

EUROPEAN UNION  
DELEGATION OF THE EUROPEAN UNION TO THE REPUBLIC OF KOREA

Head of Trade and Economy Section

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## NOTE TO THE FILE

### **Subject: Summary of the Recent Korean Special Act on Imported Food Safety Control**

In 2013, the Korean National Assembly began consolidating of all imported food regulations, which were previously scattered among various acts, into one overarching law, which is the new Special Act on Imported Food Safety Control. The Act has entered into force on 4 February 2016 and certain provisions related to food manufacturing facilities and livestock products establishments registrations received 6 months grace period. The main purpose of this Act is to establish a legal frame that enables the Ministry of Food and Drug Safety (MFDS) to control imported food prior to importation and re-enforce its food safety control by including overseas inspections. The major change from the previous system is the introduction of a prior registration system by MFDS involving inspections on 1) general food, on 2) fresh meat (livestock products subject to quarantine) and on 3) processed livestock products (livestock products NOT subject to quarantine, such as dairy, egg and sterilized meat products). On livestock products, the new Act is applied to category of livestock products and establishments that will be newly imported and registered since 4 February 2016. Livestock products and establishments which have been imported prior to the date of enter into force are grandfathered.

The EU considers that livestock products will be the mainly affected product among other products traded with Korea, and further engagement from Member State officials is needed.

#### **1. Registration of General Imported Food Manufacturing Facilities<sup>1</sup>**

General food (food, food additives, apparatus, containers and packages, functional health food) manufacturers, who intend to export to Korea, should have their facilities registered at the MFDS 7 days prior to import declaration either by the exporter or the importer. The registration is operated via post/fax or on-line, which requests information about the facility, such as the name, location, contact information, exporting products and so on. When in need of any further verification, the MFDS may request verification, update, additional information and inspections. Trade partners may discuss with the MFDS to facilitate the registration process. The validity of the registration expires in 2 years, thus an

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<sup>1</sup> A facility (including a ship in which seafood is produced or processed) that is located overseas and engages in the production, manufacturing, processing, packaging, or storage of imported food, etc. (except livestock products)

exporter/importer should re-register when necessary. MFDS has the authority to inspect foreign manufacturing facilities either before or after the registration by informing foreign operators directly. In case foreign operators do not cooperate, an import ban can be imposed. The operation of the registration process has a grace period of 6 months.

## **2. Fresh Meat Import Requirements**

The single authorization system applied to fresh meat products (chilled or frozen beef, pork and poultry meat and its by-products) under the Ministry of Agriculture, Food and Rural Affairs (MAFRA) has been divided under two Ministries. MAFRA will continue in controlling animal health features, while sanitary control on livestock products has newly been transferred to MFDS. As a consequence, in order to open the market for new livestock products, the government of the exporting country should negotiate with both MAFRA and MFDS to obtain 1) import health/sanitation requirements, 2) health/sanitation certificates and 3) meat establishment approvals (registrations). Products and establishments that have already been approved and have historical record of being exported to Korea between the periods of June 1998 to 3 February 2016, are exempted from this new regulation, and are grandfathered. However, from February 4, for all fresh meat import declarations, a copy of the health certificate by the exporting government should be accompanied by the original certificate when submitted to MAFRA and MFDS. In addition to the health certificate, submission of two BSE<sup>2</sup>-free certificates is also required for eligible products. The operation of the establishment registration process to MFDS has a grace period of 6 months, and it will be approved either through pre-listing, document-based assessment, or inspections. Trade partners may discuss with MFDS in order to facilitate the registration procedure.

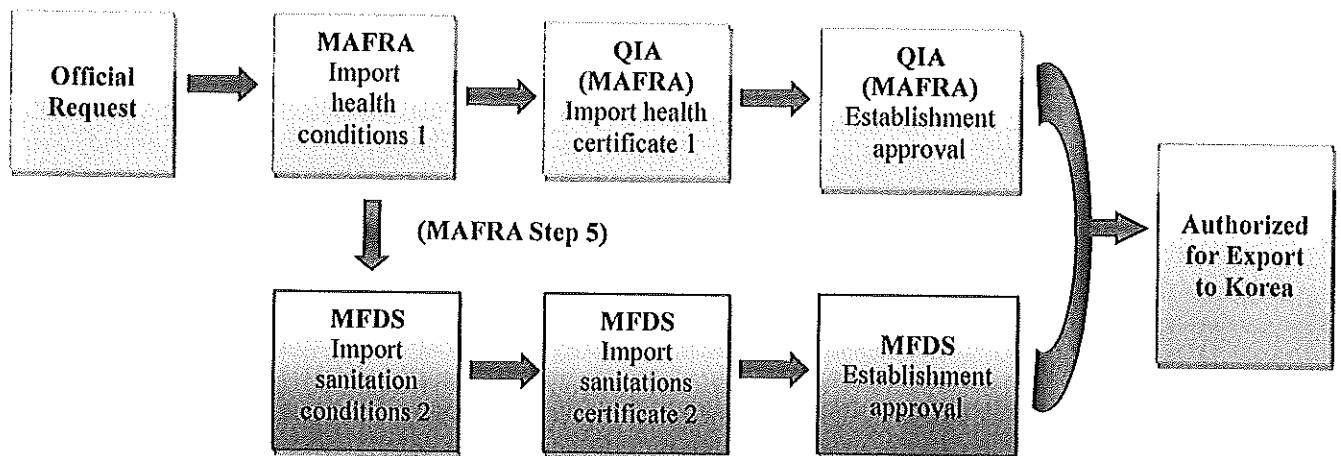
### **Procedure to introduce new products into the Korean market:**

- 1) **Import health requirement (condition):** The exporting government should initiate the negotiation with MAFRA for a risk assessment and prepare the import health conditions based on the 8 step negotiation procedure. When MAFRA considers appropriate to authorize the product (step 5) it informs MFDS who starts its sanitary assessment to establish import sanitation requirements. An inspection will be individually performed by each Ministry during the negotiations. In order to assure the assessment procedure held by both Ministries, the exporting government should submit the official request to both Ministries.
- 2) **Import health certificates:** The exporting government should discuss with both Ministries to establish a certificate in respect to their competencies (animal disease / sanitary control) when the import health /sanitation requirements are finalized. The imported product should be accompanied by the agreed two certificates to be submitted to each relevant ministry during import declaration.
- 3) **Establishment approval:** The exporting government should submit to both Ministries the list of meat establishments willing to export to Korea for its approval and registration. In case an inspection is needed prior to approval, a joint inspection from both Ministries will be proposed. The list of establishments should be updated in a regular basis.

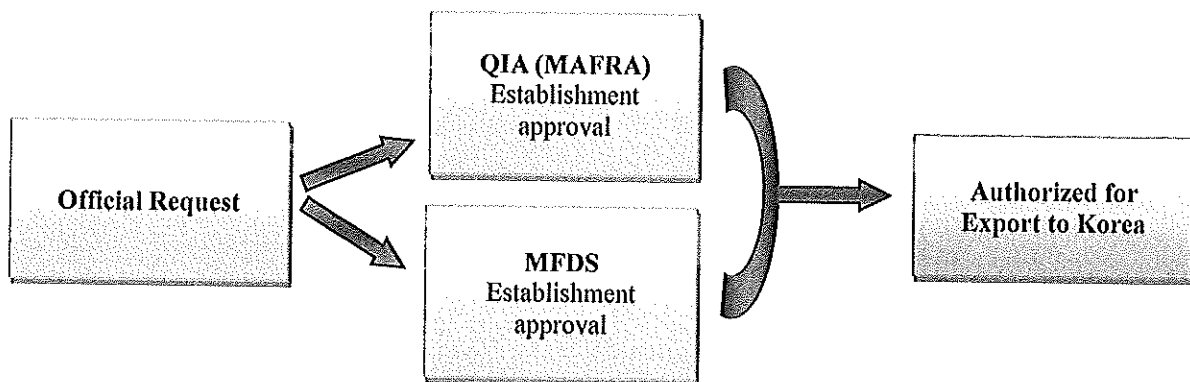
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<sup>2</sup> Bovine Spongiform Encephalopathy.

### (1) New fresh meat import negotiation procedure



### (2) Establishment approval procedure for authorized fresh meat products



### (3) 8 steps import health conditions negotiation procedure under MAFRA

- Step 1: Reception of the official request and internal assessment to start an official negotiation
- Step 2: Send questionnaire to the trade partner
- Step 3: Review questionnaire replies and documents
- Step 4: On-site inspection
- Step 5: Decision to authorize import
- Step 6: Bilateral negotiation on import health conditions (requirements)
- Step 7: Announce the agreed bilateral import health conditions (requirements)
- Step 8: Meat establishments approval and settle import health certificate

### 3. Processed Meat Products Import Requirements

From February 4, 2016, processed meat products which are not subject to quarantine such as dairy, egg and sterilized meat products, are subject to sanitary assessment by MFDS. The assessment involves a 6 step negotiation with the government of the exporting country to establish import sanitation requirements, import sanitation certificates and receive establishment approvals and be registered (Annex 3). MFDS may perform an on-site inspection during the negotiations and post-inspections may also be performed when necessary. This applies to new category of processed meat products and to new establishments which have not been exported to Korea from June 1998 to 3 February 2016. The operation of the establishment registration process has a grace period of 6 months (until 4 August 2016) and it will be approved either through pre-listing, document-based assessment, or inspections. Trade partners may discuss with MFDS in order to facilitate the approval procedure. The list of establishments should be updated in a regular basis.

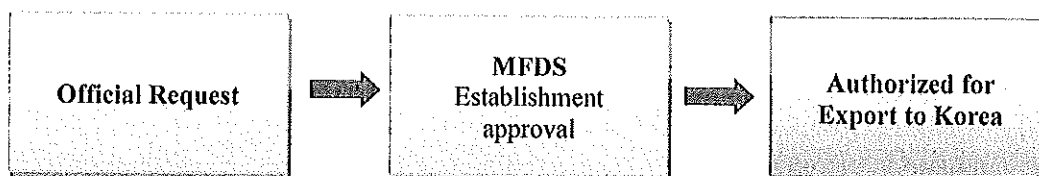
Establishments and category of products, which has historical record to have been exported to Korea from June 1998 to 3 February 2016 are exempted from this requirement and will be grandfathered. Prior to the Act, these products required submitting a pasteurization certificate (only applied to dairy products) and neither import sanitation requirements nor approval of establishments were required. In order to identify the category of products and the list of establishments eligible for grandfathering, MFDS sent the list containing these information to the government of the exporting countries (February and March 2016) and is awaiting an updated list to be enlisted in their system by 31 March.

However, in accordance to the new Act, MFDS is preparing a draft of a sanitation certificate for the import declaration procedure applicable to processed meat products that have been imported since 1998 until 3 February 2016. This draft will be soon proposed to its trade partners, in order to finalize a bilaterally agreed certificate for processed meat products import declaration. Until this procedure is finalized, all processed meat products are allowed to be imported under the former system.

#### (1) New processed meat import negotiation procedure



#### (2) Establishment approval procedure for authorized processed meat products



### 3) 6 steps sanitary assessment procedure under MFDS

- Step 1: Reception of the official request and send sanitation questionnaire
- Step 2: Review questionnaire replies and documents
- Step 3: On-site inspection
- Step 4: Decision to authorize import
- Step 5: Bilateral negotiation on import sanitation conditions and certificate
- Step 6: Approval and registration of establishments

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Paolo CARIDI  
Head of Trade and Economy Section

Prepared by Mi-Gyoung KIM, EU Delegation to the Republic of Korea, March 2016p