cycle safety management and rapid commercialization of advanced biopharmaceuticals and create assessment foundations in accordance with the mid- to long-term R&D roadmap for the advanced biopharmaceuticals established in 2020.

5. Research on Safety Management of Herbal Medicine

To strengthen its quality and safety management for herbal medicines (crude drugs), the MFDS has developed test methods and expanded standards and specifications, while securing herbal medicine resources and thus solidifying a ground for leading the international standards, in an effort to actively respond to and lead global changes like the Nagoya Protocol.

To improve the quality of medicinal herbs, the MFDS implemented pre- and post-safety management by conducting cross-validation at the import stage, benzopyran testing/risk assessment at the Drug Master File (DMF) registration stage, and quality inspection at the distribution stage. It also developed advanced analytical methods such as DNA barcodes and chemical profiles for a total of 55 cases (until 2020) for medicinal herbs that cannot be verified with sensory tests. The Ministry developed tests of harmful substances such as benzopyrenes and heavy metals and monitored and conducted risk assessments regarding 600 cases of 57 kinds of medicinal herbs. The MFDS produced and released promotional videos (Book of Food and Drugs: 40 video clips, 2019-2020) to ensure that consumers can easily understand safety control of medicinal herbs.

The MFDS completed "Research to Collect and Examine National Herbal Medicine Resources" securing around 49,000 pieces of information and specimen as part of an effort to preserve and harness national herbal resources, mainly in response to the Nagoya Protocol. In addition, it started providing the "National Herbal Medicine Information"" to the public, compiling information and research cases collected so far. Following the opening of 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 to manage subtropical herbal medicine. The Jeju Center started construction works in January 2020 and has completed excavation and framework construction. The Ministry held the "Online Groundbreaking Ceremony" for the new center (May) to advertise the new construction project.

The MFDS has continued "Research on the Development of International Standards for Herbal Medicine" to identify and propose international standards in the standardization area of herbal medicine (ISO/TC249) led by China, and the Ministry's constant efforts led to the proposal of new projects such as "Standard Specifications for Schisandra." The Ministry continued international cooperation such as participation in the Forum for the Harmonization of Herbal Medicine (FHH). In addition, it signed an ODA agreement with the WHO/WPRO and prepared training programs for civil servants from the Philippines (online training scheduled in February - March 2021).

In 2021, 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 form a basis to expand the National Herbal Medicine Resource Management Centers and propose new tasks regarding standardizing herbal medicines (ISO/TC249) to lead the international quality and safety management standards of the field.

6. Research on Safety Management of Cosmetics and Quasi-Drugs

The MFDS Cosmetics Research Division is in charge of implementing R&D projects on the assessment technology for safety and efficacy of cosmetics, quasi-drugs and hygiene products. The division facilitates safety management through a proposal to revise public notices, advancement of standards and specifications, and creation of the guidelines for testing methods and efficacy evaluation. With the division, the MFDS checked the level of contamination and assessed risks of substances and products with possible safety risks to human health. To relieve consumers' concern, it communicated with the public based on precise information obtained from the science-based assessment results and, if necessary, suggested safety standards. The Ministry released the results of risk assessments of 29 types of dioxins in sanitary pads and panty liners that are categorized as quasi-drugs. In relation to cosmetics, to promptly respond to risk information in foreign nations such as European countries and to review the validity of domestic standards, it conducted risk assessments and suggested safety standards of blue 124, a pigment for hair dyeing. It also revised the "Standards and Specifications for Hygiene Products" by improving phthalate tests for disposable diapers among hygiene products.

The MFDS created promotional content for the safe use of cosmetics and quasi-drugs and provided safety information through media reports. In order to improve the transparency and reliability of the safety standard setting for cosmetics, it releases the "Cosmetics Risk Assessment Report." It also published the risk assessment report containing the information on the toxicity and the level of exposure to the human body with regard to 10 substances such as "4-methylbenzylidene camphor," a UV blocking substance that has a maximum allowed amount in cosmetics. In addition, the MFDS publicized four types of card news for consumers and educational material to share correct information on natural & organic cosmetics in newspapers published by consumers.

To advance the licensing work efficiency and voluntary quality management capacity of the industry, the Ministry has made constant research efforts for improvement and development of standards/specifications and creation and distribution of guidelines. It developed simultaneous analysis for pigments, which are ingredients with a maximum tolerance in cosmetics, and ingredient analysis for substances prohibited from mixing including nitromethane. Based on the achievement, it revised the "Guidelines for the Analysis of Ingredients with a Maximum Tolerance in Cosmetics" and the "Guidelines for the Analysis of Cosmetic Ingredients Prohibited from Mixing." Furthermore, the MFDS wrote the guidelines for efficacy assessments of functional cosmetics effective for "lesser hair loss" and "lesser itchiness" while proposing efficacy assessments of quasi-drug dental manicures and standardized testing method for standard and specifications for portable oxygen to incorporate them in guidelines. The MFDS believes that it would be able to contribute to not only protecting consumers and securing quality reliability but also achieving efficient and swift approval, report and review procedures through the prepared standard testing methods, guidelines, and testing methods in the official compendium for cosmetics, quasi-drugs and hygiene products. It also plans to continue to operate the "Consultative Body of the Industry/Academia/Research Institutes/Government Network" to collect opinions from the industry and the testing and inspecting agencies, thereby reflecting various ideas during research on guidelines and testing methods.

7. Research on Safety Management of Medical Devices

Advances in technology following the Fourth Industrial Revolution are leading changes in many fields of society. Especially, in the medical device field, advanced technology is rapidly applied, and new medical devices are being developed one after another.

Understanding the necessity to secure evaluation technology to safely supply advanced medical devices and combination medical devices to the people, the Medical Device Research Division pushed ahead with research to support the advancement of medical device safety management to adopt policies and systems for efficient safety management throughout the entire life cycle of medical devices, including assuring their safety from technology development to commercialization and before/after product release.

With a goal of commercialization support for next-generation medical equipment and safe application of advanced technology to patients, four ministries, the MFDS, the Ministry of Science and ICT (MSIT), the Ministry of Trade, Industry and Energy (MOTIE), and the Ministry of Health and Welfare (MOWH) are currently pushing to carry out the "Inter-Ministerial Project Supporting R&D of Medical Devices Throughout the Life Cycle" and the "Inter-Ministerial Project for Technological Convergence of AI and Biorobots." On top of it, the MFDS is in cooperation with the Korea Center for Disease Control (KCDC) and the MOTIE to implement the "Inter-Ministerial Project on Infectious Disease R&D in Relation to the Prevention and Control" in order to create a healthier and safer medical environment.

To develop In Vitro Diagnostic (IVD) medical devices, the Ministry has been manufacturing and selling IVD reference standards since 2013 and strived to ensure the safety of IVD medical devices by selling 148 reference standards in 2020.

The Medical Device Research Division of the MFDS will push ahead with continuous investment and research to safely apply AI, next-generation production technology, and information technology of the Fourth Industrial Revolution to medical devices. It will also continue to conduct international standardization projects and international harmonization research so that excellent technology can become the international standard and lead the global medical device market.

Section 4

Development of Safety Evaluation Technology for Food and Drugs

1. Korea National Toxicology 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 for both food and drugs has become a hot issue. In view of recent incidents about pesticides in eggs and harmful substances in sanitary pads, the need for interest and research has increasingly grown. In addition, after the humidifier disinfectant 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 the safety management in a preemptive manner, in order to reassure the public about food and drug safety-related social issues.

The MFDS has continuously implemented toxicity tests for food ingredients and medicinal herbs. It has also been operating Tox-info, a system that provides toxicity information to the public. The Ministry collects additional toxicity information

on chemical substances related to food and drugs every year, and 3,977 pieces of information on toxicity and 568 on poisoning have been collected and provided to the public and emergency medical workers.

In 2021, the MFDS will expand the subjects of tests and toxicity information collection into hygiene products, including sterilizer preservatives in order to carry out the governmental task (No. 57-4. Strengthening the Integrated Risk and Safety Evaluation of Substances and Products Hazardous to Human Health).

2. Development of Alternative Methods to Animal Tests and the Advancement of Non-Clinical Trials

There is a growing need to develop alternative test methods to safely assess cosmetics as the EU has banned animal testing. In Korea, revision of the Cosmetics Act (No. 14027, revision: February 2016, effectuation: February 2017) in 2017 prohibited the distribution and sale of animal-tested cosmetic products, making it necessary to find alternative test methods. The MFDS founded the Korean Center for the Validation of Alternative Methods (KoCVAM) in 2009 and signed the International Cooperation on Alternative Test Methods (ICATM) in 2011 with the EU, the US, Japan, and Canada to actively engage in developing the guidelines for alternative testing methods. The animal replacement testing methods in Korea registered as OECD toxicity test guidelines by the MFDS are “Skin Sensitization Test Method Using Flow Cytometry (LLNA:BrdU-FCM) (2018)” and the “Eye Irritation Test Using a Human Cornea Model MCTT HCETM (2019).”

With the adoption of the “Skin Sensitization Test Using a Human Skin Model KeraSkin TM” as the OECD test guideline development task in 2020, the MFDS put efforts for enlisting domestically developed animal replacement tests through international expertise assessments. At the same time, the Ministry published the “Guidelines for Animal Replacement Tests for Cosmetics Toxicity (guidelines

for civil petitioners) (24 guidelines so far) and held the "Workshop to Transfer Technology on Animal Replacement Tests" for the industry. The MFDS plans to continue its activities in 2021 to introduce and promote animal replacement tests as well as research on animal replacement tests including "Validation Research on In Chemico Skin Sensitization Test Method (DPRA)," "Research on Pre-Validation of an Alternative to Eye Irritation Tests for Ophthalmic Medical Devices," and "Research on Pre-Validation of an Alternative to Skin Sensitization for Medical Devices."

The acceleration of the growth of non-clinical study markets at home and abroad asserts the importance of producing non-clinical study data that are reliable and comply with the OECD Good Laboratory Practice (GLP) for mutual accreditation among OECD member countries. Thus, the MFDS has been surveying the status of non-clinical study agencies that follow the OECD GLP guidelines every year, to guarantee the international level of drug safety. It has also been providing training programs for non-clinical study experts and new drug researchers every year since 2008 for better non-clinical study infrastructure.

In 2020, it held a total of seven workshops including the "Educational Program for Nurturing Professional Personnel in Non-clinical Studies" (five times) and the "Educational Program for Connection of Non-clinical Studies and Clinical Studies" (two times) while operating the "Online Educational Program on the Non-clinical Study Management Standards" for regular training on non-clinical study management standards.

On top of it, the Ministry constantly developed guidelines for better understanding of GLP for non-clinical study agencies via "Research for a Guidebook on Non-clinical Study Management Standards," "Research on Considerations in the Application to the Tests on Biological Safety of Medical Devices," and "Research to Advance the GLP." In 2020, it published the test-specific guidelines (seven kinds) for considerations in applying GLP to safety tests of medical devices. The guidelines were distributed to GLP institutes.

The MFDS will remain committed in 2021 to enhance capacity to assess safety

of domestic non-clinical studies by surveying the status at the OECD level and developing GLP guidelines.

3. Research on Safety Management of Narcotic Drugs and Establishment of the Next-Generation Safety Evaluation Base

The distribution of new narcotics is soaring in Korea as they are more easily available than existing narcotics, increasing the number of drug users in various age groups and thus requiring a prompt countermeasure at the national level. Hence, the MFDS has built and operated a system to assess the risk of new narcotics at all times as a ministry in charge of narcotics control. With increasing narcotic cases, the Clinical Research Division provided assessment results of eight temporary narcotics regarding the effect on the central nervous system, dependence, and cardiotoxicity for narcotics designation. With the revision of the Enforcement Decree of the Narcotics Control Act in March 2019, it has become mandatory by law to assess the risk of temporary narcotics, advancing the specialty of the narcotics assessment system beginning from 2020. The MFDS will synthesize at least 20 standard substances to assess the risk of new narcotics and expand the assessment items of temporary narcotics to prepare a global-level technical review report. Additionally, the Ministry intends to strengthen the cooperative ties among government agencies in charge of narcotic testing/analysis to facilitate information sharing by building an integrated database on narcotics information.

Meanwhile, the Clinical Research Division is pushing ahead with next-generation safety assessment technology to boost the domestic development of new pharmaceuticals. As the global trend is to use AI in developing new medicines, the Division designed an algorithm to assess and anticipate the pharmaceutical safety concerning the cardiovascular system based on the clinical big data as well as a test method to assess drug safety using cardiac muscle cells derived from induced

pluripotent stem cell of humans. Using big data on the interaction of drugs and machine learning, it will study drug-drug and drug-food interactions for the purpose of research on the safe use and assessment of pharmaceuticals to constantly provide drug safety information.

4. Securing Public Safety through Advancement of Clinical Evaluation and Reduction of Side Effects

With changes in the social structure such as the aging population and the paradigm shift to patient-oriented medical treatment, it has become more significant to prevent side effects and ensure the safety of drugs. It is also gradually expanding to use clinical assessments, based on computer technology, for efficacy and safety evaluation of drugs. Therefore, with a view to laying foundations to safely use drugs for the vulnerable and the sensitive such as children, women, and seniors, the MFDS has been contributing to establishing policy & technology foundations for the safe use of pharmaceuticals through various efforts such as providing scientific basis including appropriate information on usage and dosage, drafting plans for systematic advancement of clinical trials, and enlarging a technological basis for clinical assessments of drugs.

In 2020, the MFDS prepared infrastructure to improve the clinical trial risk control system and the review of electronic informed consent by the Institutional Review Board (IRB); provided information on the guidelines by overseas regulatory bodies including the WHO and the FDA, in relation with clinical trials for COVID-19, as well as information on the status of the use of Real world data (RWD)/Real World Evidence (RWE); and laid foundations to use a patient-reported outcome measurement system, i.e. PRO-CTCAE to assess the quality of patient-oriented medical services and reduce adverse events. The Ministry prepared information on the safe use of dexmedetomidine for children such as proper usage and dosage and

strengthened the cooperative network for the industry/academia/research institutes/government by hosting a symposium on the research trend regarding the brain disease modeling using organoid. It is also making its best efforts to form the basis for precision medicine such as identifying the gene that causes anticancer drug resistance specific among Koreans using tailor-made pharmacogenomics.

In future, the MFDS will continue to 1) prepare a plan for an integrated management system by clinical trial product for effective clinical trial management; 2) create a patient-reported outcome measurement system PRO-CTCAE appropriate for Korea for the vulnerable such as children and the elderly to use drugs safely; 3) establish scientific grounds for vulnerable people to properly use drugs using modeling and simulation; 4) prepare the guidelines for the usage and dosage of each drug based on pharmacogenomics and provide pharmacogenomic information via Drug Safety Korea; and 5) develop an infrastructure plan to introduce regulations based on medical big data and a natural language processing technology regarding side effect reports.

5. Enhancement of Food and Drug Safety Management by Advanced Analysis

The Advanced Analysis Center was reorganized as an organization directly under the National Institute of Food and Drug Safety Evaluation in August 2020 for ensuring swift response against emergencies regarding food and drugs. It has been playing its role as one of main bodies of the MFDS in charge of preventing illegal production and sale of food and drugs. The center presented analysis results on 360 samples upon the request of the policy division of the headquarters and relevant institutions (Korea Customs Service, National Police Agency, and Public Prosecutors' Office). For reliable testing and analysis results, it obtained a certificate as an internationally accredited testing organization (ISO 17025) from the Korea Laboratory Accreditation Scheme

(KOLAS) for 12 items. With the revision of the Act on Testing and Inspection in the Food and Drug Industry in 2019, the proficiency evaluation work was transferred from the headquarters to the center, making it in charge of proficiency assessment of testing and inspecting agencies (250 or so) designated by the MFDS. Under the Framework Convention on Tobacco Control (FCTC) of the WHO, the MFDS expanded analytical methods for harmful substances in tobaccos (including e-cigarettes) to build infrastructure on the measurement and disclosure of tobacco components. In particular, as lung damage or even deaths were caused by e-cigarettes in the U.S. and similar cases were reported in Korea, the MFDS strongly recommended suspension of using e-liquids in cooperation with the MOWH and the KCDC. As part of further pan-ministry countermeasures taken afterward, the Ministry also swiftly announced its relevant achievements including analysis results of nicotine and substances that are suspected to cause lung damage (six substances including vitamin E acetate) among products distributed in Korea (October 5).

6. Advancement of Development, Preservation and Utilization of Laboratory Animal Resources

Laboratory animals are essential bioresources to explore new drug candidates, develop food and drugs, and study evaluation technologies on their safety and efficacy. However, most of them are imported from developed countries because Korea has weak infrastructure necessary to develop and use disease model animals compared to domestic demand. In this context, domestically produced laboratory animal resources are to be secured for domestic bioresource research and infrastructure expansion. Furthermore, since biological samples such as organs and tissue of laboratory animals can be utilized as research resources, it is necessary to establish a system to share them with other researchers. According to the Act on the Acquisition, Management, and Utilization of Biological Research Resources, the MFDS secures, preserves, and manages laboratory animals as a biological resource center for disease model mouses for health and medical areas. In 2020, it additionally obtained disease model animal resources (two kinds for cancer, two kinds for the immune system). As a result, its strain maintenance and resource utilization system now has 89 kinds of model mouses for major incurable diseases. At the same time, the Ministry secured 66,857 resources derived from laboratory animals including tissue, serums, and cells by operating the Laboratory Animal Resource Bank and regional institutes to build infrastructure that facilitates obtaining and using resources from laboratory animals. To create an environment for effective drug development, it will support domestic research activities through assessment standard studies and technical R&D for food and drug safety and efficacy using domestically developed disease model animals. The MFDS intends to constantly collect useful laboratory animal resources through the Laboratory Animal Resource Bank, thereby enhancing the infrastructure to share them with associated agencies and researchers.

Section 5

Advancement of the National Lot Release System and Reinforcement of Expertise

1. Status of the National Lot Release and Advancement of Quality Control (QC)

For biological products such as vaccines and plasma-derived products, the MFDS is implementing the National Lot Release System (NLRS) that the state checks the quality of products one more time, and the National Institute of Food and Drug Safety Evaluation (NIFDS) affiliated with the MFDS is in charge of biological products.

As of December 31, 2020, 184 items are eligible for lot release. In 2020, a total of 2,424 lots were approved for release, down 70 lots from 2019 (Table 5-2). But applications for lot release is expected to increase steadily due to the growing domestic vaccine share and the expansion of manufacturing facilities for plasma-derived products.

Table 5-2 Number of National Lot Release Cases in the Last 10 Years

(As of Dec 31, 2020, Unit: Lot, Source: 2020 Annual Report on National Lot Release)

Category \ Year	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020
Total	1,772	2,007	2,255	2,369	2,334	2,375	2,467	2,528	2,493	2,424
Vaccine Products	941	900	995	922	856	885	919	865	841	865
Botulinum Toxin Products	92	152	242	471	536	597	521	545	523	449
Plasma-derived products	739	955	1,018	976	942	893	1,027	1,118	1,129	1,110

Since April 1, 2016, the MFDS has operated the Biological Product NLRS based on risk analysis. In 2021, it will confirm the risk level for 184 items and accordingly review lot release tests and manufacturing and QC data. The Ministry is pushing to improve the system by detailed agenda such as preparing a periodic inspection plan under the “Comprehensive NLRS Improvement Plan” established in 2019 to lay the foundation for establishing a leading NLRS in 2020. In addition, the MFDS established and revised 28 standard operating procedures (SOP), 19 test records, and 22 “Checklists to Examine National Lot Release Manufacturing and QC Summary” to overhaul the quality assurance system; and manages eight manuals by revising two manuals, including the “Comprehensive Risk Assessment and Notification Procedure for National Lot Release Drugs.” In 2020, the MFDS revised the “detailed guidelines to assess the risk level of national lot release medicine” by reflecting features of each vaccine and plasma-derived product to strengthen an inspection test on the potency and safety of national lot release drugs at risk level 2. To supplement the exemption of drugs at risk level 1 from a semi-permanent inspection test, the Ministry prepared and carried out a plan for assigning and performing randomized inspection tests for botulinum toxin products.

The MFDS has operating a public-private consultative body to improve the efficiency of quality management and promote international harmonization through information and technology exchanges between labs.

15 manufacturers and two quality inspection institutions are participating in

the "Vaccine QC Laboratory Network (Lab-Net)." In 2020, the MFDS achieved results such as establishing national reference standards for Sabin polivirus strain inactivated poliomyelitis vaccine and diphtheria toxins, standardizing the identification test method for Haemophilus influenza B vaccine, and higher proficiency in aluminum content tests. In addition, it held the 2020 Workshop for the Biological Product QC Lab-Net for internal and external experts on vaccines and plasma-derived products.

In the field of plasma-derived products, the Ministry operates the "Public-Private Council for Blood Product Quality Research" involving domestic manufacturers, importers, blood collection centers and related ministries. In 2020, it performed a joint study to standardize the complement system test on human immunoglobulin drugs and establish national reference standards for human immunoglobulin (polymeric test) by operating a sub-division of "Plasma-Derived Product QC Lab-Net" with manufacturers. In 2021, the MFDS plans to improve the pseudovirus-based neutralization assay for hepatitis B surface antigen antibodies, a human immunoglobulin drug.

2. International Cooperation Activities

In order to strengthen the capabilities for safety control of biological products and discuss and exchange information on regulatory issues, the MFDS is carrying out various cooperative projects 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 Western Pacific Region National Control Laboratories (WPR-NCLs).

Since 2006, the MFDS signed the WHO's Technical Service Agreement (TSA), and has accordingly been entrusted with tests for vaccines supplied to the WHO. In 2020, the MFDS was entrusted with tests for 7 lots of vaccines including BCG vaccine, pertussis vaccine, Japanese encephalitis vaccine, cholera vaccine and influenza vaccine; implemented potency assays; and sent the results to the WHO.

In addition, the MFDS hosted the "WPR-NCL Workshop" in September 2020 in order to bolster cooperation between WPR-NCLs. Experts from Korea, Japan, Vietnam, and those from the WHO West Pacific Regional Office participated in the workshop and shared safety and quality control trends of the WTO and others over blood and plasma-derived products. Especially, they discussed how to prepare a "contact point list" for activating the network between WPR-NCLs, by sharing information and surveying the demand for joint research to establish national reference standards.

The International Quality Control Laboratory of Drug and Food (NQL) played a role as a global leader in biological pharmaceutical quality by hosting an international joint study involving four countries and seven organizations: the MFDS, Japan's National Institute of Infectious Diseases (NIID), Vietnam's National Institute for Quality Control of Vaccines and Biologicals (NICVB), Indonesia's National Quality Control Laboratory of Drug and Food (NQCLDF), etc.

The MFDS joined in programs to establish a reference standard for thrombin, which was led by the UK National Institute for Biological Standards, and Control (NIBSC) and to standardize a thrombin identification assay for human immunoglobulin, which was organized by the US FDA. It also participated in the international joint Ig study (for electrophoresis testing) and in the WHO Expert Committee on Biological Standardization (ECBS) to discuss plans to establish reference standards for Blood Coagulation Factor 8 and 13.

In 2021, the Ministry will hold the 6th "WPR-NCL Workshop" in September in conjunction with the Global Bio Conference, involving WPR-NCL experts in quality management. It will also lead international joint research as well as engage in international joint research at the request of foreign state regulators.

3. Enhancement of Quality Control in the National Lot Release Inspection Tests and Operation of the Proficiency Program

In order to ensure the retrospective ability and international credibility of test results, the MFDS established methodical quality control (QC) and quality assurance systems for test analysis tasks, and in December 2004, according to approval requirements of the International Organization for standardization (ISO) (ISO/IEC 17025), the Ministry was recognized as an authorized testing institute. In addition, to ensure objectivity and reliability of testing capabilities, the MFDS continuously participates in international proficiency programs and operates an international proficiency program to check QC levels of domestic manufacturers.

In 2020, the MFDS conducted an internal review and on-site KOLAS evaluation to expand the scope of its accreditation and finally won additional accreditation for six plasma-derived products. As a result, MFDS is now operating ISO/IEC 17025 for 26 test items. In addition, the MFDS took part in the International Proficiency Program organized by the EDQM, and received accreditation for its quality inspection capability at the international level regarding the influenza vaccine HA assay and endotoxin assay, and formulated an aluminum assay as a domestic proficiency program. Like this, the MFDS verified the testing capability of each testing institution and secured its reliability.

In 2021, the MFDS will continue to operate an international accredited test institution for 26 test items, complete legal training, evaluate internal and external proficiency, maintain the retrospectiveness of equipment and revise the SOP for testing methods. In order to examine its international quality test capability, it also plans to participate in the International Proficiency Program hosted by the EDQM, especially for the potency assay of coagulation factor 9 and Ig total protein assay. The MFDS will take on position as a reliable test analysis and research institution by developing its international testing and analysis capabilities in the areas of vaccine and plasma-derived products.

chapter 6

COVID-19

Section 1

COVID-19 Response System of the MFDS

1. The MFDS as a Part of the Central Disaster and Safety Countermeasures Headquarters

The Central Disaster and Safety Countermeasures Headquarters (CDSCHQ) is an organization established by the Ministry of Interior and Safety (MOIS) to oversee and coordinate matters concerning response to and recovery from big disasters. The head of the CDSCHQ may direct the Central Disaster Management Headquarters, the Si/Do Disaster and Safety Countermeasures Headquarters, and the Si/Gun/Gu Disaster and Safety Countermeasures Headquarters, if necessary.

The COVID-19 CDSCHQ consists of 1) disease prevention and control and 2) pan-government support, with 223 people in 8 units for the former under the control of the Ministry of Health and Welfare (MOHW) and 51 people in 5 units for the latter under the control of the MOIS (as of Apr. 8, 2021). As part of the ministerial cooperation team, the MFDS works with the Office for Government Policy Coordination, MOIS, MOHW, Ministry of Education, Ministry of Defense, Ministry of Culture, Sports and Tourism, Ministry of Employment and Labor, Ministry of Environment, National Police Agency, and National Fire Agency. The MFDS is committed to responding to COVID-19 with a focus on requests from ministries and sites.

2. COVID-19 Crisis Response Headquarters of the MFDS

On January 27, 2020, the CDSCHQ raised the crisis alert level from “caution” to “alert” and established the COVID-19 Crisis Response Headquarters (COVID-19 CRH) in the MFDS based on the “National Crisis Management Guidelines (Presidential Ordinance)” and the “Infectious Disease Disaster Manual.”

The main roles of the MFDS COVID-19 CRH are situation control, on-site response, external cooperation with related ministries and agencies, and communication with the public. The CRH activities are divided into the first half of 2020, when mask supply problems occurred, and the second half, when the supply of treatments and vaccines became a major issue. The MFDS is making all-out efforts to cope with COVID-19 by quickly reforming its organization and functions according to issues during each period.

Table 6-1 Installation of the COVID-19 Crisis Response Headquarters

(As of Jun. 18, 2021, Source: COVID-19 Response Division)

Date		Description	Personnel
2020	Jan. 27	Organized the HQ according to alert escalation from Caution to Alert	33
	Feb. 5	Expanded the HQ in preparation for a prolonged crisis	176
	Feb. 20	Organized the Daegu-Gyeongbuk Headquarters	206
	Apr. 21	Disbanded the Daegu-Gyeongbuk Headquarters, Established the Daily Prevention and Control Office	186
	May 18	Adjust personnel following the resumption of mask export	172
	Dec. 16	Coordinate the HQ around therapies & vaccines	150
2021	Jan. 14	Established the sub-headquarters for therapy & vaccine release approval	224

A. First Phase of the COVID-19 CRH

After the first outbreak of COVID-19, the CRH was organized and operated focusing on stabilizing supply and demand of masks. With the Vice Minister of the MFDS as its head, the COVID-19 CRH planned the mask supply and demand stabilization policy, which is represented by the "publicly distributed face mask system," encouraged mask manufacturers to increase production, managed distribution sites such as pharmacies and wholesale stores, and conducted intensive crackdown on mask hoarding and unfair trade. It also pushed for rapid development and supply of MFDS diagnostic reagents, etc.

B. Second Phase of the CRH

In July 2020, after supply and demand of masks stabilized and supply of publicly distributed face masks ended, rapid introduction of COVID-19 treatments and vaccines has emerged as a major issue. Around November, overseas regulators began to approve the COVID-19 vaccine, and the MFDS COVID-19 CRH reorganized itself into a treatment and vaccine-oriented system. In January 2021, when domestic approval and evaluation began in earnest, the MFDS established an additional sub-headquarters for approval and evaluation of treatments and vaccines and lot release approval to make the best efforts to supply them in a timely manner.

3. COVID-19 Response Division of the MFDS

As the COVID-19 pandemic seemed to go on, the government decided to form a temporary organization in each ministry so that it could juggle COVID-19 response work and basic work. The MFDS, a major ministry of COVID-19 response including masks and diagnostic reagents, also established the COVID-19 Response Division (1 president, 6 members) under the "Regulation on the Establishment and Operation of the Emergency Response Organization for Supporting the Supply of Medical Products, including COVID-19 Medical Masks, Etc. (MFDS Instruction)." The MFDS will run the division until Apr. 8, 2022.

The role of the COVID-19 Response Division changed, in a similar way to the re-organization of the COVID-19 CRH in response to changes in COVID-19 issues. In the first half of 2020, to solve the problem of stabilizing the supply and demand of masks as a top priority, the phase 1 emergency response unit planned a step-by-step reform measure for the publicly distributed face mask system and a government stockpile and inventory management plan through analysis of the mask supply trend and future prospects; prepared measures to support export of COVID-19 prevention products such as test kits; and discovered and managed other potential issues.

To prevent the recurrence of unstable supply and demand of masks, the MFDS is performing constant monitoring based on production report data by company and on the results of the price survey of Statistics Korea. Finally, the MFDS plans to record and evaluate the crisis response process to enhance the effectiveness of the COVID-19 response and to improve crisis response capabilities.

Section 2

Effective Response of COVID-19 by Sector

1. Measures for Stabilizing Mask Supply and Demand

A. Operation of the Publicly Distributed Face Mask System

1) Background

Due to the explosive increase in mask demand in the early days of the COVID-19 outbreak, mask supply became quite unstable as shown in the out-of-stock situation and price increase. Accordingly, a rapid mask supply and demand stabilization policy was needed so that anyone could use masks. It was because masks were essential to overcome the public health emergency.

2) Achievements

After the first outbreak (January 2020), COVID-19 rapidly spread mainly in Daegu and North Gyeongsang Province (Gyeongbuk), and demand for masks increased drastically. As a result, the so-called “mask chaos” occurred and it paralyzed market

functions, which led to disturbance of distribution order, price surge and shortage of masks, etc. In a national crisis triggered by the infectious disease, people felt anxious about not getting masks essential for disease prevention and control and called on the government to intervene in the market.

Therefore, to stabilize the supply and demand of masks, the government enforced an emergency supply and demand adjustment measure for the first time since the legislation of the Price Stabilization Act in 1976. Major measures include enlarged mask production and export regulation, public distribution, and control in demand through the five-day rotation face mask distribution system. With pan-governmental cooperation, the MFDS quickly enacted the “Mask Emergency Supply and Demand Adjustment Measure (notice of the MFDS)” and revised it nine times by December 2020, factoring in the status of mask supply. Through this, the Ministry contributed to stabilizing mask supply and demand and restoring market functions.

A) Implementation of a Publicly Distributed Face Mask System

The representative emergency supply and demand adjustment measure is public distribution of masks. It is a system that requires all mask producers to release a certain percentage of the production on the day to government-designated public sales places (publicly distributed face masks). The MFDS expanded the supply volume itself by eliminating cases of stacking up masks in a warehouse to sell them at a higher price or by hoarding them at a store during the distribution process; and controlled the consumer price to 1,500 won per sheet to stabilize it. The Ministry adjusted the public release ratio several times by continuously monitoring market conditions and terminated the public distribution system in July 2012 when the supply and demand stabilized.

B) Regulation on Export to Increase Domestic Supply and Support Activity to Increase Production

For stable mask supply, the MFDS controlled export and supported increase

in production. In order to secure domestic supplies, in March 2020, the MFDS completely prohibited masks from being taken and exported overseas through peddlers, etc. As domestic supply and demand improved, the Ministry gradually eased export regulation, and allowed some exceptional overseas shipments for humanitarian purposes to the soldiers dispatched abroad, families living abroad, and countries troubled by a severe COVID-19 situation. In October 2020, it lifted the regulation on export completely from the time when oversupply was expected, and crafted export support measures with related ministries to dispose of mask inventory.

Table 6-2 Status of Mask Export Regulation

(As of Dec 31, 2020, Source: Quasi-drug Policy Division)

Feb. 26, 2020	Mar. 6, 2020	Jun. 1, 2020	Jun. 18, 2020	Jul. 12, 2020	Sep. 15, 2020	Oct. 23, 2020
Medical & surgical masks Export within 10%	Ban on export	Medical masks alone Export within 10%	Medical masks alone Export within 30%	Medical masks alone Export within 50%	Medical & surgical & KF-AD masks Export within 50%	Lifted the restriction on export (export permission)

To increase mask production, the MFDS dispatched a total of 18,300 employees (February 25-April 22, cumulative) from the headquarters and local offices to all mask plants to encourage production and address difficulties on the ground. In addition, the MFDS directly checked on-site daily production and sales, including holidays, and thoroughly managed to prevent illegal distribution of masks.

It promoted the increase of new producers and the expansion of licensed items through better regulations and rapid permission. It maximized production efficiency by easing packaging regulation (allowing large-capacity packaging in individual packaging), permitted vendors to sell small portions to reduce packaging personnel, and reduced quality inspections of finished products (enhanced process inspection and post-release inspection). In addition, the Ministry increased domestic supply by easing import requirements by allowing exceptional import without item permission (2,209 approvals, March-April) for use in companies, distribution among vulnerable groups by local governments, and donation.

C) Implementation of a Five-Day Rotation Face Mask Distribution System for Fair Distribution of Masks, Priority Supply to Emergency Sources of Demand

To distribute insufficient masks as fairly and efficiently as possible, the MFDS carried out demand control measures represented by the “Five-Day Rotation Face Mask Distribution System.” By doing so, it designated the number of publicly distributed face masks and the day of the week for purchase depending on the date of birth, and permitted only purchases through pharmacies. In order to prevent duplicate purchases, the Ministry set up a purchase history confirmation system and made sure that pharmacists sell masks after confirming the purchase history through the ID card. The MFDS improved the system by reflecting the needs of the public as much as possible, including expanding the exceptional range of proxy purchases for the vulnerable who have difficulty buying masks personally.

Table 6-3 Changes in the Mask Purchase System

(As of Dec 31, 2020, Source: Quasi-drug Policy Division)

Date	Description
March 6	■ Start publicly distributed face mask sale of 2 pieces per person
March 9	■ Implement a five-day rotation face mask distribution system according to the year of birth
March 23-April 6	■ Expand the scope of proxy purchase: Pregnant women, nursing hospital patients, national veterans, people in the long-term care facility, people who were born between 2002 and 2009, inpatients
April 20	■ Expand the scope of proxy purchases - Family members on the family relationship certificate and foreigners who stay long in Korea without health insurance
April 27	■ Increase purchase quantity: Purchase quantity for one person per week: 2 → 3 pieces ■ Improve convenience of purchase: Accept the purchase of masks by an agent on the designated day of the week
May 18	■ Expand the scope of proxy purchase: Allow vicarious purchase to all family members (housemates) ■ Improve convenience of purchase: Allow purchases allocating quantity to the weekday and weekend
June 1	■ Terminate the five-day rotation purchase system ■ Purchase quantity for one person per week for those under 18: 3 → 5 pieces
June 18	■ Increase purchase quantity: Purchase quantity for one person per week : 3-5 → 10 pieces
July 11	■ Finish public supply

In addition to selling masks for the general public through pharmacies, the MFDS first supplied masks to sources in emergency needs such as infectious disease special management area and medical institutions. The Ministry secured 25.2 billion won to supply 32 million masks to vulnerable groups and medical institutions in Daegu and Gyeongbuk and provided 2.7 million masks (2.5 billion won) for pharmacy workers in charge of selling publicly distributed face masks on the front of COVID-19 prevention and control.

D) Support for Development of Light Masks for Disease Prevention and Control in Summer

As the number of cases of avoiding wearing masks in the summer increased due to high temperatures, the MFDS established lightweight and breathable "KF-anti droplet masks" (revised the notice about the designation on the scope of quasi-drugs) and supported their supply in June 2020. The KF-anti droplet (KF-AD) mask has fewer layers (4 layers → 2 layers), less than half the weight than medical masks such as KF94 masks, and has various shapes (which can use public health production facilities), e.g. three-dimensional and flat shapes. On top of it, the MFDS contributed to increasing production by supporting the development of SMS filters that have a higher production efficiency with the same performance as filters (MBs) mainly used in mask manufacturing, and by matching KF-AD mask producers and filter producers (from June).

E) Mask Governance Based on Close Public-Private Cooperation and Communication

The MFDS organized and operated (February-December) the "Mask Supply and Demand Stability Task Force" involving the Office for Government Policy Coordination, Ministry of Economy and Finance, Ministry of Trade, Industry and Energy, Ministry of SMEs and Startups, Public Procurement Service, and Statistics Korea in order to stabilize supply of masks. The Ministry discussed and determined major measures and checked progress between ministries (41 times). In addition, it operated "public-private policy consultative meetings" (July-October, 14 times) to reliably supply masks to areas and medical institutions with low accessibility to publicly distributed face masks such as islands and mountainous areas.

The MFDS accurately informed and transparently disclosed various stabilization measures centered on mask supply and demand conditions and emergency adjustment measures, enlisting public participation and cooperation. Public briefings on the supply and demand of masks were held every day in the first half of the year (February-June) and every week in the second half (July-December). The MFDS provided diverse safety information on masks, including mask selection criteria and how to wear them.

Mask production increased up to 3.9 times in weekly production compared to the early days of the COVID-19 outbreak, and market functions recovered, with prices continuously falling. Eventually, the notice of emergency supply and demand adjustment measures for masks was officially abolished in May 2021.

In the 2020 food and drug policy consumer awareness survey of 1,000 people in the national communication group operated by the MFDS, 78.8% of the respondents said the Ministry strived to stabilize supply and demand of masks. This indicates that the public is positively evaluating its measures to stabilize supply and demand of masks.

Moreover, domestic and foreign media positively assessed active mask policies of the Ministry such as the market intervention process through the government's measures to stabilize supply of masks, priority supply to medical staff, and recommendation of wearing masks. This is a proof that the MFDS contributed to enhancing the status of Korea's response to COVID-19, too.

B. Operation of the Center for Reporting Mask Hoards

1) Background

As COVID-19 spread around communities, demand for medical masks and hand sanitizers exploded since they are essential for preventing infection. In order to

resolve the disturbance of market order by stacking or hoarding masks in warehouses or selling them at exorbitantly higher prices, the (MOEF) Notice on the Prohibition of Hoarding Medical Masks and Hand Sanitizers based on the Price Stabilization Act was enacted and implemented.

2) Achievements

A) Rapid Establishment and Operation of the Reporting Center on Hoarding Medical Masks, Etc.

The MFDS established and operated the “Reporting Center on Hoarding Medical Masks, Etc.” since February 5, 2020 as a control tower for preventing and eradicating illegal activities such as hoarding related products. The MFDS established the dedicated reporting center on the Ministry website so that anyone could easily report suspicious situations like stockpiling, and operated a separate telephone line at all times. In addition, it received and handled complaints over soaring prices, unilateral cancellation of online orders, and long-term delivery delays. Hence, the Ministry greatly alleviated inconvenience of the public.

B) Operation Result of the Reporting Center on Hoarding Medical Masks, Etc.

The MFDS Reporting Center handled reports as follows. A total of 23,701 cases were received and reported, of which 3,004 cases were suspected of hoarding medical masks and hand sanitizers; 6,062 cases were suspected of price hikes and violations of the Pharmaceutical Affairs Act; and 14,635 other cases were filed, including delivery complaints, etc. Among them, the MFDS investigated all suspicious hoarding cases and accused them when their violation was confirmed; advised the seller to adjust the price for suspicious cases on a price hike, etc.; and handled reports on the violation of the Pharmaceutical Affairs Act, such as suspected false masks and illegal advertisements, through administrative examinations and investigations, etc.

The MFDS Hoarding Response Team found 69 cases through self-enforcement, including filing cases of the report center: 43 cases of hoarding, 24 cases of violations of emergency supply and demand adjustment measures, 1 case of smuggling and 1 case of unfair profit.

On February 21, 2020, the MFDS caught a company (based in Busan) that hoarded 5.24 million medical masks, and urgently provided 2.21 million of them to Daegu and Gyeongbuk, where a number of COVID-19 patients were occurring.

However, the supply of masks was not able to meet the skyrocketing demand despite tougher crackdowns on hoarding and more transparent distribution processes such as mask production and supply. So, the government decided to set a five-day special self-report period from March 10 to 14, 202o to induce early supply of the hoards to the local market. The MFDS announced: 1) that if mask sellers reported their hoarding activity during this period, the punishment would be deferred; and 2) that the Public Procurement Service would buy reported goods at an appropriate price and would not provide reporting details to the National Tax Service for such purposes as tax verification. As a result, the MFDS received voluntary reports about 156,000 medical masks and distributed them to the public.

Furthermore, the MFDS detected that distributors and sellers did not distribute and sell large amounts of medical masks stored at airports, ports, and big logistics warehouses. They could not export masks owing to national measures such as freezing the quantity and supply price of publicly distributed face masks. In response, the MFDS conducted a special investigation with the police and the Korea Customs Service to check about 4.49 million medical masks stored in the warehouse of the Incheon International Airport and distribute them domestically.

Apart from it, KF-AD masks were sold out right after their first approval in 2020, and re-sold online and offline at high prices. To address this issue, the Ministry conducted various activities. For example, it monitored used goods trading websites for 26 days, from June 8 to July 3, 2020, checking about 1,300 posts for reselling KF-AD masks and guided the writers through comments, notes, and phone calls.

C. Operation of a Pan-Government Enforcement Task Force

1) Background

A) Necessity for Operating a Pan-Government Enforcement Task Force to Stabilize Supply and Demand of Masks

As the nationwide spread of COVID-19 caused a shortage of health and surgical masks (hereinafter referred to as “masks”), there was a need for efforts to stabilize supply and demand of masks to prevent COVID-19.

In addition, as public anxiety escalated due to disturbed distribution such as price hikes that were incurred by mask hoarding, it was urgent to organize a temporary organization to conduct on-site inspections of all mask manufacturers, distributors and sellers and help production by quickly resolving the manufacturers’ troubles.

To this end, a pan-government enforcement task force was organized involving six ministries[1] and operated from Jan. 31, 2020 under the supervision of MFDS Pharmaceutical Management Division.

2) Achievements

A) Inspection According to Implementation, Etc. of the Notice on Hoarding

The standards for hoarding were established according to the enactment and implementation (Feb. 5, 2020) of the Notice on the Prohibition of Hoarding Medical Masks and Hand Sanitizers (MOEF notice). The MFDS intensively inspected hoarding or avoidance of sale for profiteering.

To this end, the Pan-Government Enforcement Task Force with 30 teams inspected distributors suspected of market disruption such as wholesalers, and tried to improve the supply and demand of masks by releasing stockpiles and encouraging more production.

1 MFDS, National Police Agency, National Tax Service, Fair Trade Commission, Korea Customs Service, and local governments

B) Tighter Inspections Following the Implementation of Emergency Supply and Demand Adjustment Measures

The MFDS took emergency supply and demand adjustment measures (Feb. 12, 2020) to conduct additional performance inspections on daily reports, such as production and sales volumes granted to manufacturers and vendors. The measures (Feb. 26, 2020) were revised to designate pharmacies and post offices as public sales places; require all mask manufacturers in Korea to supply them with 50% of their daily mask production and restrict export. In response, the Ministry inspected the manufacturers by making its increased staff present every day in approximately 150 production sites and further checked whether they complied with the regulation on public sale of masks.

As the mandatory supply quantity of daily masks was adjusted to 80% due to an amendment to emergency supply and demand adjustment measures (Mar. 6, 2020), the role of the Pan-Government Enforcement Task Force became more important. And now that a large portion of domestic mask production was supplied through public sales outlets, the MFDS made all-out efforts to encourage more production, and identify and resolve difficulties such as raw material supply, product distribution (transport), shortage of production personnel.

C) Phased Mitigation and End of Inspection

The supply and demand situation gradually improved as the mask production rose due to more manufacturers and production devices and better raw materials supply.

As a result, the Ministry reduced the inspection scale, cycle, etc. by lengthening the cycle from daily on-site inspection of all manufacturers to two to three times a week and by cutting back on-site inspection personnel.

In accordance with the revised mask supply and demand management plan (Jul. 11, 2020), the public sales obligation of medical masks was terminated and the restriction on the purchase quantity was abolished. So, the MFDS completed regular inspections of medical mask manufacturers in the second week of July 2020, but

carried out frequent on-site inspections once a week through inspection of surgical mask manufacturers and review of production and public sales reporting.

Since the obligation to sell masks including surgical masks for public good was abolished (Sep. 15, 2020), the MFDS ended weekly inspection on their manufacturers from the second week of September 2020. Thus, the Pan-Government Enforcement Task Force finished its activity after accomplishing its objective of stable mask supply, and the Notice on the Prohibition of Hoarding Medical masks and Hand Sanitizers was officially abolished in March 2021.

2. Support for Rapid Supply and Export of COVID-19 Diagnostic Reagents

1) Background

In January 2020, there were domestic and international crises[2]. So, in vitro diagnostic (IVD) reagents were needed to diagnose emerging infectious diseases to establish an efficient prevention and control system such as screening and isolation of those infected with COVID-19. No country in the world, however, had such reagents.

According to Article 46(2) of the Medical Devices Act, the MFDS approved a COVID-19 diagnostic reagent, which secured diagnosis accuracy through performance tests and expert reviews, for the first time on February 4, 2020 for temporary manufacture (import), sale, and use of products requested by a central administrative agency (including the Korea Disease Control and Prevention Agency (KDCA)).

Since then, a total of 16 products could be used at the disease prevention and control site. In the process, the Ministry approved seven items for confirmation tests to diagnose COVID-19 infections, including those approved on February 4, and permitted nine more emergency products at the request of the KDCA for products that could confirm test results within an hour to sort out emergency patients requiring first aid.

In addition, it provided support through the “Fast Approval Plan for COVID-19 Diagnostic Reagents” so that products approved for emergency use can obtain formal permission in Korea.

Korea has been responding efficiently by developing high-accuracy diagnostic reagents quickly from scratch and using them for COVID-19 prevention and control. As the pandemic promptly spread worldwide, the country was recognized as a model and the demand for domestic diagnostic reagents soared.

2) Achievements

A) Swift Input of IVDDs into Disease Prevention and Control Sites for Large-Scale Testing from Early Days

The legal processing period for licensing the manufacture of in vitro diagnostic medical devices (IVDDs) is 80 days, but it is usually longer because they go through supplementary procedures for documents. However, in an attempt to respond quickly to emergency situations, the first product was approved in seven days[3] after performance evaluation applied with the “Emergency Use Approval (EUA)” system, allowing the product to be used immediately at the disease prevention and control site.

B) Prevention of Early Spread by Screening and Isolating Infected Persons through Prompt and Accurate Confirmation of Results

For a prompt and accurate test of COVID-19 infection, test results could be confirmed within six hours and the products, which use the scientifically most

2 (Domestic) New coronavirus crisis alert level: Alert (Jan. 27, 2020) (Attention → Caution → Alert), (WHO) Declared an international public health emergency (Jan. 31, 2020).

3 When the first patient occurred in Korea in January 2020, the KDCA discussed how to push for EUA, held private company briefings (Jan. 27, 2020), publicized application for EUA (Jan. 28, 2020), and completed approval of the first product (Feb. 4, 2020).

accurate “gene amplification” method, were provided to the field to quickly sort out and isolate infected people. They played a key role in the Korea’s response to COVID-19.

As a result, Korea’s response model, which actively copes with COVID-19 from the beginning based on excellent accuracy of domestic diagnostic reagents and mass inspection capability, was evaluated as a global model.[4]

C) Confirmation of Korea-proposed Diagnostic Technology as an International Standard

The method of diagnosing infectious diseases such as COVID-19*, which was proposed by Korea, was published as an international standard by the International Organization for Standardization (ISO) on December 2.

* In vitro diagnostic test systems — Nucleic acid amplification-based examination procedures for detection and identification of microbial pathogens — Laboratory quality practice guide (ISO 17822)

The proposal is about the procedure and method for operating IVD tests using “gene amplification” to diagnose infectious diseases. It can be applied to various diagnostic tests such as a real-time PCR method for COVID-19 reagents.

D) Support for Fast Approval and Evaluation to Shift to Formal Permission

In preparation for a prolonged COVID-19, the MFDS came up with the “COVID-19 Diagnostic Reagent Fast Approval Support Plan” in April 2020 to help the approval[5] within an average of three months by shortening the evaluation period that had usually taken at least one year (including preparation period for supplementary materials).

The Fast Approval Support Plan was to quickly assist with clinical performance tests by enabling 1:1 customized consulting[6] and matching medical institutes with companies that had difficulty securing COVID-19 samples, and to review the associated item before others when materials were submitted to apply for approval. This served as a basis for determining measures such as manufacturing suspension of the products approved for emergency use. In addition, due to the longer-than-expected COVID-19, the Ministry introduced self-test kits as an auxiliary means to expand pre-emptive inspection, and has given technical advice to enterprises even before they apply for permission by designating a dedicated evaluator to help rapid product development.

Table 6-4 Approval of COVID-19 Diagnostic Reagents

(As of May 31, 2021, Unit: Case, Source: Innovative and Diagnostic Medical Device Policy Division)

Total	Gene	Antigen	Antibody
42	22	8	12

E) Surging Export of Domestic Diagnostic Reagents

As COVID-19 spread across Europe and the U.S. beyond Asia in the first half of 2020, competition to secure Korean test kits intensified. Their export fully began in April and rose sharply following a surge in confirmed cases after July. The export values reached new highs in a series (on a monthly basis): $220 million in April, $390 million in September, $412 million in October, and $546 million in November. They recorded $3.64 billion for the year of 2020. By May 2021, 318 products (gene 137, antigen 92, antibody 89) had been licensed for export, with a total of $4.759 billion exported to 185 countries worldwide. Top 4 countries – Germany (33%), India (8%), Italy (7.3%), and the Netherlands (6.6%) – accounted for more than 50% of total exports. This performance is attributed to the excellence of domestic products and the recognition of Korea’s response to COVID-19 as an exemplary case in major foreign countries such as the U.S. and Europe.

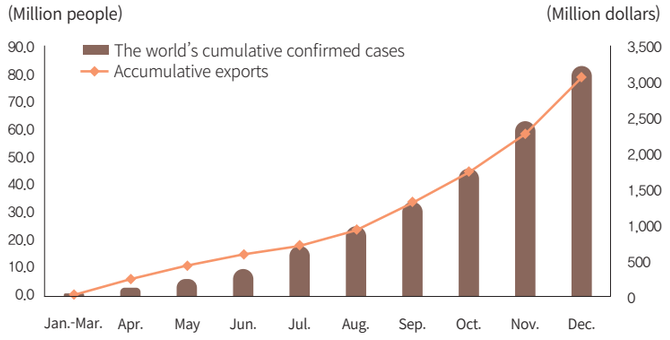
4 The OECD ranked Korea as No. 1 in the COVID-19 response evaluation index by country (Sustainable development report 2020, Cambridge University press, June 2020)

5 As of the end of December 2020, 13 products (Gene 9, antigen 2, antibody 2)

6 Approval helper: A program to support commercialization including shortening the approval and evaluation period by supporting each company from the beginning of product development to GMP, testing, and permission (from 2005). 29 items from 19 companies have been designated.

Image 6-1 Trends of the Export of COVID-19 Diagnostic Reagents and World Confirmed Cases

(As of May 31, 2020, Unit: Million people, Source: Innovative and Diagnostic Medical Device Division)



3) Improvement Plan

Although the development of COVID-19 treatments and vaccines is underway, the pandemic situation has not yet ended. Thus, the MFDS plans to keep supporting the development and permission of diagnostic reagents to tackle new expansive COVID-19 situations such as variant viruses.

Based on the upgraded recognition of domestic diagnostic reagents thanks to COVID-19, the Ministry will provide field-oriented assistance such as quality control and listening to difficulties to help manufacturers obtain IVDDs with good performance and supply safe products.

3. Support for Fast Approval, Evaluation and Development of Treatments and Vaccines

1) Background

Since the first outbreak of COVID-19 in Korea in January 2020, the MFDS has made efforts to prevent further spread through the publicly distributed face mask system, etc. But the number of confirmed cases has increased gradually. At the same time, the need for vaccines has been raised to build herd immunity for treatment and prevention purposes.

However, COVID-19 was a new strain of the coronavirus, and there were no drugs or vaccines worldwide, which accelerated the development of treatments and vaccines in domestic and international pharmaceutical industries. There were global needs to immediately use COVID-19 treatments and vaccines at medical sites and secure their supply for the post-COVID-19 era.

Therefore, the Ministry will also establish a full-cycle support system for treatments and vaccines, ranging from development to authorization, so that effective and safe products can be released quickly while minimizing trial and error in the development. In addition, the MFDS will actively cope with public health emergencies such as the epidemic of infectious diseases so that it can respond to severe domestic and international COVID-19 outbreaks and support the rapid return of people to their daily lives.

2) Achievements

A) Support for Expedited Review by Establishing a Specialized Organization for COVID-19 Treatment and Vaccine

The MFDS has organized and operated a dedicated review team for each development stage, including the initial development stage of COVID-19 treatments

and their clinical preparation and approval application stages. In particular, it forms and operates a dedicated approval review team 90 days before the scheduled date of application for permission, and thoroughly conducts prior counseling and rolling review before applying for permission. In doing so, the Ministry is trying to be methodical in the process of approval and examination.

In addition, it runs the Approval Review Team's evaluation of submitted data on non-clinical trials, clinical trials, and quality in an in-depth review (cooperative review) method by field to further enhance expertise and objectivity.

Image 6-2 A Plan to Operate Exclusive Evaluation Team for Each Stage of Development

(As of Mar. 4, 2021, Source: Pharmaceutical Policy Division)

Initial Development Stage	Clinical Preparation Stage	Approval Application Stage
R&D Review Team Present a direction for minimizing trial and error in R&D, such as quality, non-clinical trials, clinical trials, etc.	**Clinical Trial Review Team** Prior counseling, expedited review, and approval of clinical trials	**Approval Review Team** Prior counseling, rolling review, and expedited review / approval of approval data

For prompt approval of COVID-19 treatments and vaccines, the "Approval Review Team" discussed the preparation and schedule of data submission and issues before permission with the applicant for a COVID-19 treatment and vaccine to identify and responded to issues of the relevant item in advance. Furthermore, as soon as the applicant prepares data on quality, non-clinical trials, clinical trials, etc., the team fully reviewed the safety and effectiveness of the vaccine through rolling review before permission and reduced the required time after the application of approval. The MFDS thoroughly verified safety and effectiveness of COVID-19 treatments and vaccines through review by field and external experts in the "COVID-19 Treatment and Vaccine Approval Review Team" so that safe and effective treatments and vaccines could be used for the public. Particularly, in order to secure objectivity and transparency in COVID-19 treatment/vaccine authorization and evaluation, the MFDS established the "Advisory Group for Verifying Safety and Effectiveness of COVID-19 Treatments and Vaccines" and the "Final Review Committee" in addition to the "Central Pharmaceutical Affairs Review Committee" pursuant to the Pharmaceutical Affairs Act.

Image 6-3 Threefold Consultation Procedure for COVID-19 Treatment and Vaccine Approval

(As of Dec. 31, 2020, Source: Director for Novel Products Approval)

B) Operation of a High-Intensity Expedited Commercialization Program (GO–Fast Program)

The "GO-Fast Program" is a program operated by the MFDS since April 2020 to accelerate the development of domestic treatments and vaccines, thoroughly examine and quickly adopt foreign treatments and vaccines, and to differentiate assistance for research and development of candidate materials, clinical approval, permission, review, technical information sharing, international cooperation, etc.

Especially, the Ministry made sure that Investigational New Drug Application (IND) is processed within 15 days for new materials and 7 days for already approved drugs or the drugs with additional efficacy and effectiveness (drug repositioning) during clinical trials. Hence, the MFDS helps the products quickly enter clinical trials.

Image 6-4 GO–Fast Program

(As of Jan. 2, 2021, Source: Expedited Review Division)

GO–Fast Program

- ✓ **R&D support:** Scientific advice and resource sharing at the development stage
- ✓ **Approval and review support:** Professional consulting by experienced examiners in approval and review; exemption and prompt examination of submitted materials during IND and item permission
- ✓ **Support for sharing technical information:** Providing information on clinical approval status and approval/review
- ✓ **Support for international cooperation:** Establishing a hotline to strengthen cooperation with overseas regulators and resolve difficulties in developing products

C) Support for Rapid Clinical Trials

The MFDS has actively improved regulations such as procedures for clinical trials in hospitals and the like so that the clinical trial, a key process in the development of COVID-19 treatments and vaccines, can be carried out quickly.

First of all, to shorten the evaluation period of the Institutional Review Board (IRB), the MFDS allowed multiple clinical agencies to perform joint review and pushed ahead with establishing a central clinical review committee in which the government can lead integrated evaluation.

In addition, regarding procedures for the consent on participating in clinical trials, the MFDS rationalized them by permitting explanation on the landline instead of handwritten signatures and photographic data, etc. in consideration of the situation of patients or guardians in quarantine.

The Ministry quickly took measures as well: even if a hospital that had treated COVID-19 patients was not a designated clinical testing institution, it could conduct clinical trials under the supervision of the already designated hospital; and even an institution that analyzes specialized clinical samples for COVID-19 without the MFDS designation could implement sample analysis through entrustment from and to designated institutions.

D) Promotion of Commercialization through Rapid Approval and Evaluation of COVID-19 Treatments and Vaccines

In the case of vaccines, the MFDS shortened the existing approval and evaluation period (more than 180 days) to 40 days or less through rolling review by item and prompt permission and evaluation by the Approval Review Team, and as of June 15, 2021, five COVID-19 vaccines were approved as follows.

Table 6-5 COVID-19 Vaccine Approval

(As of May 31, 2020, Source: Director for Novel Products Approval)

No.	Product Name	Approval Date	Platform
1	AstraZeneca Korea COVID-19 vaccine inj.	2021.2.10.	Virus vector vaccine (manufacture)
2		2021.5.21.	Virus vector vaccine (import)
3	Comirnaty Inj. (Tozinameran)	2021.3.5.	mRNA vaccine
4	COVID-19 vaccine Janssen inj.	2021.4.7.	Virus vector vaccine
5	Moderna COVID-19 vaccine inj.	2021.5.21.	mRNA vaccine

In the case of therapeutic products, the MFDS allowed Gilead's COVID-19 treatment "Remdesivir" to be specially imported and supplied in cooperation with the Korea Disease Control and Prevention Agency (KDCA) and external experts on June 3, 2020. Given the spread of COVID-19 and the global permission status, the Ministry enabled "Remdesivir" to be licensed as of July 24, 2020 for stable and continuous supply to medical sites. "Regkirona Inj.," a COVID-19 antibody treatment developed by Celltrion, started a rolling review application on Nov. 20, 2020, applied for an official item approval on Dec. 29, 2020, and received permission on Feb. 5, 2021. Regkirona Inj. is the first Korean drug to hav been licensed as a treatment for COVID-19.

※ COVID-19 Covax Vaccine Approved for Emergency Use

The MFDS pushed for emergency use approval (EUA) of Covax Facility's vaccine in cooperation with related central administrative agencies such as the MOHW and

the KDCA to quickly supply COVID-19 vaccines to Korea.

On March 9, 2021, the Special Act on the Promotion of Development and Emergency Supply of Medical Products in Response to Public Health Emergency was enacted and promulgated, which provided a legal basis for rapid emergency use and stable supply of medical products such as vaccines and treatments.

The KDCA requested EUA of the COVID-19 vaccine to be supplied from Covax Facility, and the MFDS decided to approve emergency use after undergoing an advisory procedure through deliberation of the Committee for the Safety Management and Supply of Medical Products in Response to Public Health Emergency.

The MFDS approved the supply of 117,000 COVID-19 vaccine doses from Pfizer on Feb. 3, 2021, 1.67 million doses from AstraZeneca on May 7, and 297,000 doses from Pfizer on May 20.

In addition, it approved the emergency use of 1.o13 million doses in Janssen Inj. on June 3, which was provided by the U.S. government through follow-up to the Korea-U.S. summit (May 21) to be used quickly after it was introduced.

E) Laying the Foundation for Fast National Lot Release of COVID-19 Vaccines

Items that require rapid supply for public health, such as vaccines for pandemic infectious diseases, can apply for lot release approval even before the item permission is completed. The MFDS made an amendment to the notification relating to national lot release for the items subject to fast approval so that the Ministry can separately determine their test items and submitted materials and respond flexibly and actively to situations.

In order to approve the national lot release of COVID-19 vaccines developed in a new technology platform, the MFDS arranged a COVID-19 vaccine test laboratories from August 2020, such as a platform-specific RNA analysis room for testing; reinforced cutting-edge analysis equipment that can test the quality of virus vector vaccines, mRNA vaccines, and synthetic antigen vaccines; and established the “Emerging Infectious Disease Vaccines Division,” an organization dedicated to fast lot release approval, on Feb. 26, 2021, to build infrastructure.

Relying on this, the MFDS analyzed platform-specific information and established a test method for AstraZeneca vaccine (5 items), Pfizer vaccine (7 items), and Janssen vaccine (7 items). To verify the safety of emerging infectious disease vaccines such as COVID-19 vaccines based on new technology, it is pushing for the construction of a special test and inspection building. In addition, the Ministry shortened the national lot release approval period, which takes more than two to three months on average, to 20 days so as to support rapid vaccine supply. It also is assisting with vaccination of all Koreans by releasing a total of 12.567 million doses of COVID-19 vaccines until May 31.

3) Improvement Plan

A) Efforts for Swift Commercialization and the Supply of Safe Treatments and Vaccines

The MFDS plans to quickly supply safety-verified vaccines to medical sites through systems such as “conditional item approval” to fight against severe domestic and international COVID-19 outbreaks and support rapid return of people to daily life.

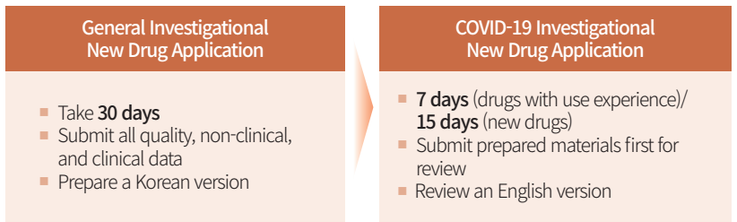
By strictly verifying safety and effectiveness through the “COVID-19 Treatment and Vaccine Approval Review Team” and threefold advisory procedures, the MFDS is to actively respond to public health emergencies such as an epidemic. It will promptly supply safety-verified vaccines to medical sites, too.

B) Close Consultation through Composition and Operation of a Dedicated Review Team for Each Product in the Clinical Approval Stage

The MFDS plans to designate quality, non-clinical, and clinical review teams to conduct scientific evaluation using expert pools including an initial clinical advisory group and an expert committee for each clinical stage, and perform priority evaluation with simplified procedures such as reviewing English materials.

Image 6-5 Shorter Evaluation Period than Usual for Investigational New Drug Application (IND)

(As of Mar. 4, 2021, Source: Pharmaceutical Policy Division)



C) Customized Item Management to Promote Entry into Approval

As regards item approval and evaluation, the MFDS continuously operated the Approval Review Team to shorten the review period (180 days → 40 days) from 90 days before approval application through rolling review of permission data, quick examination of expected problems, and expedited review.

D) Enhancing Accessibility to Development of COVID-19 Treatments through Case Analysis

The MFDS will provide cases at each stage of development to promote the development of COVID-19 treatments by publishing 1) COVID-19 Treatment and Vaccine Development Consultation Book, 2) COVID-19 Clinical Trial Casebook, and 3) COVID-19 Treatment and Vaccine Approval Casebook. By doing so, it will further the development of COVID-19 treatments through improved accessibility to real cases.

In addition, it plans to offer information on COVID-19 animal models, such as characteristics of domestically developed animal efficacy models and precautions in evaluating their effectiveness.

E) Support for Customized Full-Cycle Quality Control for Development of COVID-19 Vaccines in Korea

The MFDS will launch the “Korean Vaccine Project” from May 2021 to achieve self-sufficiency of made-in-Korea COVID-19 vaccines to establish sovereignty over vaccines and respond to ongoing changes in coronavirus strains, while quickly introducing overseas vaccines.

The MFDS plans to continuously operating a rapid national lot release system to early achieve a goal for the vaccination rate and build herd immunization of the entire nation. To support quality control for each platform of COVID-19 vaccines developed in Korea, the Ministry will minimize trial and error following vaccine development and to support fast commercialization by operating a “Customized Full-Cycle Quality Control Counseling System” and publishing “National Lot Release Guidelines for Each Platform.” In addition, it will acquire facilities of Biosafety Level 3 for handling high-risk microbes and reinforce high-tech analysis test equipment to preemptively cope with the pandemic of emerging infectious diseases such as coronavirus after COVID-19.

4. Strengthening Daily Disease Prevention and Control Such as Restaurants and Cafes

1) Background

Since the outbreak of domestic and foreign crises relating to COVID-19 in January 2020, the MFDS requested manufacturers, etc. through related associations to prepare for the prevention of COVID-19 by informing them of handwashing and mask-wearing rules. Since March 12, the Ministry also started to intensively manage entertainment bars, karaoke bars, nightclub-style bars, and the bars for meeting a man or woman, where many people are concentrated in enclosed spaces, to check whether to comply with the rules. Especially, it tried to minimize the situation of not wearing masks and effectively curb the spread of COVID-19 by continuing to check whether restaurants and cafes in contact with people’ lives as well as entertainment facilities follow the rules. Cooperation with related associations, etc. was essential

to strengthen disease prevention and control measures at restaurants and the like. Therefore, the Ministry held several meetings with applicable associations and companies, including the Korea Foodservice Industry Association, and asked for cooperation from time to time.

2) Achievements

A) Enhanced Management of Facilities at Risk of Mass Infection

On April 7, 2020, the MFDS announced measures to intensify control of clubs and other facilities at risk of mass infection for continuous and tight disease prevention and control. It bolstered management by expanding inspection bodies from local governments alone to local governments, police and consumer food hygiene monitors for joint inspection and conducted late-night inspections reflecting the characteristics of entertainment facilities. Moreover, on May 6, the Ministry prepared guidelines for daily prevention and control along with the Central Incident Control Headquarters and thereby introduced more effective management measures for restaurants, cafes, etc. Further, as cases of mass infection occurred in restaurants, etc., the MFDS announced measures to strengthen COVID-19 prevention and control measures at restaurants on June 24, performing publicity and campaign activities to the public for blocking three Cs (crowded, close-contact, and closed settings).

Image 6-6 Measures to Strengthen Disease Prevention and Control of Restaurants

(As of Jun. 24, 2020)

"Blocking Three Cs
(Crowded, Close-contact, and Closed settings)"

- ▲ Two-part meal time system
- ▲ Installation of a partition between tables (top) and one-person tables
- ▲ Promote outdoor business, delivery and packaging
- ▲ Strong recommendation to wear a mask

On August 7, the Ministry introduced a fourfold management system based on public-private cooperation to beef up disease prevention and control. This is how it works: (Stage 1) Businesses do self-inspection; (Stage 2) associations deploy autonomous instructors to verify and inspect self-inspection of Businesses; (Stage 3) local governments carry out on-site inspection of prevention and control rules; and (Stage 4) the MFDS and local governments conduct joint inspection. The MFDS established a tight network for the fourfold management system of businesses, associations, local governments, and the MFDS. Accordingly, it reported to the Central Incident Control Headquarters the plan to conduct on-site inspection of daily prevention and control in cafes (Aug. 7, 2020), the disease prevention and control measure for stage 2 social distancing in Seoul and Gyeonggi-do (Aug. 17, 2020) and the follow-up measure to strengthen social distancing in the metropolitan area (Aug. 30, 2020).

Image 6-7 Measures to Strengthen Disease Prevention and Control of Cafes

(As of Aug. 7, 2020)

"Fourfold disease prevention and control system based on public-private cooperation"

(1) (Business) Self-inspection
(2) (Association) On-site inspection by autonomous instructors
(3) (Local government) On-site inspection of rule compliance
(4) (MFDS) Joint inspection by the MFDS and local governments

Meanwhile, the Ministry improved the system for sustainable prevention and control. It amended the Enforcement Rule of the Food Sanitation Act so as to require workers to wear masks, businesses to place hand sanitization devices or supplies. To facilitate daily prevention and control, the MFDS revised the standards for restaurant sanitation grades (public notice) to give additional points in designating a grade for the business that practices daily prevention and control measures such as installing partitions and social distancing.

B) Precisely Pinpointing Inspection for a Certain Period

After the disease prevention and control system was stabilized, the MFDS executed pinpointing inspection for a certain period of time. In preparation for the Chuseok holiday movement, the MFDS worked with the Korea Expressway Corporation from September 12 to October 4 to come up with a special management plan for highway service areas that likely attract a large floating population. The MFDS suspended food sale at highway service areas for the first time in history; guided the users regarding traffic volume through the Variable Message Sign (VMS) to disperse them; separated restaurant entrances to reduce congestion; induced people to observe disease prevention and control measures including wearing a mask; and operated a triple (MFDS, Korea Expressway Corporation, and local governments) management system. Through this, the Ministry examined 220 highway service areas and 3,991 restaurants around national roads and tourist attractions and administratively instructed 22 locations. Meanwhile, it also implemented preventive and hygienic measures for the fall foliage season. From October 19 to 23, the MFDS inspected 220 highway service areas, including private areas, and 9,229 restaurants, around national and public parks and tourist attractions to provide administrative guidance on 55 places where people did not wear masks and entry lists were insufficient. As Halloween Day approached at the end of October, everyone at the MFDS was bound to be nervous due to the memory about community-associated infection beginning from Itaewon in May 2020. As a result, the MFDS, local governments, and police conducted a joint inspection of entertainment facilities in areas teemed with young people like Itaewon, the vicinity of Hongik University, etc. at late night (9:00 p.m. to 3:00 a.m.) on weekends. It was able to prevent the spread of community-associated infection by examining 2,733 entertainment facilities in Seoul (Itaewon, vicinity of Hongik University, Gangnam Station, Konkuk Univ. Station, and Sinchon Station), Incheon (Bupyeong), Gyeonggi-do (Suwon) and Busan (Seomyeon). It also banned people from gathering at 61 places. In addition to such inspection, the MFDS consulted with businesses and associations to induce autonomous closure, and many stores joined the drive to overcome COVID-19. Besides, at the end of the year, there were more meetings and events, such as Christmas and year-end parties, so the MFDS had to be alert to a greater risk of spreading infection. In response, the Ministry conducted intensive inspections of 599 large family restaurants popular for meetings and events from December 18, 2020 to January 3, 2021. Especially, in order to induce voluntary compliance with disease prevention and control rules, the MFDS distributed rule-printed 100,000 medical masks to users of restaurants on major streets with big floating populations, for three days from the 17th simultaneously in 17 cities and provinces nationwide.

3) Improvement Plan

In future, the MFDS plans to improve disease prevention and control rules to ensure that they can fully apply to facilities including restaurants and cafes and to check their performance of those measures. The Ministry will also continue to enhance communication for COVID-19 prevention and control with related associations in restaurant, highway service area, bakery, and pub business.

chapter 7

Appendix

1. Ministers · Commissioners · Vice Ministers in MFDS

1) Ministers

Name	Terms of Office
Kim Kang-Rip	Nov. 2, 2020 ~
Lee Eui-kyung	Mar. 9, 2019 ~ Nov. 1, 2020
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
Kim Jin-Seok	Mar. 30, 2021 ~
Yang Jin-young	Jan. 20, 2020 ~ Mar. 30, 2021
Choi Sung-rak	Aug. 20, 2017 ~ Dec. 17, 2019
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

Feb. 26, 2021	○ Reflected the required number of personnel for 2020 (1 Division, +16 persons). - (Headquarters) Established the Innovative Diagnostic Medical Device Policy Division. - (Required number) Increased 19 persons (1 class-4 officer, 1 class-4/5 officer, 9 class-6 officers, 1 senior research officer, 2 researchers). * HQ (11): Established the Innovative Diagnostic Device Policy Division (4), advanced biopharmaceutical safety management (3), safety management of quasi-drugs including masks (2), on-site inspection for sanitary evaluation of imports (2) * National Institute of Food and Drug Safety Evaluation (NIFDS) (3): Evaluation of quasi-drugs including masks (2), research on quasi-drugs including masks (1, temporary) * Regional offices (5): Inspection of overseas pharmaceutical manufacturers (5) ○ Reflected on-demand organization for COVID-19 vaccine tests (+1 Division, 23 persons, temporary). - (NIFDS) Established the Vaccine Testing Division for New Infectious Diseases. - (Quota) Increased 23 persons (1 class-4 officer, 8 senior research officers, 14 researchers). ○ The cooperation quota became full-time officials (2). - 1 class-4 officer for livestock safety surveys, 1 class-5 officer for marine product safety surveys ○ Coordinated local testing and analysis work of regional offices. - Changed a division name (Imported Food Analysis Division → Food Standard Analysis Division), adjusted work by test item between the Food Standard Analysis Division and the Harmful Substance Analysis Division.
Dec. 31, 2020	○ Reflected the performance evaluation result of new personnel (40 food safety control workers became part of the regular workforce). ○ Extended the operation of the Total Labor Cost System for 2 years (until Dec. 31, 2022).
Aug. 31, 2020	○ Reorganized the medical product approval and evaluation system reflecting on-demand organization results. - (HQ) Replaced 2 divisions, Established the Approval Office and the High-Tech Product Approval Office. - (NIFDS) Replaced 2 divisions, Established Preliminary Consultation Division and the Fast Evaluation Division. * On-demand organization result: +18 (NIFDS +18), re-allocation ±22 (NIFDS → HQ) ○ Established the "Big Data Policy Analysis Team" (re-arranged 7) using the Total Labor Cost System (until Jun. 31, 2023). ○ Reorganization to ensure efficiency in the organizational operation by bureau

Classification	Description
Director for Planning and Finance	· Director for ICT Management and Statistics → Director for ICT Management (changed name)
Consumer Risk Prevention Bureau	· Customer Risk Prevention Policy Division → Risk Prevention Policy Division (changed name) · Integrated Food Information Service Division → Integrated Food Data Planning Division (changed name) · Laboratory Audit and Policy Division → Laboratory Audit and Policy Division (changed name)
Food Safety Policy Bureau	· Food Safety Management Division → General Audit and Policy Division (changed name) · Food Safety Labelling and Certification Division → Food Safety Certification Division (changed name) · Alcoholic Beverages Safety Management and Planning Division (removed) → Food Policy of Labelling and Advertising Division (established)
Food and the Consumer Safety Bureau	· Agro-Livestock and Fishery Products Policy Division/Safety Division → Livestock Products Safety Policy Division, Agro-Fishery Products Safety Policy Division

Aug. 31, 2020	Pharmaceutical Safety Bureau: · Clinical Trials Management Division → Clinical Trials Policy Division (changed name) NIFDS: · Change of affiliation - Vaccines Division, Blood Products Division (Immediate affiliation → Biopharmaceutical and Herbal Medicine Evaluation Department) - Advanced Analysis Team (Toxicological Research Division → Immediate affiliation) · Name change - Research Planning Coordination Division, Advanced Analysis Team, Nutrition and Functional Research Team, New Hazardous Substances Team, Cardiovascular Drugs Division, Oncology Treatment Products Division, Cardiovascular Devices Division, Biological Products Research Division, Advanced Bioproducts Division, Cosmetics Research Team → Planning and Coordination Division, Advanced Analysis Center, Nutrition and Functional Research Division, New Hazardous Substances Division, Cardiovascular and Neurology Products Division, Oncology and Antimicrobial Products Division, Cardiovascular and Imaging Devices Division, Biologics Research Division, Advanced Bioconvergence Therapy Research Division, Cosmetics Research Division · Gastroenterology and Antimicrobial Product Division (removed) → Advanced Drugs Quality Evaluation Division (established)
May 8, 2020	○ Reflected the results of performance evaluation on new organizations (integrated the Integrated Food Information Service Division into a regular organization). ○ Designated new personnel evaluation targets. - Designated 16 people in charge of food safety management in local offices (until Dec. 31, 2022)
Feb. 27, 2020	○ Reflected the required number of personnel for 2020 (1 Division, 1 Inspection Office, +48 persons) - (HQ) Established the Sanitary Goods Policy Division and (Regional FDS) Established the Cheonan Imported Food Inspection Office - (Required number) Increased 48 persons (3 class 5 officers, 8 class 6 officers, 10 class 7 officers, 19 class 8 officers, 6 class 9 officers, 12 researchers) ○ Reflected the performance evaluation result of new divisions - Narcotics safety planning director, Narcotics Management Division → Extended the evaluation period one more year (~ Feb. 28, 2021) ○ Changed open type positions (1 director General level 1, 1 manager level)
Jan. 9, 2020	○ Reflection of professional civil servants - Designating "Food safety management sector" as a professional civil servant (general staff 8 class 5 officers → 8 professional civil servants)
May. 7, 2019	○ 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
Mar. 4, 2019	○ 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

Dec. 11, 2018	○ 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 Operation and management of corporations; Operation of the self-quality inspection system; Food Safety Labelling and Certification Division → Food Safety Policy Division Emergency response to GMO; Imported Food Policy Division → Import and Distribution Safety Division Management of inedible agricultural/fishery products; Food Safety Management Division → Import and Distribution Safety Division Setting nutrient standards for processed foods; Food Safety Labelling and Certification Division → Dietary and Nutritional Safety Division ○ 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)
Mar. 30, 2018	○ 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
Jan. 1, 2018	○ 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)
Sep. 28, 2017	○ 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
May. 26, 2017	○ 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.

Mar. 21, 2017

○ Reshuffle of bureaus and divisions related to food
- Reshuffle relevant bureaus and divisions to strengthen safety management of imported food and to ensure efficiency of food safety management
  * Reshuffle Food Nutrition and Dietary Safety Bureau to Food and Consumer Safety Bureau
  * Reshuffle Agro-Livestock and Fishery Products Safety Bureau to Imported Food Safety Policy Bureau

Classification	Description	
	Bureau	Division
Food Nutrition and Dietary Safety Bureau	Food Safety Policy Bureau	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)

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	Director for Planning and Finance	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
	Director for Organization and Management Innovation	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.
	Director for Regulatory Reform and Legal Affairs	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
	Director for International Cooperation	Direct and coordinate international trading and international cooperation projects pertaining to food and drugs; manage resident officers of overseas diplomatic offices
	Director for ICT Management	Establish and evaluate a mid-to long-term informatization plan for food and drugs; operate, maintain and repair the information systems
	Director for Customer Support	Establish and execute comprehensive plans for better customer satisfaction; develop a customer support policy; direct and coordinate civil complaints and operate counseling centers
	Director for Emergency Planning and Safety	Control and coordinate the overall plan and training schedule to cope with national emergencies; manage resources adequately for responding to emergencies (supplies, companies, etc.)
	Big Data Policy Analysis Team	Perform planning and identification and system preparation for public data and big data on food and medicine, etc. and general control of policy statistics
Criminal Investigation Division		Investigate criminal acts involving food and drugs; identify and investigate habitual and intentional crimes related to food and drugs
Director for Audit and Inspection		Audit the MFDS, its agencies and groups and handle and analyse the audit results
Director for Approval Management		Matters concerning the operation of permission and the permission system for medicines, etc., and the improvement of the permission and examination system
Director for Novel Products Approval		Matters concerning the permission of biopharmaceuticals, quasi-drugs, and medical devices; the classification and permission of combination medical products and the operation of their permission system
General Affairs Division		Documents, general affairs, personnel, use, accounting, and facility work
Consumer Risk Prevention Bureau	Risk Prevention Policy Division	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
	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 Data Planning Division	Link and integrate food safety information of central administrative agencies and establish and coordinate its utilization policies, and manage and support the operation of the integrated food safety information network
	Testing and Inspection Policy Division	Enact and revise statutes related to testing and inspection of food, medicine, etc. and coordinate system improvement, strengthen inspection quality of testing and inspection institutions, and formulate comprehensive development plans
	Hygiene Products Policy Division	Establish and operate safety management policies for hygiene products, and supervise monitoring affairs Devise and implement a comprehensive plan for hygiene products
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.
	General Audit and Policy 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 Certification Division	Establishment and adjustment of a comprehensive plan for HACCP in accordance with 「Food Sanitation Act」, 「Livestock Products Sanitary Control Act」, enactment and revision of related laws and announcements and system improvement
	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
	Food Policy of Labelling and Advertising Division	Establishment of food, etc. labeling/advertising policy and system improvement Operation of labeling standards and operation of labeling/advertising demonstration system
	Food Standards Planning Office — Food Standards Division	Establish and execute a total plan for improving food standards and specifications
	Food Standards Planning Office — 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 Standards Planning Office — 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.

Department			Main Functions
Imported Food Safety Policy Bureau	Imported Food Policy Division		Establish a comprehensive plan for the safety management of imported food; and enact and amend regulations and notifications to improve them
	On-site Inspection Division		Establish a comprehensive plan for the safety management of overseas manufacturers; and conduct import sanitation assessment of livestock products
	Imported Food Inspection Management Division		Establish and coordinate a plan for the inspection of imported food items, etc.; and designate inspection items
	Imported Food Distribution Safety Division		Establish a comprehensive plan for guidance and crackdown on businesses related to imported food; establish and manage a plan for the collection and inspection of imported food, etc.
Food and the Consumer Safety Bureau	Dietary and Nutritional Safety Policy Division		Establish and implement food nutrition safety policies and a comprehensive plan; safety management of children's dietary life and matters related to nutrition and safety of children's favorite foods
	Livestock Products Policy Division		Supervise and coordinate sanitary and safety management plans for domestic livestock products; respond to accidents and accidents concerning livestock products; investigate livestock product safety; establish the collection, inspection, guidance/crackdown plans for livestock products, etc.
	Agro-Fishery Products Safety Division		Supervise and coordinate sanitary and safety management plans for domestic agro-fishery products; respond to accidents and accidents concerning agro-fishery products; investigate safety of agro-fishery products; establish the collection, inspection, guidance/crackdown plans for agro-fishery products, etc.;
	Foodborne Diseases Prevention and Surveillance Division		Establish and implement a comprehensive plan for the prevention of food poisoning; operate a pan-governmental committee for countering the outbreaks of foodborne diseases; and educate, promote, and evaluate the measures to prevent food poisoning
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 Policy Division		Direct coordination and establishment of the policies related to clinical trials; approve and manage clinical trial plans for medicine
	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
	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.

Department		Main Functions
Bio pharma-ceuticals and Herbal Medicine Bureau	Biopharmaceutical Policy Division	Establish and coordinate safety-related policies, such as biological products, genetic recombination drugs, advanced biopharmaceuticals, human tissue, raw material plasma, and human cells
	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 Division	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	Develop medical device policies and establish comprehensive plans, designate and classify medical devices, manage medical device permission and international cooperation
	Innovative and Diagnostic Medical Device Policy Division	Establish, coordinate, and develop policies for matters concerning designation, operation, and permission related to innovative medical devices and IVDDs
	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 26 June, Unit: persons)

Position / Agency, Division	Total	Political Appointee Service	General Service												Management Operation Service		
		Minister	Senior Official (Senior Civil Servant)	3·4	Grade 4	4·5	Grade 5	6	7	8	9	Senior researcher	Researcher	Senior Professional Officer	7	8	9
Total	1,998	1	24	12	52	31	214	331	343	168	78	171	539	8	6	2	18
HQ	641	1	11	10	37	13	134	135	121	9	7	40	99	8	4	2	10
Agency	1,357	-	13	2	15	18	80	196	222	159	71	131	440	-	2	-	8
NIFDS	449	-	7	-	7	1	26	11	7	19	5	117	246	-	2	-	1
Regional Office of FDA	908	-	6	2	8	17	54	185	215	140	66	14	194	-	-	-	7
Seoul Regional Office of FDA	144	-	1	1	1	3	8	32	39	17	11	3	25	-	-	-	3
Busan Regional Office of FDA	227	-	1	1	4	1	16	39	54	48	12	2	48	-	-	-	1
Gyeongin Regional Office of FDA	321	-	1	-	3	3	17	67	60	44	27	6	91	-	-	-	2
Daegu Regional Office of FDA	56	-	1	-	-	3	3	13	15	9	4	1	7	-	-	-	-
Gwangju Regional Office of FDA	77	-	1	-	-	4	5	15	23	11	6	1	10	-	-	-	1
Daejeon Regional Office of FDA	83	-	1	-	-	3	5	19	24	11	6	1	13	-	-	-	-

2) History of Change in Prescribed Numbers

Feb. 26, 2021	1,998 persons (42 persons increased) - Required personnel for 2021: 19 persons • Established the Innovative Diagnostic Medical Device Policy Division: 4 persons • Advanced biopharmaceutical safety management: 3 persons • Safety management of quasi-drugs including masks: 2 persons • On-site inspection for sanitary evaluation of imports: 2 persons • Evaluation of quasi-drugs including masks: 2 persons • Research on quasi-drugs including masks: 1 persons • Inspection of overseas pharmaceutical manufacturers: 5 persons - On-demand organization for COVID-19 vaccine tests: 23 persons • Emerging Infectious Disease Vaccines Division: 23 persons
Aug. 25, 2020	1,956 persons (18 persons increased, 22 persons re-arranged) - On-demand organization: 18 persons (NIFDS +18 persons), re-arranged ±22 persons (NIFDS → HQ) • Evaluate medical products: 18 persons • Transfer approval/evaluation affairs: ±22 persons
Feb. 27, 2020	1,938 persons(48 persons increased) - required personnel for 2020 : 48 persons • Management of overseas drug manufacturers: 3 persons • Organization management: 1 person • HACCP post-management: 8 persons • Safety management of the imported food distribution stage: 19 persons • Safety management of the imported food customs clearance stage: 17 persons
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 Related to the MFDS

Act (22)	Enforcement Decree (24)	Enforcement Rule (Ordinance of the Prime Minister)(27)
Framework Act on Food Safety	Enforcement Decree of the Framework Act on Food Safety	
Food Sanitation Act	Enforcement Decree of the Food Sanitation Act	Enforcement Rule of the Food Sanitation Act
		Rule on the Health Examination of Workers in Food Sanitation
Special Act on Imported Food Safety Control	Enforcement Decree of the Special Act on Imported Food Safety Control	Enforcement Rule of the Special Act on Imported Food Safety Control
Act on the Establishment and Operation of the Korea Agency of HACCP Accreditation & Service	Enforcement Decree of the Act on the Establishment and Operation of the Korea Agency of HACCP Accreditation & Service	
Health Functional Foods Act	Enforcement Decree of the Health Functional Foods Act	Enforcement Rule of the Health Functional Foods Act
Special Act on Safety Management of Children's Dietary Lifestyle	Enforcement Decree of the Special Act on Safety Management of Children's Dietary Lifestyle	Enforcement Rule of the Special Act on Safety Management of Children's Dietary Lifestyle
Livestock Products Sanitary Control Act	Enforcement Decree of the Livestock Products Sanitary Control Act	Enforcement Rule of the Livestock Products Sanitary Control Act
Agricultural and Fishery Products Quality Control Act	Enforcement Decree of the Agricultural and Fishery Products Quality Control Act	Rule on the Labeling of Genetically Modified Agricultural and Fishery Products and the Safety Investigation, Etc. of Agricultural and Fishery Products
Special Act on the Promotion of Development and Emergency Supply of Medical Products in Response to Public Health Crisis		
Pharmaceutical Affairs Act	Enforcement Decree of the Pharmaceutical Affairs Act	Regulation on Safety of Pharmaceutical Products, Etc.
	Regulation on the Damage Relief of Side Effects	Enforcement Rule of the Regulation on the Damage Relief of Side Effects
	Decree on the Facility Criteria for Manufacturers and Importers of Pharmaceutical Products, Etc.	Enforcement Rule of the Decree on the Facility Criteria for Manufacturers and Importers of Pharmaceutical Products, Etc.
		Rule on the Manufacture and Sale of Biological Products, Etc.
Narcotics Control Act	Enforcement Decree of the Narcotics Control Act	Enforcement Rule of the Narcotics Control Act
Cosmetics Act	Enforcement Decree of the Cosmetics Act	Enforcement Rule of the Cosmetics Act
Medical Devices Act	Enforcement Decree of the Medical Devices Act	Enforcement Rule of the Medical Devices Act
Laboratory Animal Act	Enforcement Decree of the Laboratory Animal Act	Enforcement Rule of the Laboratory Animal Act
Safety, Management, Etc. of Human Tissue Act	Enforcement Decree of the Safety, Management, Etc. of Human Tissue Act	Rule on the Safety of Human Tissue
Act on Testing and Inspection in the Food and Drug Industry	Enforcement Decree of the Act on Testing and Inspection in the Food and Drug Industry	Enforcement Rule of the Act on Testing and Inspection in the Food and Drug Industry
		Rule on the Testing and Inspection Entrustment of the Ministry of Food and Drug Safety and Its Affiliated Institutes
Act on the Promotion of Technology for Ensuring the Safety of Food, Drugs, Etc.	Enforcement Decree of the Act on the Promotion of Technology for Ensuring the Safety of Food, Drugs, Etc.	Enforcement Rule of the Act on the Promotion of Technology for Ensuring the Safety of Food, Drugs, Etc.
Cleansing & Hygiene Products Control Act	Enforcement Decree of the Cleansing & Hygiene Products Control Act	Enforcement Rule of the Cleansing & Hygiene Products Control Act
Act on Labeling and Advertising of Foods	Enforcement Decree of the Act on Labeling and Advertising of Foods	Enforcement Rule of the Act on Labeling and Advertising of Foods
Act on the Safety and Support of Advanced Regenerative Medicines and Advanced Biopharmaceuticals	Enforcement Decree of the Act on the Safety and Support of Advanced Regenerative Medicines and Advanced Biopharmaceuticals	Rule on the Safety and Support of Advanced Biopharmaceuticals
Act on In Vitro Diagnostic Medical Devices	Enforcement Decree of the Act on In Vitro Diagnostic Medical Devices	Enforcement Rule of the Act on In Vitro Diagnostic Medical Devices
Act on Nurturing Medical Devices Industry and Supporting Innovative Medical Devices	Enforcement Decree of the Act on Nurturing Medical Devices Industry and Supporting Innovative Medical Devices	Decree of the Act on Nurturing Medical Devices Industry and Supporting Innovative Medical Devices
	Organization of the Ministry of Food and Drug Safety and Its Affiliated Institutes	Rule on the Organization of the Ministry of Food and Drug Safety and Its Affiliated Institutes
		Rule on the Establishment and Supervision of Non-Profit Organizations under the Ministry of Food and Drug Safety
		Enforcement Rule of the Emergency Resources Management Act under the Ministry of Food and Drug Safety

■ Contributors

(As of 25 Jun, 2021)

Classification	Contents	Division	Director	Contributors
	Foreword, Contents	Big Data-based Policy Analysis Team	Park Seon-Yeong	Lee Soo-Yeon
				Kim Bo-Hyeong
I. Outline	1. Vision, Objectives, and Core Strategies	Director for Planning and Finance	Kim Hyun-Jung	Jung Byungsun
	2. Organization·Affiliated Organizations	Director for Organization and Management Innovation	Kim Hyun-Seon	Kim Yeong-Jun
	3. History			
	4. 2020 Achievements and 2021 Work Plan	Director for Planning and Finance	Kim Hyun-Jung	Jung Byungsun
II. Food Safety	Section 1. Strengthening of the Food Safety Management System			
	1. Strengthening of Safety of Food Production·Manufacturing			
	A. Facilitation of the Standards of Food Safety Management Accreditation(HACCP)	Food Safety Certification Division	Go Ji-Hun	Lee Je-Myung
				Hwang Su-Jin
	2. Enhancing the Safety Management of Foods Being Distributed·Consumed			
	A. Nationwide Joint Crackdown	General Audit and Policy Division	Choi Jong-Dong	Sim Yeon
				Kim Myeong-Su
	B. Reinforcement of Safety Management for Alcoholic Beverages			Sim Yeon
				Min Hye-Ok
	C. Reinforcing Collection·Inspection of Foods Being Distributed			Park Hyun-Jung
				Lee Ji-Sun
	D. Operation of the Food Traceability Management System	Food Safety Certification Division	Go Ji-Hun	Hwang Soon-Im
				Park Su-Ji
	E. Establishment of Hazardous Food Recalling System and Reinforcement of Information Sharing with Consumers	General Audit and Policy Division	Choi Jong-Dong	Park Hyun-Jung
				Seo Sun-Jung
	F. Improvement of the Food System to Provide More Information to Consumers	Food Policy of Labelling and Advertising Division	Park Dong-Hee	Yoo You-Soon
				Kim Min-Ji
	G. Establishment of a Private and Public Joint Monitoring System	General Audit and Policy Division	Choi Jong-Dong	Jung Young-Ae
				Lee Soo-Yeob
	H. Management of Foreign Substances in Food			Jung Young-Ae
				Lee Soo-Yeob
	3. Strengthening Safety Supervision on Health Functional Foods and Resonable Regulation Improvement			
	A. Enhancement of Safety Supervision for Health Functional Foods	Health Functional Food Policy Division	Son Young-Wook	Choi Eun-Jin
		Nutrition and Functional Food Research Division	Lee Hye-Young	Kim Kyu-Heon
	B. Reasonable Improvement of Regulations Regarding Health Functional Foods	Health Functional Food Policy Division	Son Young-Wook	Choi Eun-Jin
	4. Enhancement of Safety Management of Agriculture, Livestock, and Fishery Products from Production to Consumption			
	A. Safety Management of Agro-Fishery Products in production & Distribution Stages	Agro-Fishery Products Safety Policy Division	Oh Kyu Seob	Son Sung-Yol
				Won Mi-Young
	B. Safety Management of Livestock Products in production & Distribution Stages	Livestock Products Safety Policy Division	Kim Cheol-Hee	Choi Ki-Hwan
				Park Mal-suk
	Section 2. Enhanced Safety Management of Imported Food and Securing of Distribution Safety			
	1. Enhanced Safety Management of Imported Food and Securing of Distribution Safety	Imported Food Policy Division	Kim Sol	Ma Jung-Ae
				Choi Woo-Jeong
	2. Reinforcement of Imported Food Safety Management before Customs Clearance	On-site Inspection Division	Jeong Jeong-Soon	Jung In-Kwon
	3. Reinforcement of Safety Management in Customs Clearance Stage of Imported Food	Imported Food Inspection Division	Lee Ho-dong	Jang Hyeon-Cheol
				Park Jin-Ah
	4. Reinforcement of Safety Management in the Distribution Stage of Imported Foods	Imported Food Distribution Safety Division	Rhee Seong Do	Lim Young-In
	5. Reinforcement of Safety Management for Novel Foods including Genetically Modified Foods	Novel Food Division	Park Jong-Seok	Shin Ji-Eun
		Food Policy of Labelling and Advertising Division	Park Dong-Hee	Kim Mi-Ja
		Imported Food Inspection Division	Lee Ho-dong	Park Jin-Ah
		Imported Food Distribution Safety Division	Rhee Seong Do	Surl Chan-Gu
	Section 3. Scientific Management of Standards and Specifications for Food, Etc.			
	1. Improving Food Safety Standards and Specifications	Food Standard Division	Lee Kang-Bong	Choi Youn-Ju
		Residues and Contaminants Standard Division	Shin Yeong min	Jeong Ji-Yoon
	2. Improving and Reinforcing Standards and Specifications on Food Additives, Equipment, Containers, and Packaging	Food Additives Standard Division	Oh Keum-Soon	Cho Tae-Yong
	Section 4. 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	Oh Young-Jin	Go Dae-Woong
	B. Strengthening the Safety of Children's Diet			Kim HyungJung

Classification	Contents	Division	Director	Contributors
II. Food Safety	2. Prevention of Food Poisoning through Building up Favorable Hygienic Surroundings of the Restaurant and Meal Service	Foodborne Diseases Prevention and Surveillance Division	Kim Sung-Il	Kim Ji-young
				Park Eun-jin
	3. Strengthening of Safety Management of Nation's Nutrition	Dietary and Nutritional Safety Policy Division	Oh Young-Jin	Choi Gyeo-Seon
				Kim Soo-Hyeon
III. Medical Products Safety	Section 1. Ensuring a Healthy Life for People through Safe Medicines			
	1. Advancement of Pharmaceutical Manufacturing and Quality Control	Pharmaceutical Quality Division	Kang Young-A	Chung Myung Hoon
				Kang Shin Kook
	2. Advancement of Pharmaceutical Approval and Review System			
	A. Establishment of a Globally Competent Medicine Approval and Evaluation System	Director for Approval Management	Lee Sujung	Moon Hyun-Ju
		Pharmaceutical Standardization Division	Kim Mi-Jeong	Kang Na-Roo
		Pre-Submission Consultation Division	Choi Youngju	Seong Su-Kyoung
		Expedited Review Division of Medicine and Medical Devices	Kim Hee-Sung	Song Young-Me
	B. Vitalization of Cooperative Projects with Foreign Regulatory Authorities	Pharmaceutical Policy Division	Moon Eun-hee	Hyun Miyoung
				Shin Naye
	C. Improving Public Confidence by Improving the Quality of Clinical Trials and Expanding Patient Treatment Opportunities	Clinical Trials Policy Division	Kim Jung-Mi	Jung Byung-Soon
				Kim Ji-Ae
				Kim Hee-Seon
				Byun Jung-Ah
	3. Strengthening the Safety Management of Approved Pharmaceuticals			
	A. Stronger Pharmaceutical Safety Management for the Entire Lifecycle from Manufacturing/Import to Distribution/ Consumption	Pharmaceutical Management Division	Kim Nam-Soo	Lee Ji-Eun
	B. Collection, Evaluation, Production, and Supply of Safety Information on Released Drug Products	Pharmaceutical Safety Evaluation Division	Kim Jeong-Yeon	Lee In-Sun
	C. Adverse Drug Relief System [Damage Relief System for Adverse Drug Reactions]			Yang Dong-In
	D. Stable Supply of Rare and Essential Medicines	Pharmaceutical Policy Division	Moon Eun-hee	Kim Seon-Young
				Kang Won-Goo
	4. Stable Operation of the License and Patent Linkage System	Pharmaceutical Intellectual Property Policy T/F	Moon Eun-hee	Han Eun-Kyung
				Jung Sung-Won
	5. Laying the Foundations for Safe Use of Narcotics	Narcotics Policy Division	Kim Il-Soo	Lee Ha-Young
				Oh Chang-Hoon

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III. Medical Products Safety	6. Strengthening Safety Management of Narcotic Drugs			
	A. Implementation of a "Helper for Safe Use" System against Misuse and Abuse of Narcotics	Narcotics Management Division	Kim Jeong Yeon	Han Won-Sun
				Oh Seung-Min
	B. Creation of an Autonomous Misuse Prevention Environment Based on Big Data	Narcotics Management Division	Kim Jeong Yeon	Song Hyun-Sue
				Oh Seung-Min
	7. Support for Rapid Approval and Commercialization of Medical Products including Convergence Medical Devices			
	A. Enhancement of Efficiency and Consistency in Handling Civil Complaints about Medical Devices	Director for Approval Management	Lee Su-Jung	Moon Hyun-Ju
	B. Establishment of a Foundation to Standardize and Advance the Approval and Evaluation Standards for Medical Products	Director for Novel Products Approval	Jeong Hyeon-Cheol	Kim Hyeon-jeong
	C. Support for Rapid Commercialization of Convergence Medical Products			Lee Jin-Soo
	8. Establishment of a Public Health Crisis Response System	Pharmaceutical Policy Division	Moon Eun-hee	Kim Seon-Young
				Kang Won-Goo
	Section 2. Advancing Safety Management of Biopharmaceuticals and Leading Innovative Growth of the Industry			
	1. Safety Management of Biopharmaceuticals and Human Tissues	Biopharmaceutical Quality Management Division	Kim Eun-Joo	Lee Kyeong-Wook
		Advanced Biopharmaceutical Policy T/F	Kim Sang Hyun	Kim Ji Won
	2. Providing Medicinal Herbs Trusted by the Public and Safety Management of Natural Medicine	Herbal Medicine Policy Division	Go Ho-Yeon	Kang In-Ho
				Kim Ji-Yu
	3. Strengthening Industrial Competitiveness through Safety Management of Cosmetics	Cosmetic Policy Division	Choi Mi-Ra	Lee Man-Deok
				Bang Jun-Ho
	4. Quasi-Drug Safety Management Trusted by the Public	Quasi-drug Policy Division	Park Gong-Soo	Jang Yun-Seock
				Na Zey-Ei
	5. Support for Biopharmaceuticals, Etc. Going Global and Strengthening Global Cooperation			
	A. Support for for Biopharmaceuticals, Etc. Going Global	Biopharmaceutical Policy Division	Kim Chun-Rae	Kim Min-jo
				Chang Tae-Ho
	B. Securing of Global Competitiveness of Biopharmaceuticals through International Cooperation			Kim Hyeon-Su
	6. Advancement of Approval & Evaluation System for Biopharmaceuticals			

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III. Medical Products Safety	A. Advancement of Approval & Evaluation System for Biopharmaceuticals and Initiation of International Standards	Biologics Division	Kim Jae-Ok	Lim Jae-Hyeon
				Jin Mi-Ryeong
		Recombinant Protein Products Division	Jung Ji-Won	Kin Eun-kyeong
				Song Hyeon
	B. Advancement of Approval & Evaluation of Herbal Medicinal Products	Herbal Medicinal Products Division	Park Ju-Young	Hwang Sun-yi
				Lee Jae-jun
	C. Efficient Improvement of Evaluation System for Quasi-Drugs and Cosmetics	Cosmetic Research Division	Jungyun Chang	Park Soon-yeong
				Hyeon Seong Ye
	Section 3. Establishing a Medical Device Safety Management System that Leads Industry 4.0			
	1. Construction of the Foundation for Innovative Growth of Medical Devices and Establishment of Their Lifecycle Safety Management System	Innovation and Diagnostic Medical Devices Policy Division	Roh Hye-Won	Lee Hoon
				Hwang Hye-Jin
		Medical Device Policy Division	Lee Nam-Hee	Kim Min-Jung
				Nam Soo-Hyun
		Medical Device Management Division	Choi Jang-yong	Kim Young-Mi
				Kim Hyeon-Jun
	2. Strengthening Consumer-Centered Medical Device Safety Management System	Medical Device Management Division	Choi Jang-yong	Son Mi-Jung
				Park Sunny
				Kim Young-Mi
				Kim Hyeon-Jun
				Son Mi-Jung
				Park Sunny
				Lim Kyoung-Taek
				Jo Jeong-Jin
	3. Establishment of a Safety Evaluation System for Medical Devices	Medical Device Safety Evaluation Division	Seong Hong-Mo	Yang Won-Seon
				Kim Gui-Eun
				Kim Se-Jung
	4. Advancement of Medical Device Approval Review Process	Digital Health Devices T/F	Kang Young-Kyu	Kim Hyun-Soo
		In-vitro Diagnostic Devices Division	Lee Won-Kyu	Ryu Seung-Rel
		Cardiovascular and Imaging Devices Division	Park Chang-Won	Park Hae-Dae
		Orthopedic and Restorative Devices Division	Jeong Jin-Baek	Kim Kook-Han
		Dental and Gastroenterology Devices Division	Park Ki-Sook	Lim Chun-Il
III. Medical Products Safety	4. Advancement of Medical Device Approval Review Process	High-tech Medical Devices Division	Hong Choong-Man	Jung Seung-Hwan
				Park Jong-Ho
		Orthopedic and Restorative Devices Division	Jeong Jin-Baek	Kim Kook-Han
		Dental and Gastroenterology Devices Division	Park Ki-Sook	Lim Chun-Il
IV. 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	Risk Prevention Policy Division	Ju Seon-Tae	Kwon Tae-hee
	2. Preliminary Survey on Food and Drug Risk Factors for Risk Prevention	Risk Prevention Policy Division	Ju Seon-Tae	Lim Dong-Choon
		Hygiene Products Policy Division	Park Young-Min	Ko Jun-Yeong
	3. Establishment of the Roadmap for Research & Development on Food and Drug Safety Technology	Risk Prevention Policy Division	Ju Seon-Tae	Cha Sang-Jun
				Jung Saet-Byeol
	4. Strengthening the Cooperative System on Food and Drug Safety Issues between MFDS and Korea Consumer Agency			Cha Sang-Jun
	5. Prevention of Consumer Damage by Blocking False/Exaggerative Online Advertisements	Cyber Investigation Bureau	Chae Gyu-Han	Kim Myung-Ho
				Cheon Se-Kyeong
	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 T/F	Shin In-Soo	Choi Won-Young
				So Dam-Yi
	2. Disseminating a Food·Drugs Safety Culture Based on Communication Tailored to Regions and Classes			Ko Min-Ji
				Hwang Jong-Seon
				Im Seon-Mee
	Section 3. Expansion of Sharing·Disclosure·Use of Food and Drug Safety Information			
	1. Collecting·Analyzing·Utilizing Food and Drug Safety Information	Risk Information Division	Kim Dal-Hwan	Cheung Chi-Yeun
	2. Linkage·Integration of Pan-Governmental Food Safety Information and Advancement of Food Administration	Integrated Food Data Planning Division	Jung Young-Sook	Jeong Jin-Mok
				Kim Ji-In
	Section 4. Enhancing International Competitiveness through the Advancement of Testing and Inspection Agencies			
	1. Advancement of Testing and Inspection Agencies Management System in the Food and Drug Area	Laboratory Audit and Policy Division	Kim Il	Lee Ji-Young
	2. Strengthening the International Competitiveness of Testing and Inspection and Ensuring the Quality of Inspection			Kim Chang-Soo

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IV. Risk Prevention	Section 5. Establishment of a Safety Management System for Hygiene Products			
	1. Establishing a Foundation for Safety Management of Hygiene Products	Hygiene Products Policy Division	Park Young-Min	Park Mi-Sun
	A. Improvement of the Hygiene Products Safety Management System			Lee Hai-Eun
	B. Management of the Standards and Specifications for Hygiene Products			Kim Ki-Ju
	2. Safety Management of Distributed Hygiene Products			Lee Seung-Ho
	A. Safety Management of Domestically Distributed Hygiene Products			Seong Hyo-Sil
	B. Safety Management of Imported Hygiene Products			Kang Min-Seung
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 and Drugs, Etc.	Planning & Coordination Division	Kang Ju-hye	Hong Jeong-hee
				Kim Ji-Myoung
	2. Impartial Research Management and Provision of Services for Researchers	Research Management T/F	Jeon Dae-hoon	Koh Young-ho
				Lee Ji-Won
	3. Outcome Management for Research and Development Projects			Park Jwa-haeng
				Kim Dong-Hee
	Section 2. Expanding Risk Assessment for Scientific Food Safety Management			
	1. Improvement of the Risk Assessment System with Expanded National and International Cooperation	Food Safety Risk Assessment Division	Kang Yoon-sook	Kim Seung-Hwan
				Jeong Ji-Yeon
	2. Advancement of the Risk Assessment System for Residual Substances in Agricultural, Livestock and Marine Products	Pesticide and Verterinary Drug Residues Division	Yoon Hae-Jung	Choi Jang-Duck
				Park Su-Jeong
	3. Strengthening the Scientific Basis for Reducing Hazardous Contaminants in Food	Food Contaminants Division	Koo Yong-Eui	Lee Hwa-Jeong
				Kang Young Woon
	4. Microbiological Risk Assessment and Development of Microbial Testing Methods in Foods	Food Microbiology Division	Kim Soon-Han	Kim Mi-Gyeong
				Lee Jeong-Su
	5. Strengthening Safety Management of Food Additives, Utensils, Containers and Packaging, and Hygiene Products	Food Additives and Packages Division	Lee Jong-Kwon	Nam Hye-Seon
				Hwang Joung-Boon
	6. Establishing a Basis for Safety Management of Food Nutrition, Dietary Life, and Functional Health Foods	Nutrition and Functional Food Research Division	Lee Hye-Young	Kim Jong-Soo
				Kim Kyu-Heon
	7. Strengthening the Scientific Surveillance System for Adulterated Foods	New Hazardous Substances Division	Lee Eun-ju	Kim Hyeong-Soo
				Lim Ho-Soo

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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	Drug Research Division	Park SangAeh	Oh HoKyung
	2. Research on Safety Management of Pharmaceuticals			
	3. Research on Prevention and Safety Control of Infectious Diseases	Biologics Research Division	Lee Kwang-Moon	Chun Hyung-Ok
				Park Eun-Hye
	4. Research on Biopharmaceutical Safety Management	Advanced Therapy Products Research Division	Park Mi-sun	Kang Soyeong
	5. Research on Safety Management of Herbal Medicine	Herbal Medicine Research Division	Jo Su-Yeol	Lee Chul-Hyun
				Lee Byung-Hee
	6. Research on Safety Management of Cosmetics and Quasi-Drugs	Cosmetics Research Division	Son Kyeong-Hun	Min Chung-Sik
				Kim Sang-Seop
	7. Research on Management of Medical Devices Safety	Medical Device Research Division	Jeong Ho-Sang	Kim San
V. Research and Development for Food and Drug Safety	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	Oh Jae-ho	Lee Jeong-Pyo
				Shin Hyo-Sook
	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 on Safety Management of Drugs and Construction of the Next Generation Safety Evaluation Basis	Pharmacological Research Division	Choi Sun-Ok	Kang Mi-Sun
				Lee Jin-Moo
	4. Securing Public Safety through Advancement of Clinical Evaluation and Reduction of Side Effects	Clinical Research Division	Lee Yoon-Sook	Lee Yeune Hee
				Park Donghyun
	5. Enhancement of Food and Drug Safety Management by Advanced Analysis System	Center for Advanced Analysis	Baek Seon-yeong	Kim Jin-Ho
				Park Hyoung-Joon
	6. Advancement of Development, Preservation, and Utilization of Laboratory Animal Resources	Laboratory Animal Resources Division	Kim Jun-Gyou	Lee Su-Hae
				Kim Myoung-Jun
	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	Kim Jong-Won	Hwang In-Yeong
	2. International Cooperation Activities	Blood Products Division	Sohn Kyung-Hee	Shim Sun-Bo
	3. Strengthening the Quality Management Function in National Testing and Operation of the Proficiency Program			

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	1. The MFDS as a Part of the Central Disaster and Safety Countermeasures Headquarters	COVID-19 Response Division	Park Nam-Soo	Park Won-Young
	2. COVID-19 Crisis Response Headquarters of the MFDS	Risk Prevention Policy Division	Ju Seon-Tae	Lee Sung
	3. COVID-19 Response Division of the MFDS			
	Section 2. Effective Response of COVID-19 by Sector			
	1. Measures for Stabilizing Mask Supply and Demand			
	A. Operation of the Publicly Distributed Face Mask System	Quasi-drug Policy Division	Park Gong-Soo	Na Zey-Ei
	B. Operation of the Center for Reporting Mask Hoards	Criminal Investigation Division	Han Un-Seob	Cho Min-Joo
	C. Operation of a Pan-Government Enforcement Task Force	Pharmaceutical Management Division	Kim Nam-Soo	Kim Hyung-Seok
	2. Support for Rapid Supply and Export of COVID-19 Diagnostic Reagents	Innovation and Diagnostic Medical Devices Policy Division	Roh Hye-Won	Hwang Hye-Jin
	3. Support for Fast Approval, Evaluation and Development of Treatments and Vaccines	Director for Approval Management	Lee Sujung	Kim Ji-Seon
		Director for Novel Products Approval	Jeong Hyeon-Cheol	Nam Joo-Sun
		Clinical Trials Policy Division	Kim Jung-Mi	Kim Hee-Seon
		Biopharmaceutical Quality Management Division	Kim Eun-Joo	Choi Oh-Seok
		Emerging Infectious Disease Vaccines Division	Oh Ho Jung	Kim Sun-Hee
		Expedited Review Division of Medicine and Medical Devices	Kim Hee-Sung	Song Young-Me
	4. Strengthening Daily Disease Prevention and Control Such as Restaurants and Cafes	General Audit and Policy Division	Choi Jong-Dong	Sim Yeon
				Choi Soo-Jin
VII. Appendix	1. Ministers/Commissioners/Vice Ministers in MFDS	General Affairs Division	Choi Hyeon-Cheol	Lee Yong-jun
	2. Changes in the Number of Staff	Director for Organization and Management Innovation	Kim Hyun-Seon	Kim Yeong-Jun
	3. Roles and Responsibilities (HQ)			
	4. Number of Staff			
	5. Laws and Regulations under the Ministry of Food and Drug Safety	Director for Regulatory Reform and Legal Affairs	Choi Ji-un	Mun Geum-yeong

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