

FOL e-Newsletter

The Newsletter of MFDS-Designated Foreign Official Laboratories

What has been changed?



On February 25, 2013, the South Korea's first female president, Park Geun-hye, was inaugurated and declared that she would focus to safeguard the public from what she has defined four major social problems – substandard food, sexual violence, domestic abuse, and school violence. Park believes providing safe food to people is as important as national security.

The Korea Food & Drug Administration (KFDA) was elevated to Ministry status on March 23, 2013 as part of government reorganization, becoming the Ministry of Food and Drug Safety (MFDS) and has undergone a major reconstruction aimed at strengthening its ability to ensure the safety of food supply from farm to table.

One of the big changes is that its responsibilities have expanded to cover livestock, fishery, and agricultural products. Previously, they were regulated under the Ministry for Food, Agriculture, Forestry, and Fisheries but now, the MFDS is able to regulate the entire food chain including all stages of production, processing, distribution, and marketing of food.

The bureau responsible for overall food safety, Food Safety Bureau, is now divided into three different bureaus with different and distinct responsibilities; Food Safety Policy bureau, Food Nutrition and Dietary Safety Bureau, and Agro-Livestock and Fishery Products Safety Bureau.

As one of the comprehensive countermeasures in line with the President's pledge to protect the public from substandard food, a special task force called "Substandard Food Eradication Team" has been formed. Its main duties are establishing of a master plan to eradicate substandard food and cooperating with the authorities concerned.

The MFDS has been reformed as a ministry-level agency primarily in response to concerns about food safety and promises that we put great efforts to serve as a control tower and protect the safety of the overall food supply.

Korea Food and Drug Administration	Ministry of Food and Drug Safety
Office of Planning and Coordination	Director General for Planning and Coordination
Risk Prevention Policy Bureau	Customer Risk Prevention Bureau
Food Safety Bureau	Food Safety Policy Bureau
Pharmaceutical Safety Bureau	Food Nutrition and Dietary Safety Bureau
Biopharmaceuticals and Herbal Medicine Bureau	Agro-Livestock and Fishery Products Safety Bureau
Medical Device Safety Bureau	Pharmaceutical Safety Bureau
	Biopharmaceuticals and Herbal Medicine Bureau
	Medical Device Safety Bureau
1 Office and 5 Bureaus	1 Office and 7 Bureaus



Safety Control of Food

	Production	Imported Food	Distribution	Marketing
Agricultural products	MAFRA	MFDS	MFDS	MFDS
Fishery products	MAFRA	MFDS	MFDS	MFDS
Livestock products	MAFRA	MAFRA	MFDS	MFDS
Processed foods	MFDS	MFDS	MFDS	MFDS

	Production	Imported Food	Distribution	Marketing
Agricultural products	MFDS + MAFRA	MFDS	MFDS	MFDS
Fishery products	MFDS + MAFRA	MFDS	MFDS	MFDS
Livestock products	MFDS + MAFRA	MFDS	MFDS	MFDS
Processed foods	MFDS	MFDS	MFDS	MFDS

 Ministry of Food and Drug Safety (MFDS)
  Ministry of Agriculture, Food and Rural Affairs (MAFRA)
  Ministry of Food and Drug Safety (MFDS) + Ministry of Agriculture, Food and Rural Affairs (MAFRA)

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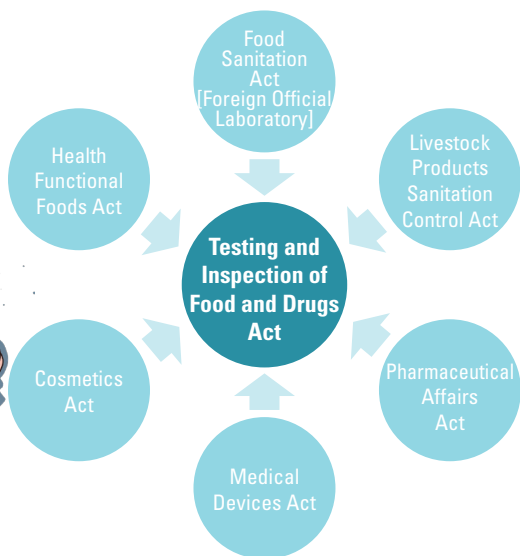
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Enactment of the "Testing and Inspection of Food and Drugs Act"



The Ministry of Food and Drug Safety designates and regulates testing laboratories for food, drugs, medical devices, cosmetics, and livestock products as well as Foreign Official Laboratories. MFDS-designated testing laboratories have been managed under 6 different laws depending on a particular field of designation obtained. The meaning of the terms found in the laws were not always clear and unequivocal and may have caused confusion and misunderstanding. Also, the issue of non-compliance with international quality assurance standards was a big obstacle to be resolved. To address these issues and for fairness and equity in administrative actions, testing laboratory management regulations under 6 different laws (including Food Sanitation Act, Pharmaceutical Affairs Act, etc.) have been consolidated into a single act, Testing and Inspection of Food and Drugs Act. It will enter into force on July 31, 2014.

Key features of the new law are as follows:

- Establishment of unified testing laboratory regulations and procedures for designation, approval of changes in designation status, and penalty surcharge
- Compliance with the globally recognized standard (ISO/IEC 17025, General requirements for the competence of testing and calibration laboratories)
- Expanded proficiency testing programs
- Compulsory training/education
- Establishment and management of the Laboratory Information Management System (LIMS)
- Promotion of development of testing laboratory operating system

Key features concerning Foreign Official Laboratories are as follows:

- Establishment of legal basis for designation of Foreign Official Laboratories
- User fees may be charged when a laboratory seeks to get designated and an on-site audit is required
- Mandatory participation in proficiency testing program annually
- Regular on-site audits



The Enforcement Decree and Enforcement Regulation are currently under pre-announcement of legislation and any suggestions or comments are welcome. Further information can be found at <http://www.mfds.go.kr/index.do?mid=688&pageNo=1&seq=22189&cmd=v>

Amendment to the "Provisions on the Standards, etc. for Authorization of Foreign Official Laboratories"

The regulations concerning Foreign Official Laboratories have been amended as of December 17, 2013. The new changes have been introduced to increase the efficiency of designation application process.

- Designation application / Approval of changes and its supporting documents can now also be submitted electronically.
- Forms prescribed to the Provisions are revised to be bilingual, Korean and English.
- In the designation application form, testing scopes are specified in categories of agricultural products, food additives, Genetically Modified foods, etc.

Amended Provisions

Article 3 (Application for the Laboratory and Authorization)	Article 6 (Approval of changes in designated details)	Forms prescribed to the Provisions
1) A party who wishes to be designated as a Foreign Official Laboratory shall submit an application in the form 1 (including electronic documents) prescribed herewith with attached following required documents. The application can be submitted via the government of the exporting country or directly to the Minister of the MFDS.	1) When any of the following changes is made by a Foreign Official Laboratory, the laboratory shall immediately notify the Minister of the MFDS for approval of these changes by submitting the form 3 (including electronic documents) prescribed herewith.	Previously, forms prescribed to the Provisions (including designation application, approval of changes, and certificate of laboratory test) were only available in Korean which caused inconvenience to non-Korean speakers. Amended forms are now available both in Korean and English.

*Red indicates the amendments made to the Provisions

Please note that the "Provisions on the Standards, etc. for Authorization of Foreign Official Laboratories" will be consolidated into the "Testing and Inspection of Food and Drugs Act" as of July 31, 2014. For more information, please visit our official English homepage at <http://www.mfds.go.kr/eng/index.do?nMenuCode+78>

About MFDS's Proficiency Testing Programs



Osong IPTP is specially designed for Foreign Official Laboratories and has been run as a separate program from domestic proficiency testing program. However, starting July 31, 2014, as the Testing and Inspection of Food and Drugs Act enters into force, Osong IPTP will be operated in the same manner as a proficiency testing program designed for MFDS-designated domestic testing laboratories.

The major difference between MFDS-designated domestic testing laboratories and Foreign Official Laboratories in terms of proficiency testing is whether annual proficiency testing participation is required by law or not. MFDS-designated domestic testing laboratories are required by law to participate in MFDS's proficiency testing program every year.

Testing items are classified into three categories;

	Testing items
Food chemistry	Food additives, Pesticide residues, Nutritional contents, Utensils and packages, Radiation irradiated foods, etc.
Food microbiology	Food poisoning bacteria, etc. present in food
Genetic testing	Genetically Modified(GM) foods, Norovirus, etc.

Evaluation of results is conducted as follows:

Z-scores	$Z = \frac{(\chi - X)}{\sigma}$	- χ : participant's reported value
		- X : assigned value - σ : standard deviation

$|Z| \leq 2$: satisfactory, $2 < |Z| < 3$: questionable, $|Z| \geq 3$: unsatisfactory

Test result lying between a z-score of -2 and +2 is considered 'satisfactory'. If a participant's z-score lies between the range of $2 < |Z| < 3$, it is considered a questionable result and if it lies outside $|Z| \geq 3$, it deems to be unsatisfactory.

As a necessary corrective action, a laboratory should evaluate analytical procedures for possible sources of error if the participant's z-score lies between the range of $2 < |Z| < 3$. In addition to evaluation of possible sources or error, further proficiency testing is provided to ensure the competence of a laboratory if z-scores lies outside $|Z| \geq 3$.

When new law enters into force, if a participant's result is unsatisfactory and has not agreed to take necessary corrective actions, the MFDS has the authority to suspend designation status of a testing laboratory.

About KRISS (Korea Research Institute of Standards and Science)

Test materials for Osong IPTP are prepared by Korea Research Institute of Standards and Science. We would like to give you a brief instruction where the test materials for MFDS's proficiency testing programs are prepared.

Founded in 1975 as the national metrology institute of Korea, KRISS (Korea Research Institute of standards and Science) has been assigned to conduct missions to promote the industrial competitiveness of Korea by advancing measurement standards, science, and technologies. KRISS establishes and disseminates national measurement standards that have secured international equivalency within the framework of the CIPM MRA. KRISS employs approximately 400 full-time staff. The Division of Metrology for Quality of Life under KRISS serves as the nation's reference laboratory by providing measurement standards in the fields of chemical analysis, bioanalysis, and ionizing radiation. One of the primary missions of the division is the development and dissemination of CRMs and proficiency test samples.



To assess the reliability of testing results carried out by the MFDS-designated Foreign Official Laboratories, the MFDS conducts Osong International Proficiency Testing Program (Osong IPTP) every year. In 2013, two rounds of the Osong IPTP were conducted and 14 Foreign Official Laboratories from 6 countries have participated. Laboratory performance was assessed using z-scores and all the participated FOLs submitted test results of $|Z| \leq 2$ indicating a satisfactory performance.

	IPTP-05	IPTP-06
Matrix	Infant formula	Garlic powder
Analytes	Riboflavin (Vitamin B ₂)	Cadmium and Lead

The following laboratories have participated in the 2013 Osong IPTP; Export Inspection Agency-Chennai, National-Agro-Forestry-Fisheries Quality Assurance Department – Branch I, II, IV, V, VI, SGS India, OMIC Thailand, SGS shanghai, OMIC U.S.A., Qindao Korea-Sino Foods Industry, SGS Thailand, Oregon Department of Agriculture Laboratory Services, OMIC Australia.

MFDS's International Affairs

MOU between the MFDS and the NDA

On June 13, 2013, the MFDS has signed a MOU with the National Drug Authority of Uganda (NDA). Under this MOU, two agencies agreed to promote cooperation between two countries in the field of drug and regulatory affairs relating to drugs and medical devices.



The MOU will serve as an important milestone for the two nations to facilitate sharing of information regarding drugs and medical devices which would further contribute in protecting and improving the public health in both countries.

MOU between the MFDS and the URPLWMiPB

On June 5, 2013, the MFDS and the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products of the Republic of Poland (URPLWMiPB) concluded a MOU to exchange information and cooperate in the field of pharmaceutical products and medical devices.

Two nations share the common goal of protecting the public health in the Republic of Korea and the Republic of Poland by ensuring the safety, quality and efficacy of the pharmaceutical products and medical devices and agreed to commit to support joint efforts to provide safe pharmaceutical products and medical devices to their respective populations.

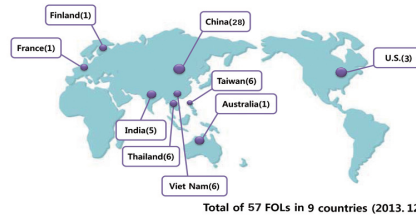
New designation

We have a new addition to our list of Foreign Official Laboratories. Genetic ID NA, Inc. (May 24, 2013) and Inspection and Quarantine Technical Center of Jining Entry-Exit Inspection and Quarantine Bureau (November 28, 2013) have been designated by the MFDS as a Foreign Official Laboratory. Genetic ID NA, Inc. is the second laboratory to be designated for GM (Genetically Modified) food testing.

- Genetic ID NA, Inc, USA
- Inspection and Quarantine Technical Center of Jining Entry-Exit Inspection and Quarantine Bureau, China

As of December 2013, total of 57 Foreign Official Laboratories in 9 countries have been designated by the MFDS.

FOLs around the World



Introduction of FOL members (OMIC Australia)

In each issue of the newsletter, we are featuring one (or two) of the MFDS-designated Foreign Official Laboratories. This issue of FOL e-newsletter, we would like to introduce OMIC Australia.



OMIC Australia was designated as a MFDS Foreign Official Laboratory in 2000, and is the only FOL in Australia.

Located in Melbourne, Victoria, OMIC Australia is a member of the OMIC group of companies (Overseas Merchandise Inspection Company), and employs over 20 staff analyzing food samples for nutritional and microbiological parameters, as well as chemical residues and GMO.

In addition to participating as a MFDS-designated Foreign Official Laboratory, OMIC Australia: is certified to ISO 9001:2008; is accredited with the National Association of Testing Authorities, Australia (NATA); is a Quarantine Approved Premise with DAFF Biosecurity (Department of Agriculture, Fisheries and Forestry, Australia); is a registered Foreign Official Laboratory with the MHLW (Ministry of Health, Labor and Welfare, Japan); and has Authorized Analysts under the Victorian Food Act.

MFDS's Mobile Laboratory



The Mobile Food Poisoning Testing Laboratory Buses are introduced to allow real-time detection of presence of food poisoning bacteria and help stop spreading of food poisoning. The Mobile Food Poisoning Testing Laboratory is equipped with various testing equipment and RT-PCR for faster identification of the food borne microorganisms on-site. It also serves an educational purpose in raising public awareness of the food borne illness.

Key features are:

- Rapid testing facility, meeting room, preprocessing, gene analysis facility, etc.
- Real-time PCR allows detecting 16 different types of food poisoning bacteria on site within 4 hours of an incident.
- Hand washing education materials, food poisoning prevention video clip, and other educational materials are fully prepared.

