

THIS REPORT CONTAINS ASSESSMENTS OF COMMODITY AND TRADE ISSUES MADE BY  
USDA STAFF AND NOT NECESSARILY STATEMENTS OF OFFICIAL U.S. GOVERNMENT  
POLICY

Voluntary  Public

**Date:** 3/11/2016

**GAIN Report Number:** KS1609

## **Korea - Republic of**

**Post:** Seoul

### **Korea's Special Act on Imported Food Safety Management**

**Report Categories:**

FAIRS Subject Report

**Approved By:**

Ross G. Kreamer

**Prepared By:**

Seung Ah Chung

**Report Highlights:**

The Ministry of Food & Drug Safety (hereinafter referred to as MFDS) implemented the Special Act on Safety Management of Imported Food (hereinafter referred to as the Special Act) and the implementing regulations on February 4, 2016. The Special Act, providing a framework for imported food polices, consolidated all polices and measures relevant to imported food that were scattered in multiple Acts to achieve an efficient management of imported food. Two noticeable changes that have been introduced to the Special Act are 1) mandatory pre-registration of foreign food facilities and livestock establishments by MFDS and 2) a legal basis for MFDS to suspend import from foreign facilities or establishments that refuse on-site inspection. As for the mandatory pre-registration, MFDS allows a six-month grace period until August 3, 2016.

## **General Information:**

### **I. Overview**

The Ministry of Food & Drug Safety (hereinafter referred to as MFDS) implemented the Special Act on Safety Management of Imported Food (hereinafter referred to as the Special Act) and the implementing regulations on February 4, 2016. The Special Act, providing a framework for imported food polices, was proposed by law makers to improve the current import inspection system. All polices and measures relevant to imported food that had been scattered in four existing Acts were consolidated into this one unified Special Act to achieve an efficient management of imported food. Although most provisions in the Special Act already existed in other existing Acts, there are two noticeable changes that have been introduced to the Special Act to enhance safe management of imported food. These two changes are 1) mandatory pre-registration of foreign food facilities and livestock establishments by MFDS and 2) a legal basis for MFDS to suspend import from foreign facilities or establishments that refuse on-site inspection. As for the mandatory pre-registration, MFDS allows a six-month grace period until August 3, 2016. Therefore, foreign facilities that are not registered by MFDS can continue to export products to Korea until August 3, 2016 without registration. For details on the mandatory pre-registration, please see Section IV for food facilities and V for livestock establishments.

In making the Special Act, FDA's Food Safety Modernization Act (hereinafter referred to as FSMA) and Chinese "Regulation on Management of Registration of Foreign Manufacturers of Imported Food" were taken into account. Pre-registration and enhanced on-site inspection of foreign facilities seems to be influenced by FDA's FSMA.

### **II. Legal status**

<b>Special Act</b>	Established on February 3, 2015, Implemented on February 4, 2016
<b>Enforcement Decree</b>	Established on January 22, 2016; Implemented on February 4, 2016
<b>Enforcement Regulation</b>	Established on February 4, 2016; Implemented on February 4, 2016

MFDS is in the process of translating the aforementioned Act, the Decree and the Enforcement Regulation into English. Post will provide the English translation as soon as it is posted on the Korean website.

Other than the Act, the Enforcement Decree and the Enforcement Regulation, MFDS also revised existing guidelines and established new guidelines to reflect changes made in the Special Act. For example, Korea revised "Regulations on Inspection of Imported Food" on February 4, 2016 and "Guideline of Declaration and Inspection of Imported Livestock Products" on February 3, 2016.

### **III. New requirements**

**1. Mandatory pre-registration of foreign food facilities:** MFDS requires the pre-registration of

foreign facilities that wish to export food products to Korea. Food products include processed food products, agricultural products such as grains, fruits, health functional food, fishery products, food additives and food packages/containers/equipment. Manufacturers or producers of food products and packers of agricultural products shall be registered to MFDS at least 7 working days prior to import declaration. As MFDS granted a 6-month grace period for the mandatory registration, foreign facilities can continue to export products to Korea until August 4, 2016 without registration. However, if a product from a facility that is not registered by MFDS is scheduled to submit the import declaration for import inspection on August 4, 2016 or after, a given facility shall complete the registration process 7 days before importers submit the import application for import inspection. Without a proper registration, MFDS will not initiate the import clearance process.

Registration can be done by on-line or postal mail. Once the foreign manufacture is registered to MFDS, it is valid for 2 years.

Renewal of registration shall be completed at least 7 days before the registration expires.

Details on registration are provided in Section IV.

**2. Mandatory pre-registration of livestock establishment:** MFDS requires foreign livestock establishments to be registered by Korea through the exporting government. Foreign livestock facilities include slaughter and processing plants of meat products, egg processors, dairy plants, meat storage facilities, etc., that handle livestock, dairy and egg products listed in the Korean Livestock Code. As this registration is required to be done through the exporting government, MFDS plans to conduct bilateral discussion on details on registration by country.

As for U.S. livestock facilities, MFDS is likely to accept the system approval by recognizing the FSIS Meat, Poultry and Egg Inspection Directory instead of recognition of individual plants.

As for dairy plants, MFDS will recognize plants that have exported to Korea prior to the implementation of the Special Act, which is February 4, 2016, as registered plants. MFDS generated a list of plants that have exported products to Korea since 1998. MFDS requested the exporting government to verify the list to check whether the list accurately reflects all facilities that have exported to Korea. Any new dairy facilities not included in the MFDS list are required to be registered through the exporting government. Post will have bilateral discussions with MFDS on how to register new plants.

If a livestock plant also produces food products and export such products to Korea, the plant is required to be registered to MFDS following the foreign facility registration process described in Section III, 1 and Section IV. Although a livestock plant with previous export records to Korea is recognized as the registered plant, if the same plant produces food products, it must be registered to MFDS. MFDS runs the registration system for food and livestock products respectively and the plant shall be registered to the both systems.

**3. Import Sanitary Evaluation:** MFDS requires the import sanitary evaluation for livestock products based on a combination of an exporting country and categories defined in the Korean Livestock Code. Without the import sanitary evaluation, livestock products are not eligible to be exported to Korea. As

for a smooth transition, MFDS recognizes categories of livestock products by country that have records of exports of a given category of livestock products to Korea prior to the implementation of the Act, which is February 4, 2016, and does not require import sanitary evaluation.

For livestock products from the United States, most categories of livestock products have been recognized and thus do not require import sanitary evaluation. Categories of U.S. livestock products that will require import sanitary evaluation to be exported to Korea are non-fat milk, goat milk, hydrolyzed lactose milk, egg white liquid, whole egg liquid, salted egg and pidan. Please see the table below for categories that do not require import sanitary evaluation.

**A. Edible processed meat products**

<b>Countries</b>	<b>Categories eligible for export to Korea</b>	<b>Categories requiring sanitary evaluation prior to export</b>
United States	Processed rib products, dried preserved meat products, bacons, ground processed meat products, sausages, edible lard, edible tallow, processed meat extract products, seasoned meat, packaged meat, hams	None

**B. Dairy products**

<b>Countries</b>	<b>Categories eligible for export to Korea</b>	<b>Categories requiring sanitary evaluation prior to export</b>
United States	Processed milk, processed cheese, concentrated milks, fermented milks, butters, milk powders, ice creams, ice cream mixes, ice cream powders, milks, hydrolyzed milk protein products, lactose, whey, milk creams, natural cheese, low fat milks, milk formula, butter milk	Non-fat milk, hydrolyzed lactose milk, and goat milk

**C. Egg products**

<b>Countries</b>	<b>Categories eligible for export to Korea</b>	<b>Categories requiring sanitary evaluation prior to export</b>
United States	Egg white powder, egg yolk powder, egg yolk liquid, heat formed egg products, whole egg powder	Liquid egg white, whole egg liquid, salted egg and pidan

Post plans to consult with MFDS on details about import sanitary evaluation for the categories of livestock products that are required to have import sanitary evaluations.

**IV. How to register foreign facilities**

It can be done by on-line or postal mail. Either foreign facilities or Korean importers can submit the registration application to MFDS. For Korean importers, they should have pre-permission from the

foreign facility regarding the registration before they submit the registration application for foreign facilities. A sample of the registration application is provided in Appendix Table.

For on-line registration, please click the following link:

<https://impfood.mfds.go.kr>

1. First, please click a language bar on the top right corner of the screen to change a language into English.
2. On the main screen, there is a box for “Application for Registration of Foreign Food Facility.” Please click on it.
3. You will see the registration application. Items with red asterisk are required information. As for items without red asterisk, if they are not applicable, you don’t need to provide it.
4. Fill out the application and submit it. MFDS will send you a receipt confirmation email.
5. MFDS will review the submitted information and complete the registration within three working days. If MFDS finds any problem in processing your registration, they will contact you directly via email.
6. Once the registration is complete, MFDS will inform it to you via email.

For postal mail, please send the registration application to the following office:

**Food Import Policy Division**

Ministry of Food & Drug Safety

187 Osong Saengmyung 2-ro, Osong-eup, Cheongwon-gun, Chungcheongbuk-do  
South Korea 363-700

**V. How to register foreign livestock establishments including dairy products**

MFDS will continue to recognize establishments included in the FSIS Meat, Poultry, and Egg Inspection Directory (MPI Directory) as the registered establishments. Establishments other than those listed in the MPI Directory and dairy plants that have a record of export to Korea since 1998 will require the mandatory pre-registration. This should be done through the exporting government. MFDS will register foreign livestock establishments after documentation review or on-site inspection. For details on how to register new livestock plants, Post will consult with MFDS ASAP so that any new plants will complete the registration before August 4, 2016.

A sample of the registration application is provided in the Appendix Table of this GAIN report.

**VI. On-site audit of foreign facilities**

Under the previous regulations, MFDS might carry out foreign facility audits, if necessary. For example, in the past, MFDS conducted foreign facility audits if there was market intelligence or repeated violations from certain foreign facilities. However, the previous regulations failed to provide a

legal basis for MFDS to take an action against foreign facilities that refused audits. By adding a legal basis provision in the Special Act, MFDS may take a necessary action against foreign facilities that refuse audits.

When MFDS decides to conduct a foreign facility on-site audit, they will notify the exporting country government or foreign facilities of the audit plan and have prior consultation with them first. If a foreign facility refuses the on-site audit, MFDS may suspend import from that foreign facility. When the on-site audit of foreign facilities reveals issues that could result in import suspension, MFDS will ask for corrective measures before placing an import suspension. At the moment, it is not clear whether MFDS will ask for a report of the corrective measure from the foreign facility or the competent authority of the exporting government. If the corrective measure is not satisfied, MFDS may then place an import suspension on products from the foreign facility in question.

## Appendix

### 1. Application for Foreign Facility Registration - Sample

■ Form 1 (Enforcement Regulation)		(Front page)
<b>Foreign Facility</b>	<input type="checkbox"/> Application for Registration of Foreign Food Facility	
	<input type="checkbox"/> Application for Updating Registration of Foreign Food Facility	
	<input type="checkbox"/> Application for Renewing Registration of Foreign Food Facility	
※Check the applicable brackets (Business of online purchasing of imported food, etc. by proxy is excluded from registration)		
접수번호 Receipt number	접수일자 Date of receipt 년 year 월 month 일 day	처리기간 Processing time 3일 3 days
등록코드(변경등록 또는 등록갱신인 경우) Registration code (For update of registered information or renewal of registration)		
<b>Applicant Information</b>	<input type="checkbox"/> Person who establishes and operates a foreign food facility	
	<input type="checkbox"/> Importer	
	<ul style="list-style-type: none"> <li>If "Importer", provide the below information</li> </ul>	
	<ul style="list-style-type: none"> <li>■ Company name ( )</li> <li>■ Address ( )</li> <li>■ Phone number ( )</li> </ul>	<ul style="list-style-type: none"> <li>■ Business registration No. ( )</li> <li>■ E-mail address ( )</li> </ul>

Type of Registration	<input type="checkbox"/> Initial registration <input type="checkbox"/> Update of registered information <input type="checkbox"/> Renewal of registration	
Facility Information	Name of facility	Representative
	Address	Country
	Phone number including area/country code	
	E-mail	
	Fax number including area/country code, <i>Optional</i>	
Food Information	Type of food	(Types of food set by standards and specifications pursuant to Articles 7 and 9 of the Food Sanitation Act and Articles 14 and 15 of the Functional Health Foods Act)
		<input type="checkbox"/> Agricultural products <input type="checkbox"/> Processed foods <input type="checkbox"/> Apparatus, or containers and packages <input type="checkbox"/> Fishery products <input type="checkbox"/> Food additives <input type="checkbox"/> Functional health foods

(Back page)		
Business Information	Type of business	<input type="checkbox"/> Manufacturing/processing food or food additives <input type="checkbox"/> Manufacturing/processing apparatus, or containers and packages <input type="checkbox"/> Packaging agricultural products <input type="checkbox"/> Manufacturing/processing functional health foods <input type="checkbox"/> Manufacturing/processing fishery products (including vessels and aquaculture)
	Whether a food safety management system applies to the type of food above, <i>If applicable</i>	<input type="checkbox"/> No <input type="checkbox"/> Yes ※ If "Yes", check as applicable or specify the system <input type="checkbox"/> HACCP <input type="checkbox"/> ISO 22000 <input type="checkbox"/> Other ( ) ※ Whether to be certified by a certification body <input type="checkbox"/> No <input type="checkbox"/> Yes ※ If "Yes", provide the following information <input type="checkbox"/> Title of <input type="checkbox"/> Certification body ( )

		certification ( ) ■ Certification date ( )	■ Expiration date ( )
<input type="checkbox"/> The person who establishes and operates the foreign food facility concerned agrees that if the Minister of Food and Drug Safety deems it necessary, he/she may visit and inspect the foreign food facility.			
<input type="checkbox"/> The applicant certifies that the above information is true and accurate. ※ If "Importer", check the below additionally.			
<input type="checkbox"/> The person who establishes and operates the foreign food facility concerned has checked and agreed on the above registration (update of registered information, or renewal of registration)			
In accordance with Article 5 (1), 5 (2), or 5 (6) of the Special Act on Imported Food Safety Control and Article 2 (1), 2 (3) and 2 (4) of the Enforcement Rules of the same Act, I hereby apply for registration (update of registered information or renewal of registration) of registration.			
year    month    day			
Applicant		(signature or seal)	
<b>To the Minister of Food and Drug Safety, Republic of Korea</b>			

### Application Procedures

Application → Receipts of documents → Review → Approval → Notification of registration

### 2. Application for Livestock Establishment - **SAMPLE**

(Front page)

■ Form 16 (Enforcement Regulation )		
<b>Foreign Establishment</b>	<input type="checkbox"/> Application for Registration of Foreign Establishment	
	<input type="checkbox"/> Application for Updating Registration of Foreign Establishment	
※ Check the applicable brackets (Business of online purchasing of imported food, etc. by proxy is excluded from registration)		
접수번호 Receipt number	접수일자 Date of receipt 년 year 월 month 일 day	
등록번호(변경등록인 경우) Registration number (For update of registered information or cancellation of registration)		
General Information	Name of Establishment	Representative
	EST No. or Registration Number	Date of approval



		Address	
Type of Registration	<input type="checkbox"/> Initial registration <input type="checkbox"/> Update of registered information		
Status of Establishment	Person in charge of sanitation	Name	
		Phone Number including area code	
		E-mail	
	Type of business	<input type="checkbox"/> Slaughterhouse <input type="checkbox"/> Meat cutting and packaging plant <input type="checkbox"/> Shell egg packaging plant <input type="checkbox"/> Meat processing plant <input type="checkbox"/> Milk processing plant <input type="checkbox"/> Egg processing plant <input type="checkbox"/> Meat storage house	
	Whether a food safety management system applies to the item information below, <i>If applicable</i>	<input type="checkbox"/> No <input type="checkbox"/> Yes ※ If "Yes", check as applicable or specify the system <input type="checkbox"/> HACCP <input type="checkbox"/> ISO 22000 <input type="checkbox"/> Other ( ) ※ Whether to be certified by a certification body <input type="checkbox"/> No <input type="checkbox"/> Yes ※ If "Yes", provide the following information	
	<input type="checkbox"/> Title of certification ( ) <input type="checkbox"/> Certification date ( )	<input type="checkbox"/> Certification body ( ) <input type="checkbox"/> Expiration date ( )	
Species of livestock or main ingredients			

(Back page)		
Item Information	Meat and meat by-products	<input type="checkbox"/> Beef, veal, and beef or veal by-products <input type="checkbox"/> Pork and pork by-products <input type="checkbox"/> Horse meat and horse by-products <input type="checkbox"/> Mutton, lamb mutton, and mutton by-products <input type="checkbox"/> Goat meat and goat by-products <input type="checkbox"/> Venison and venison by-products <input type="checkbox"/> Donkey meat and donkey by-products <input type="checkbox"/> Rabbit meat and rabbit by-products <input type="checkbox"/> Chicken and chicken by-products

		<input type="checkbox"/> Duck meat and duck by-products <input type="checkbox"/> Turkey meat and turkey by-products <input type="checkbox"/> Goose meat and goose by-products <input type="checkbox"/> Quail meat and quail by-products <input type="checkbox"/> Pheasant meat and pheasant by-products		
	Shell eggs	<input type="checkbox"/> Chicken eggs	<input type="checkbox"/> Duck eggs	<input type="checkbox"/> Quail eggs
	Processed livestock products	<input type="checkbox"/> Processed meat products <input type="checkbox"/> Processed milk products <input type="checkbox"/> Processed egg products		
<input type="checkbox"/> The applicant agrees that if the Minister of Food and Drug Safety deems it necessary, he/she may visit and inspect the applicant's establishment.				
<input type="checkbox"/> The applicant certifies that the above Information is true and accurate.				
In accordance with Article 12 of the Special Act on Imported Food Safety Control and Articles 12 (1) and 13 (1) of the same Act, I hereby apply for registration (update of registered information) of registration.				
year      month      day				
Applicant			(signature or seal)	
<b>To the Minister of Food and Drug Safety, Republic of Korea</b>				

### Application Procedures

Application → Receipts of documents through exporting government → Review of documents or on-site inspection → Approval → Notification of registration