


Content

Title :	Operation Directions Governing Registration and Management for Factories of Petfood Exported to the European Union 
Date :	2024.02.27
Legislative :	1.Promulgated by Ministry of Agriculture on February 27, 2024
Content :	<p><b>Article 1</b> The Ministry of Agriculture (MOA) formulates this set of Directions to improve hygiene management at petfood factories to ensure that hygiene quality and export procedures of petfood destined for the European Union comply with its Commission Regulation (EU) No 142/2011 implementing Regulation (EC) No 1069/2009 of the European Parliament and of the Council.</p> <p><b>Article 2</b> According to EU regulations, those petfood factories in Taiwan aiming to export petfood to the EU should be included in the Petfood Factory Register for Exporting to the EU (the Register). Such entities may, in compliance with this set of Directions, apply to the MOA for inclusion in the Register.</p> <p><b>Article 3</b> To be included in the Register, a petfood factory should pass the MOA's hygiene assessment which consists of document review and on-site inspection of the factory.</p> <p><b>Article 4</b> For document review: a petfood factory applying for inclusion in the Register should submit to the MOA the application (Annex I) along with the following documents: 4.1 A photocopy of the factory registration. 4.2 Layout drawing of the entire petfood factory (including the factory building, the premises, production facilities and equipment). 4.3 The standard operating procedure (SOP) and a list of records routinely kept at the petfood factory. 4.4 The HACCP (Hazard Analysis and Critical Control Points) Plan: including members of the HACCP team, production processes, hazard analysis worksheets, determination of CCPs, the list of HACCPs, control ranges and monitoring of CCPs, corrective measures, raw material entry control procedures, and so on.</p> <p><b>Article 5</b> Upon receiving the application, the MOA should complete document review within 30 days. In case of incomplete application docket or revisions required, the MOA should notify the applicant to make corrections with 45 days upon receipt of the notice. When necessary, the applicant may request an extension up to 45 days, but only one extension is allowed. The application will be denied if the docket remains incorrect or incomplete beyond the deadline.</p> <p><b>Article 6</b> Once notified of having passed the document review, the petfood factory should accommodate MOA's on-site inspection within three months upon the notice.</p> <p><b>Article 7</b> For the on-site factory inspection, the MOA should form an assessment team</p>

-- with members from the competent authority at the municipality (a special municipality, county or city), relevant scholars, experts and representatives from proper agencies -- to conduct on-site inspection according to the Hygiene Assessment Criteria for Inclusion in the Petfood Factory Register for Exporting to the EU (Annex II). The assessors should enter their findings in the Hygiene Assessment Checklist for Inclusion in the Petfood Factory Register for Exporting to the EU (Annex III).

#### **Article 8**

The MOA shall send a written notice to the applicant about the outcome of hygiene assessment, and do the following:

(8.1) if the applicant has passed the hygiene assessment, the MOA is to include the factory on the Register, also send a copy, respectively, to the MOA's Animal and Plant Health Inspection Agency (APHIA) and the competent authority at the municipality where the entity is located.

(8.2) if the applicant has failed the hygiene assessment, the applicant should complete remedial actions listed on the notice within three months, followed by a report on such actions to the MOA to apply for a re-assessment. Those who fail the re-assessment should re-submit the application in accordance with Article 4.

#### **Article 9**

The inclusion in the Register is valid for three years. Before the validity expires, a factory may re-submit the application in accordance with Article 4.

#### **Article 10**

Factories on the Register should be subject to the MOA's petfood products sampling test regularly or occasionally. Upon sampling test, the factory found to violate the Standards for Types and Tolerance Levels of Pathogenic Microorganisms and Health-Hazard Materials in Pet Food is to be disciplined in accordance with stipulations in the Animal Protection Act.

#### **Article 11**

11.1 Entities on the Register should be subject to the MOA's follow-up spot-check inspection.

11.2 Entities failing the follow-up inspection may apply for a re-inspection within three months upon receipt of the notice. If an entity fails to apply for a re-inspection, or fails to pass the re-inspection before the deadline, the MOA should remove the entity from the Register.

#### **Article 12**

When there is a change to the layout (including the factory building, the premises, production facilities and equipment) of a factory on the Register, the entity should notify the MOA -- within thirty days after the change -- with layout drawings before and after, as well as relevant documents. The MOA may conduct on-site inspection or carry out necessary measures based on hazard risk assessment.

#### **Article 13**

When an entity on the Register terminates, suspends or resumes its business, it should do one of the followings:

(13.1) For business termination, the entity should notify the MOA, within thirty days after the fact, to remove it from the Register.

(13.2) For business suspension to be longer than one month but shorter than a year, the entity should notify the MOA within 15 days after the suspension starts. For business resumption, the factory should notify the MOA within 30 days after the resumption starts. The MOA may carry out follow-up inspection according to Article 11.

#### **Article 14**

The MOA may remove an entity from the Register in any of the following situations:

(14.1) Failure to apply for a renewal before the validity expires.

(14.2) Evasion of, obstruction to, or refusal of the sampling test described in Article 10, or the entity refuses to take remedial actions as required after its products fail to comply with hygiene regulations when tested; in case of a serious offense, the MOA may, on its own initiative, remove the entity from the Register.

(14.3) Evasion of, obstruction to, or refusal of the follow-up inspection described in Article 11.

(14.4) Refusal to take remedial actions as required after failing the on-site inspection by the MOA responding to a layout change notice according to Article 12; in case of a serious offense, the MOA may on its own initiative remove the entity from the Register.

(14.5) Failure to notify the authority about termination, suspension or resumption of business before the deadline stipulated in Article 13.

#### **Article 15**

When removing an entity from the Register, the MOA should notify the entity in writing, and send a copy, respectively, to the MOA's Animal and Plant Health and Inspection Agency (APHIA) and the competent authority of the municipality (a special municipality, county or city) where the factory is located.

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Attachments : Operation Directions Governing Registration and Management for Factories of Petfood Exported to the European Union.pdf

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Data Source : MONISTRY OF AGRICULTURE Laws and Regulations Retrieving System