

FOL e-Newsletter

The Newsletter of KFDA-Designated Foreign Official Laboratories

A MESSAGE FROM THE COMMISSIONER OF THE KFDA



As part of the Korea Food and Drug Administration (KFDA)'s mission to ensure the safety of domestic and imported food products, we are responsible for the designation and management of Foreign Official Laboratories and domestic food testing laboratories. KFDA-designated laboratories play one of the most important roles in achieving overall food safety and are considered to be the first step in protecting the safety of the food supply.

We have been actively working to ensure the competency and capability of KFDA-designated laboratories through continuous cooperation between the KFDA and the laboratories. Accordingly, we successfully held the 1st International Symposium on Proficiency Testing for Food and Drug and implemented several management schemes such as the Osong Laboratory Quality Assurance Scheme and the Osong International Proficiency Testing Program, which all comply with international standards. We do our best to make sure that we provide the best laboratory management schemes.

The first e-NEWSLETTER issued in May contains not only useful information on relevant rules, but also a two-way forum for communication among KFDA-designated Foreign Official Laboratories(FOL).

I would like to express my sincere congratulations on the first FOL e-NEWSLETTER and I hope it acts as a vehicle for exchanging information and ideas between the KFDA and KFDA-designated laboratories.

Commissioner of
the Korea Food and Drug Administration

Hee-Sung Lee, Ph.D.

Background

The goal of the FOL e-Newsletter is to serve as a communication tool to encourage information exchange and collaboration between the KFDA and FOL members and promote the KFDA Foreign Official Laboratory System. We are here to keep our members updated on relevant rules, the Good Laboratory Practice (GLP) system, and advanced analytical methods.

A message from the Laboratory Audit & Policy Division

Welcome to the first issue of **FOL e-Newsletter, the Foreign Official Laboratories newsletter** issued by the Laboratory Audit & Policy Division. Our division is responsible for the designation and management of domestic/foreign food testing laboratories. Our goal is to create a new tool for the exchange of information on all aspects of Foreign Official Laboratories. The FOL e-newsletter will be issued biannually. We would like to express our gratitude to everyone who contributed pieces for this first edition. This was a team effort.

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KFDA operates an International Proficiency Testing Program (Osong IPTP)

Osong International Proficiency Testing Program (Osong IPTP) has been developed by the Korea Food and Drug Administration in 2011, which is designed to improve and sustain laboratory performance and testing capabilities of KFDA-designated Foreign Official Laboratories. Participating laboratories are provided with test materials by the KFDA and the results are compared with assigned values.

Osong IPTP is operated in accordance with ISO/IEC 17043 (general requirements for proficiency testing) and the international harmonized protocol for the proficiency testing of analytical chemistry laboratories. All the steps in the proficiency testing process are handled in a fair and transparent manner with confidentiality.

In 2011, 14 laboratories from 5 different countries participated in the program (Osong IPTP-01 & 02). Most of the participated laboratories obtained "satisfactory" results and demonstrated their capabilities of analyzing chemicals.



2012 International Proficiency Testing Plan

In 2012, we are planning to have other rounds of Osong IPTP. There will be two programs: IPTP-3 and IPTP-4. The purposes of these programs respectively are: to determine the Iron and zinc content in food; and to determine the γ -HCH and α -endosulfan content in food. The test materials will be prepared by KRISS (Korea Research Institute of Standards and Science) in accordance with the requirements specified in ISO guide 34.

We look forward to your laboratory participating in our International Proficiency Testing Program.



Introduction of KFDA's Foreign Official Laboratory Management System

Foreign Official Laboratory refers to a laboratory that has been designated by the KFDA Commissioner for demonstrating the capability to perform laboratory tests and satisfies one or more of the following conditions:

1. A public laboratory established by the government of an exporting country;
2. A laboratory designated by the government of an exporting country;
3. A laboratory established and operated outside of Korea by a KFDA-designated domestic foodtesting laboratory.

When food products are imported into Korea, the report or certificate of a laboratory test issued by a Foreign Official Laboratory can be presented at the time of import declaration. In this case, an importer can be exempted from laboratory testing.

So far, 53 Foreign Official Laboratories have been designated by the KFDA. You can find the list at <http://www.kfda.go.kr/index.kfda?mid=535>



Foreign Official Laboratory Designation Process

A laboratory that wishes to be designated as a Foreign Official Laboratory is required to submit an application along with supporting documents demonstrating its testing capability to the Commissioner of the KFDA. An on-site audit is required for all applicant laboratories and a laboratory performance assessment is conducted as necessary.



Application of Test methods

KFDA designated-FOLs should carry out food testing in accordance with the following regulations:

- Korea Food Code
- Korea Food Additives Code
- Standards and Specifications for Utensils, Containers and Packaging for Food Products
- Standards and Specifications of Health Functional Food
- Test methods listed in CODEX, AOAC, PAM, etc.

For in-house methods or other test methods not listed above, a validation report should be presented.

On-site Audit

KFDA conducts an on-site audit at least once every three years to evaluate laboratory performance, including testing facilities and analysis techniques. However, the on-site audit may be exempted when one of the following documents is submitted:

- Result of laboratory performance evaluation issued by the government of an applicant laboratory
- Result of international proficiency testing

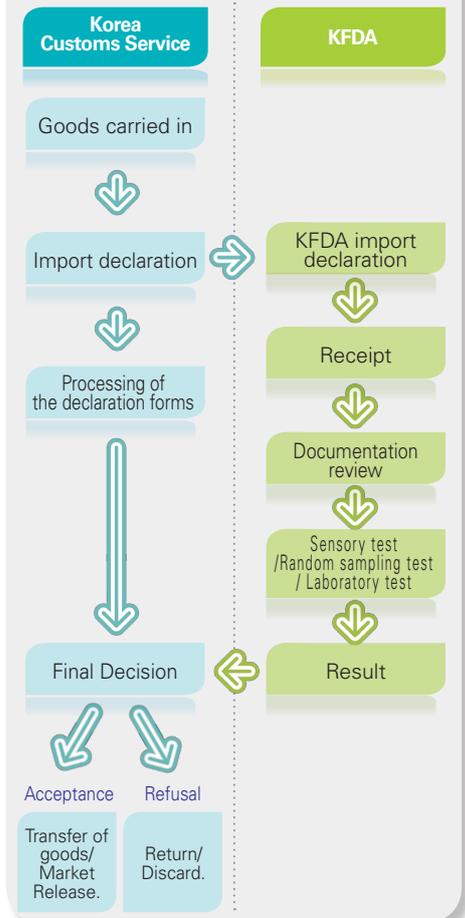
Imported Food Management System of Korea

Customs Clearance of Imported Goods entails undergoing the customs clearance process as prescribed in the Customs Act when goods are imported into Korea. Imported goods that may affect public health, environmental quality, or social security are subject to the Customs Collector Confirmation System as prescribed by the Korea Customs Service. Shipments are detained until all the

requirements are met and a clearance from a customs collector is obtained. Food products are subject to the Customs Collector Confirmation System and must undergo quarantine and inspection procedures. A number of agencies perform tests on imported food products. Responsible agencies are as follows:

| Responsible Agencies | Regional KFDA under the supervision of the KFDA | National Veterinary Research & Quarantine Service under the supervision of the Ministry for Food, Agriculture, Forestry and Fisheries | National Fisheries Products Quality Inspection Service under the supervision of the Ministry for Food, Agriculture, Forestry and Fisheries |
|----------------------|---|--|---|
| Legal basis | Food Sanitation Act Health Functional Food Act | Livestock Products Sanitary Control Act Act on the Prevention of Contagious Animal Diseases | Food Sanitation Act |
| Testing Scope | Agricultural and forest products imported for commercial use (excluding products that are subject to Livestock Products Sanitary Control Act) Food additives, utensils, containers & packages, health functional foods | Imported processed livestock products (meat, raw milk, processed meat products, beef tallow, lard, dairy products, processed egg products) | Seafood products as it originally came from the water with no additives or physical processing (Live fish and shellfish, fresh, cold-storage products, salted products, roe, smoked products, seaweed, dried products, frozen products) |

Korea's Customs Clearance System of Imported food products



Testing of Imported Food products, etc.

As set forth in the Food Sanitation Act and the Health Functional Foods Act, document review and laboratory tests should be conducted on imported food products that have been reported to the responsible

regional KFDA to check their compliance with specifications and standards.

** Imported food products include agricultural products, processed foods, food additives, utensils, containers and packaging, and health functional food*

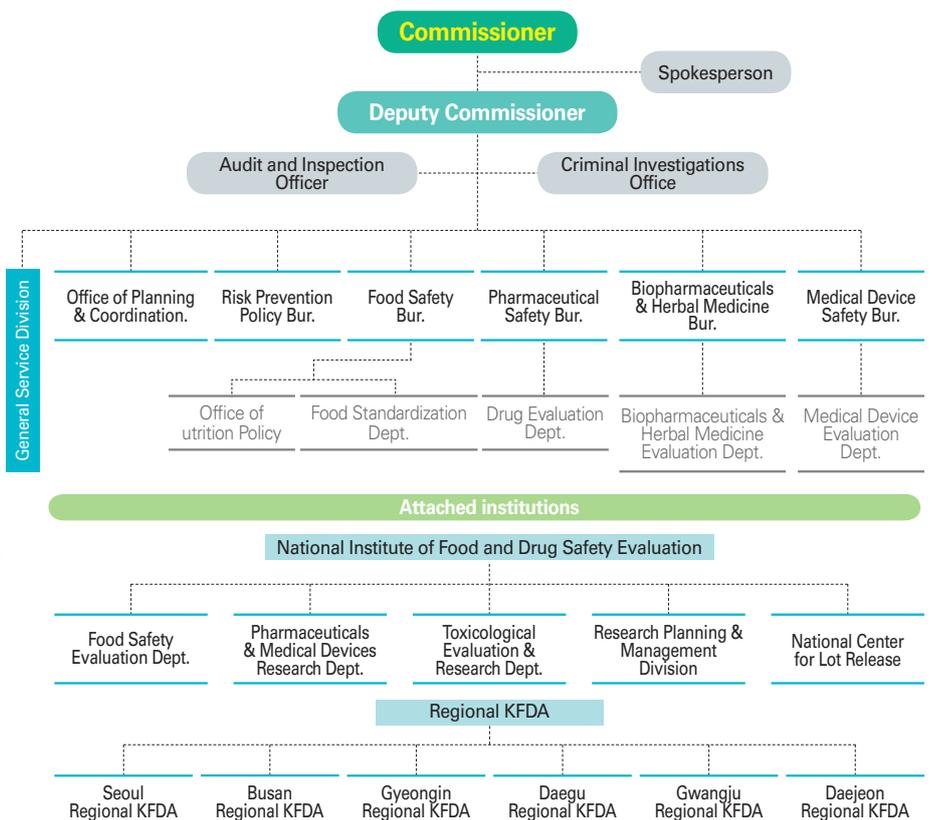
Introduction of the Korea Food & Drug Administration

Vision

Secure the Highest Level of Public Health by Ensuring Food and Drug Safety

Missions

- Prevent and Manage Food and Drug related Risks in Advance
- Rapid Response to Food and Drug Safety Risks
- Establish Communication Network and Support Relevant Parts





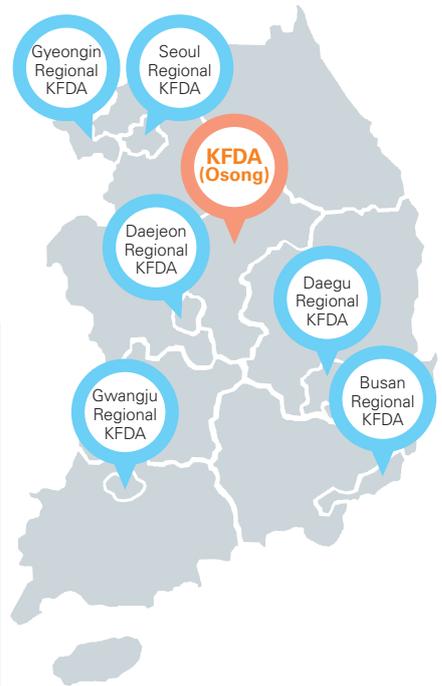
KFDA NEWS

KFDA Completed Relocation to Osong Bio-Health Science Technopolis

As part of the Korea's government relocation plan, the KFDA headquarters and five other government-run, healthcare-related agencies relocated to the Osong Health Technology

Administration Complex in 2010. The Headquarters of the KFDA is located in the center of the complex and occupies a total area of 60,000 square meters. The Osong Health Technology Administration Complex is a part of the Osong Bio-Health Science Technopolis, Korea's largest bio-cluster.

The KFDA has set new initiatives to commemorate its new location and works toward achieving KFDA's vision.



Six government agencies located in Osong Health Technology Administration Complex:



1. Korea Food & Drug Administration (KFDA)
2. Korea National Institute of Health (KNIH)
3. Korea Centers for Disease Control and Prevention (KCDC)
4. Korea Health Industry Development Institute (KHIDI)
5. National Institute of Food & Drug Safety Evaluation (NIFDS)
6. Korea Human Resource Development Institute for Health & Welfare (KOHI)

Korea's Standards and Specifications for Food Products

The Food Code contains the following information:

- Safety standards and specifications for manufacturing, processing, usage, cooking, and storing of food products and their components
- Standards and specifications for manufacturing of utensil, container, and packaging and their raw materials
- Labeling standards for food, food additives, utensils, containers, packaging, genetically modified foods, etc.
- General testing methods

The Korea Food Additives Code contains the following information:

- Standards for food additives manufacturing
- General standards for use of food additives
- Standards and specifications for each product
- General testing methods

The Health Functional Food Code contains the following information:

- Standards and specifications regarding manufacturing, processing, production, import, distribution, storage, etc. of health functional food

The 2nd International symposium

On behalf of the KFDA, we would like to extend our great appreciation for your participation, support, and efforts put in for the 1st International Proficiency Testing Symposium held in October 2011. We are excited to announce that we are going to hold the 2nd International Symposium, which will mainly focus on the quality management of analytical laboratories. Exact date and location of the symposium will be announced at a later time. We hope this symposium will provide an opportunity to strengthen cooperation and effective information-sharing between the KFDA and FOL members.

We look forward to your active participation in the 2nd symposium.

FOL Online Community

We have recently launched a new webpage for the Foreign Official Laboratory (<http://dgis.kfda.go.kr/fol.aspx>). We hope it will serve as a forum for the exchange of information among FOL members. We will also update with the latest KFDA news and other relevant information for your laboratory. We need to assign you a laboratory ID and password that will allow you to use our FOL online community. Please e-mail us back at stopyoony@korea.kr with the contact information (name, e-mail address, and phone number) of a person in charge.



Frequently Asked Questions

- Q1** What are the procedures of FOL authorization?
- A1** FOL application submission→Review of application→On-site Audit (instruments, equipment, laboratory personnel qualification and testing performance) →Decision→Notification
- Q2** Where can I find a list of laboratories designated by the KFDA?
- A2** You can find it on the KFDA website at <http://www.kfda.go.kr/index.kfda?mid=535>

