Imported food safety management in South Korea

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The importation of food products has gradually, but consistently, grown over time. Economic boundaries among countries around the world have become increasingly blurred and permeable, with the establishment of the World Trade Organization (WTO) in 1995 and the continuous proliferation of free trade agreements (FTA) in recent years. However, irrespective of the overall increase in consumption of imported food products in South Korea (Korea), the safety of imported food products remains a major concern for Korean citizens, according to the food safety survey conducted by the National Statistical Office in 2012, in which 54.7% of Korean citizens expressed their uneasiness about the safety of imported food products.

In these circumstances, the Special Act on Imported Food Safety Management (Act) was enacted on 3 February 2015, and has been in full force and effect since 4 February 2016. The enforcement of the Act is highly anticipated to lead to more efficient and consistent safety management of food products imported into Korea. It will provide a single, unified legislation that integrates various safety management regulations for imported food products. These had previously been scattered, based on the types of imported food products, among the Food Sanitation Act (FSA), the Functional Health Food Act (FHFA) and the Livestock Product Sanitary Control Act (LPSCA).

Key areas of the Act include:

- Strengthening local safety management in exporting countries.
- Managing business operators and inspecting imported food products by classification.
- More extensive tracing and tracking management of distribution history and systematic distribution management.
- Imposing greater responsibility on importers and simplifying business registration procedure.

This article summarises and comments on matters that foreign exporters and business operators importing various food products into Korea must be advised of under the Act, by:

- Comparing the import processes concerning foods, functional health foods (Health Foods) and livestock products before and after enforcement of the Act.
- Elaborating on the imported food safety management regulations that have been reinforced under the Act.

Changes in safety management of imported food products

Laws and regulations on imported food products and scope of the Act

Before enforcement of the Act, domestic and foreign foods, Health Foods and livestock products were each separately governed by the FSA, FHFA and LPSCA, respectively. Each business operator had to comply with a different standard and procedure prescribed under the relevant statute on a case-by-case basis, depending on the type of food products handled by the operator.

However, the Act sets out safety management regulations that apply across all foods, Health Foods and livestock products that are imported into Korea (collectively, the Imported Food Products) (as defined in Article 2 of the Act). Therefore, following enforcement of the Act, even though domestic foods, Health Foods and livestock products are still subject to separate applications of the FSA, FHFA and LPSCA, all foreign Imported Food Products are uniformly governed by the Act.

For reference, the FSA and FHFA have each established the Hazard Analysis and Critical Control Point (HACCP) for food and livestock products respectively. However, since the HACCP only applies to domestic foods and livestock products, the HACCP remains effective regardless of the Act being enacted and enforced.

Safety management and regulatory changes under the Act

Before the Act, the Minister of Food and Drug Safety (Minister of FDS) had regulated the safety of Imported Food Products through disparate applications of import declaration and customs inspection processes. These were prescribed under each relevant statute on Imported Food Products, such as the FSA, FHFA and LPSCA.

The enactment and enforcement of the Act has opened the door to more unified and consistent safety management of Imported Food Products, and enhanced the overall safety and quality of Imported Food Products by revamping the regulatory system for safety management.

Under the Act, a more rigorous system of imported food safety management has been created by:

- Combining the imported food safety management regulations that had been scattered among the FSA, the FHFA and the LPSCA.
- Dividing the importation process into three distinct phases (pre-importation, customs and distribution) for heightened enforcement.
- Reinforcing existing regulations and, at the same time, implementing new regulations for safety management of Imported Food Products.
**Safety management regulations of Imported Food Products before and after the Act**

A summary of changes to the safety management of Imported Food Products from the enforcement of the Act is as follows:

**HEIGHTENED STANDARDS FOR SAFETY MANAGEMENT OF IMPORTED FOOD PRODUCTS UNDER THE ACT**

**Strengthening local safety management in exporting countries**

**New system for overseas food facility registration (Article 5).** The Act implements a new system for overseas food facility registration, to:

- Collect and manage information on domestic importers and foreign exporters.
- Perform efficient sanitary and safety control of Imported Food Products, starting from the pre-importation phase using such accumulated information.

Under this new registration system, all relevant information about foreign exporters is collected, to distinguish those with and without a history of violation of any laws. This permits the application of different safety management standards and sanitary control measures to foreign exporters, before the customs phase of importation.

**Under the Act, a person who intends to import an Imported Food Product into Korea or a person who establishes and operates an overseas food facility must register the overseas food facility with the Minister of FDS, indicating the name, location, list of items produced by the facility, and any other matters prescribed by law, at least seven days before the relevant import declaration is filed. The registration of the overseas food facility is valid for two years from the date of registration.**

An importer has a legal obligation to register its overseas food facility under the Act. If the importer fails to register or fails to comply with a request for additional information from the Minister of FDS, the importer’s import declaration may be refused.

Additionally, registration of the importer can be revoked if the Minister of FDS determines that he fraudulently or improperly registered the overseas food facility under the Act.

**Heightened enforcement of on-site inspection of overseas food facilities (Article 6).** Before enactment of the Act, on-site inspections of overseas food facilities were only enforceable against foods. They could not be compelled when the overseas food facilities refused to submit to the on-site inspection request.

### PRE-IMPORTATION PHASE

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“Good overseas food facility” registration system: applicable to foods and Health Foods.

Includes new provisions for on-site inspection, period of validity and restriction on re-registration (Article 8).

“Good overseas food facility” registration system: applicable to foods and Health Foods.

Includes new provisions for on-site inspection, period of validity and restriction on re-registration (Article 8).

Livestock products

No particular regulation under the LPSCA. However, under the Act on the Prevention of Contagious Animal Diseases, import sanitation conditions of the exporting country relating to any infectious diseases or hazardous contaminants are determined and overseas establishments are registered and managed (Article 34(2)).

Import sanitation assessment:

- Assessment of the status of the sanitary control of the exporting country (Article 11).
- System for Registration of Overseas Establishment.
- Restriction of importation: livestock products can only be imported from a registered establishment (Article 12).
### CUSTOMS PHASE

In principle, all business operators and food products are subject to documentary review, sensory evaluation and close inspection and random sample testing, at the same level of scrutiny (Article 19, FSA, Article 8, FHFA and Article 15, LPSCA).

In principle, all business operators and Imported Food Products are organised and managed by classification (Article 19):

**Good.** A business operator registered as a “good importer”.

**Ordinary.** A business operator not classified as a “good importer” or “supervised importer”.

**Supervised.** A business operator who either:

- Received an administrative disposition under the Enforcement Regulation of the Act in the previous one-year period.
- Violated Article 34(1) of the Act in the previous one-year period.

**Inspection of Imported Food Products by Classification (Article 21):**

**Level 1.** An Imported Food Product, either:

- After initial importation or close inspection, has become subject to a new or higher standard and/or specification requirement.
- Returned from abroad.
- Deemed necessary to undergo a close inspection as a result of an on-site inspection.

**Level 2.**

- An Imported Food Product deemed necessary to undergo a close inspection, due to a problem or risk raised as a result of domestic and foreign food safety information on the Imported Food Product.
- The same Imported Food Product imported again by the same business operator after being determined to be non-compliant, based on the results of close inspection, random sampling tests or collection inspection.

**Level 3.** An Imported Food Product either:

- Imported by one of the “supervised importers”.
- Produced or exported from an overseas food facility from which a hazardous contaminant had been detected, that is being imported within two years after the Imported Food Products have been determined non-compliant.

**Order for Inspection.** Applicable only to foods (Article 19-4, FSA).

**Order for Inspection.** Applicable to all foods, Health Foods and livestock products (Article 22).

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### DISTRIBUTION PHASE

**Tracing and tracking management of distribution history:**

- Self-regulated system applicable to foods and Health Foods (Article 49, FSA and Article 22-2, FHFA).
- Only applicable to imported beef, among livestock products, under the Cattle and Beef Traceability Act (CBTA).

**Tracing and tracking management of distribution history:**

- Applicable to all foods, Health Foods and livestock products for each stage, from importation to sale.
- However, tracing and tracking management of imported beef is still governed by the CBTA.

**Types of business:**

- Foods: import and sales business, filing/reporting agency services, online purchasing agency services.
- Health Foods: import business, online purchasing agency services.
- Livestock products: import and sales business.

**Establishment and execution of distribution management plan (Article 24).**

**Types of business:**

- Import and sales business.
- Filing/reporting agency services.
- Online purchasing agency services.
- Storage business.

**Order for education:** applicable only to foods (Article 19-3, FSA).

**Order for education:** applicable to all foods, Health Foods and livestock products (Article 26).
The Act has heightened enforcement of on-site inspections. Not only does it enlarge the applicable scope of on-site inspections to include Health Foods, but it also permits the Minister of FDS to suspend the importation of relevant Imported Food Products, if an overseas food facility refuses an on-site inspection under Article 6 of the Act.

With respect to Imported Food Products that have been suspended from being imported into Korea, the Minister of FDS can revoke the suspension of importation when either:

• The government of an exporting country, overseas food facility, or business operator who imported the relevant Imported Food Product discovers the cause of the problem that led to suspension of importation, and makes recommendations for improvement based on the discovery.

• The Imported Food Product is later deemed to be non-hazardous.

Further, when the Minister of FDS deems it necessary to efficiently conduct an on-site inspection, he can designate and entrust the inspection to a professional, specialised sanitation audit institution (Article 9 and Article 10).

The on-site inspection system is considered to be one of the main pillars, along with preventive management and management by classification, that form the foundation of the Act.

Import sanitation assessment of livestock products (Article 11). The health risks for livestock products, such as possible communicable diseases, are relatively higher than for other processed foods or agricultural or fishery products, and livestock products must be imported after passing both quarantine and inspection. In principle, importation of livestock products is generally determined not at individual business entity level, but through execution of a treaty between countries.

The Act stipulates that only livestock products with permission obtained after an import sanitation assessment conducted by the Ministry of Food and Drug Safety (MFDS) can be imported. It also provides the MFDS with authority to conduct an import sanitation assessment before granting its permission to import certain livestock products.

If the government of an exporting country requests the Korean government to permit importation of livestock products, or where re-evaluation of the sanitary control of the exporting country is deemed necessary due to changes in international standards of the Codex Alimentarius Commission or for any other reasons, the Minister of FDS can conduct an import sanitation assessment on the sanitary control of the exporting country for each type of livestock product, as defined in Article 2(2) of the LPSCA.

Under the existing law, the following eight steps had to be taken to import livestock products into Korea:

• Review of the possibility of permitting importation of the livestock product concerned.

• Delivery of a questionnaire on import risk analysis to the government of an exporting country.

• Review of the response to the questionnaire.

• On-site inspection of the livestock sanitary condition.

• Determination on permitting importation of the livestock product.

• Consultation with the exporting country on the import sanitation requirement for the livestock product.

• Enactment and notification of the import sanitation requirement.

• Approval of export establishment and consultation on finalising the sanitary certificate form.

It is anticipated that the import sanitation assessment under the Act will implement a similar structure.

However, for those livestock products subject to quarantine under Article 31 of the Act on the Prevention of Contagious Animal Diseases, the Minister of FDS can only conduct an import sanitation assessment after the Minister of Agriculture, Food and Rural Affairs has determined that the importation of the livestock products is permissible because there is no risk of animal disease.

Based on the result of the import sanitation assessment, the Minister of FDS can determine and publish the import sanitation requirements for each exporting country or each livestock product. Any person who intends to import a livestock product must import the product from those countries or regions for which the Minister of FDS has determined and published the import sanitation requirements.

Additionally, the Minister of FDS can conduct an on-site inspection of an overseas establishment to verify whether the establishment has fulfilled the prescribed import sanitation requirements. Any person who files an import declaration of livestock products must attach a sanitary certificate issued by the government of the exporting country, in the form determined after its consultation with the Minister of FDS.

"Good importer" registration (Article 7). Unlike the existing safety management system, which only permitted the "good importer" registration for an importer of foods, the Act has broadened the applicable scope of the importers eligible to register as good importers, to include any importer of Health Foods.

For importers with the "good importer" registration, the Minister of FDS can fully or partly omit the inspection of the Imported Food Products imported. At the same time, to ensure enforcement of stringent standards for "good importer" registration, the Act has newly established, among others, provisions that:

• Permit an on-site inspection of overseas food facilities in connection with the importer.

• Limit the period of validity of the registration to three years.

• Restrict re-registration as a good importer, if the importer had its "good importer" registration revoked.

However, overseas establishments manufacturing livestock products are excluded from Article 7 of the Act because they are subject to Article 11 of the Act.

"Good overseas food facility" registration (Article 8). Under the "Advanced Verification Registration System" previously used under the FSA and FHFA for foods and Health Foods respectively, inspection of foods and Health Foods that meet certain criteria for advanced verification registration was fully or partly omitted.

The Act replaced the Advanced Verification Registration System with the Good Overseas Food Facility Registration System, where any person who establishes and operates an overseas food facility that meets criteria for registration set by the Minister of FDS can register...
the facility as a “good foreign food facility”. The registration is valid for three years from the date of registration.

The Minister of FDS can conduct an on-site inspection of the overseas food production facility to verify whether the facility meets the registration requirements. The “good overseas food facility” registration can be revoked when the Minister of FDS determines that the registration was fraudulent or improper. An overseas food facility that has its registration revoked is prohibited from filing for another “good overseas food facility” registration for three years from the date of revocation.

On registration as a “good overseas food production facility”, the initial close inspection and random sampling test of the Imported Food Products manufactured or produced by the facility are omitted during the customs phase. This can expedite the customs inspection process and substantially reduce the cost associated with the customs inspection.

Managing business operators and inspecting Imported Food Products by classification during the customs phase

Management of business operators by classification (Article 19). Under the existing safety management system, the inspection of a business operator was conducted solely based on the business operator's history of non-compliance, without proper examination of the actual sanitary conditions of relevant overseas food facilities in connection with the business operator. This was problematic because a close examination was undertaken only after a hazardous contaminant had been detected in the Imported Food Product.

To remedy this, the Act has intensified preventive management, and promotes more equitable treatment of business operators by dividing them into three classes of business operators and applying different standards to each class.

Under the Act, a business operator is classified as a “good importer,” “ordinary importer” or “supervised importer”, according to the results of inspection of the Imported Food Products, history of violations, and domestic and foreign food safety information on the Imported Food Products handled by the business operator (see Article 26(1), Enforcement Regulation of the Act).

The extent of the differential treatment of business operators based on classification includes:

- Conducting import inspection.
- Having access to a business establishment to conduct an inspection of the Imported Food Products and/or the facility and collection of the Imported Food Products necessary for the inspection ("Access, Inspection and Collection”; Article 26(2), Enforcement Regulation of the Act).

Inspection of Imported Food Products by classification (Article 21).

Under the existing safety management system, the relevant statutes for each type of Imported Food Product simply stipulated that necessary inspections had to be conducted before completion of the customs formalities. In this case, an inspection of an Imported Food Product was conducted by using, in principle, the same level of scrutiny applied to all Imported Food Products, without regard to the production conditions and features of the Imported Food Product.

To address this issue, the Act has implemented a new system of inspection that applies different standards of scrutiny for each classification of Imported Food Products. This allows the concentration of available resources and capabilities on more problematic products.

While the Minister of FDS is still required to conduct necessary inspections of an Imported Food Product before completion of the customs formalities, he can conduct the inspection differentially, by classifying the Imported Food Product into Level 1, Level 2 or Level 3. This is based on the Imported Food Product’s history of detection of any hazardous contaminant during any other inspection, and domestic and foreign food safety information on the Imported Food Product (see Exhibit 10, Article 32, Enforcement Regulation of the Act) under the method of inspection stipulated in Exhibit 9 of Article 30 of the Enforcement Regulation of the Act.

More extensive tracing and tracking system of distribution history

Tracing and tracking system of distribution history of Imported Food Products (Article 23). The tracing and tracking system of distribution history of Imported Food Products collects, records and manages all relevant information about an Imported Food Product, from importation to sale of the Imported Food Product. This permits the Minister of FDS, on occurrence of a problem with safety, to identify the cause of the problem and take any necessary measures to resolve the problem, by tracing and tracking the distribution history of the Imported Food Product.

Under the Act, if it is deemed necessary to trace and track Imported Food Products (excluding imported beef under the Livestock and Livestock Products Traceability Act) to identify the cause of the problem and take any necessary measures to resolve it, the Minister of FDS can designate certain Imported Food Products for the tracing and tracking, and require relevant business operators to register the designated Imported Food Products. However, business operators who import infant formula and business operators who import functional health foods above a certain amount must register the products for tracing and tracking, regardless of the designation by the Minister of FDS.

Distribution management plans (Article 24). While there was no particular provision under the existing law that related to the distribution management plan of Imported Food Products, the Act prescribes the Minister of FDS to establish and execute an annual distribution management plan, to verify the safety and quality of Imported Food Products in the market.

Imposing greater responsibility on importers and simplifying the business registration procedure

Expanded scope of orders for inspection and orders for education (Article 22, Article 26). The Act has extended the food products subject to orders for inspection and orders for education to include not only foods, but also Health Foods and livestock products.

Under the Act, the Minister of FDS can order a business operator to undergo an inspection of an Imported Food Product in the following cases:

- In which hazardous contaminants have been detected domestically and/or abroad.
- Which has been subject to repeated non-compliance, resulting from import inspection or Access, Inspection and Collection.
- In which concerns over the risk of detection of hazardous contaminants have been raised domestically and abroad.

Additionally, the Minister of FDS can order a business operator to undergo education on the safety and quality control of Imported Food Products.
Products if it has:

• Imported non-compliant Imported Food Products.
• Had its business suspended under Article 29 of the Act, as a result of Access, Inspection and Collection.
• Imported other Imported Food Products designated by the Minister of FDS as Imported Food Products possessing the risk of causing bodily harm.

Comprehensive business registration (Article 15). A person who intends to conduct business under the Act must register the business with the Minister of FDS. Any person who intends to make material changes to the registration must report the changes to the Minister of FDS. With the enforcement of the Act, an importer who registers to import a certain type of food products, such as processed foods, agricultural and fishery products, Health Food and livestock products, becomes eligible to import all types of food products.

Despite the registration provision, a business operator prescribed by presidential decree who imports Imported Food Products as raw materials for the manufacture of its products, with the permission obtained or registration under the FSA, FHFA or LPSCA, is deemed to have registered under the Act.

Types of business and facility standards (Article 14). Under the existing law, with respect to conducting businesses involving Imported Food Products, the FSA, FHFA and LPSCA had individually regulated a limited number of specific types of business. For instance, only import and sales business, online purchasing agency services and filing/reporting agency services under the FSA, only import business or online purchasing agency services under the FHFA and only import and sales business under the LPSCA.

However, the Act has increased the scope of business falling under its purview and comprehensively defined four types of businesses regulated under the Act, including the following without regard to the types of food products:

• Import and sales business.
• Online purchasing agency services.
• Filing/reporting agency services.
• Storage business.

PRECAUTIONS FOR BUSINESS OPERATORS FOLLOWING ENFORCEMENT OF THE ACT

The enactment and enforcement of the Act has enabled:

• More systematic safety management of Imported Food Products, by segmenting each phase of importation into pre-importation, customs and distribution.
• More efficient and consistent safety management of Imported Food Products, by combining the imported food safety regulations into a single, unified imported food safety regulation.

From the perspective of business operators, the Act can be regarded as imposing not only heightened compliance standard with mandatory obligations to register overseas food facilities and to comply with a request for on-site inspection, but also more severe legal consequences for any non-performance or non-compliance. Importing Imported Food Products will be prohibited for any non-performing and non-compliant business operators.

However, under the Act, a business operator can receive substantial benefits in the customs inspection process, by using the new systems for registration of good importers and good overseas food facilities. More equitable treatment among business operators can be accomplished by facilitating differential management of business operators and Imported Food Products, based on classification of each business operator and each Imported Food Product, respectively. Consequently, in practice, the Act can be regarded as having a highly reasonable system for safety management of Imported Food Products.

Therefore, business operators engaged in importing any Imported Food Products into Korea must:

• Carefully review and analyse the Act and its subordinate laws and regulations, to actively exploit relevant provisions favourable to their business.
• Be cautious not to overlook any matters for compliance that have been newly established, or had their scope expanded under the Act with the consolidation of imported food safety regulation that had been dispersed in separate statutes.
• Pay close attention, to not simply conduct their businesses according to past practice which may now be outdated. Failure to comply with the Act can result in potential revocation of their import licences, and other administrative dispositions and criminal sanctions.
**Professional qualifications.** Korea, 2005

**Areas of practice.** Healthcare; corporate law; corporate governance disputes; banking and financial disputes; capital market disputes; bankruptcy; corporate restructuring; M&A; financial institution M&A;

**Non-professional qualifications.** University of Washington School of Law, LL.M., 2013; University of Seoul Graduate School of Law, LL.M., 2008; Seoul National University, B.A. in German Language and Literature, 2000

**Recent transactions**

- Advised on approval of a combination product by the Ministry of Food and Drug Safety.
- Advised on approval of quasi-drugs by the Ministry of Food and Drug Safety.
- Advised on advertisement of pharmaceuticals regarding the Pharmaceutical Affairs Act.
- Advised on process and approval of importing and exporting Health Functional Food.
- Advised on advancing healthcare institutions.
- Handled company-wide Compliance Risk Management building project by LG Electronics.
- Advised on share sale of Kyobo Life Insurance by Daewoo International.
- Advised on acquisition of KPX Fine Chemical by Hanwha Chemical.

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**Publications**


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**Professional qualifications.** Korea, 2007

**Areas of practice.** Intellectual property; entertainment; sports; healthcare

**Non-professional qualifications.** University of California, Davis, School of Law, LL.M., 2014; Complete the course of Seoul National University, Graduate School of Law (Intellectual Property), 2013; Korea University, College of Law, LL.B., 2005

**Recent transactions**

- Represented Kolon Environmental Service in a preliminary injunction to prohibit a former employee’s transfer to Cheil Industries Inc.
- Represented LG Chemical in a preliminary injunction to prohibit a former employee’s transfer to SK Energy.
- Represented ATG Ceylon in a trade secret infringement case.
- Advised Sun Power regarding a trade secret management matter.
- Represented Ewha Women’s University regarding an unfair competition prohibition.
- Represented Ferragamo in several litigations regarding a trademark infringement.
- Advised a German corporate company, Ronnefeldt, regarding a domain name case.
- Represented KEFICO in a litigation regarding a trade mark in China.
- Handled litigation in a dispute for a managerial right of Rubo/Jeda.
- Handled litigation in a dispute for a managerial right of Lakeside golf course.

**Languages.** Korean, English

**Publications**

- Regulation of personal information in new fields, Asian-Mena Counsel : IP TMT Special report (co-author, 2016.1).
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Recent transactions
• Advised on sale of Kumchon by Dongwon F&B.
• Advised on the merger of Robert Bosch Korea and an affiliate.
• Advised on division of Naeil newspaper.
• Advised on an acquisition attempt on an internet hosting company by CJ O shopping.
• Advised on an acquisition attempt of Genesis BBQ, Ssangyong Cement, Dayou A-tech and Korea Asset Pricing by Eugene PE.
• Advised on an acquisition attempt of Daeryun Power and Byeolnae Energy by Veolia Korea.
• Advised on an Aircraft Finance Agreement of Hyundai Life.
• Advised on compliance with Functional Health Foods Act to Herbalife Korea.
• Advised on compliance of Safety, Management, Etc. of Human Tissue Act to Sanofi.

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