

Operation Directions Governing Registration and Management for Factories of Petfood Exported to the European Union

Article 1

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.

Article 2

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.

Article 3

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.

Article 4

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.

Article 5

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.

Article 6

Once notified of having passed the document review, the petfood factory should accommodate MOA's on-site inspection within three months upon the notice.

Article 7

For the on-site factory inspection, the MOA should form an assessment team -- 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.

Annex I

Application for Inclusion in the Petfood Factory Register for Exporting to the EU

1. Factory name (Chinese) : _____
(English) : _____
2. Person-in-charge (Chinese) : _____
(English) : _____
3. Factory address (Chinese) : _____
(English) : _____
4. Purpose of the application (please check only one):
 for listing on the Register for re-assessment for re-inspection
5. ALL products made at the factory seeking inclusion in the Petfood Factory Register for Exporting to the EU

Product name	Product type*	Animal-derived materials	country of origin of animal-derived materials	Other materials	Production method (including heating method) **	Intended for exporting to EU?
						Y/N
						Y/N
						Y/N
						Y/N
						Y/N
						Y/N
						Y/N

*Please enter ONE of the three options: canned petfood, non-canned petfood, or dental chew (dogchew).

**Production method: must describe manufacturing processes and heating treatment temperature. If only performing mixing of animal-derived ingredients but no heating, the applicant must describe the heat-treatment temperature at each material supplier, and provide the corresponding heating certificates.

6. International certifications obtained by the petfood factory (such as "GMP, HACCP, ISO etc.)

Name of Certification Standards	Certificate number	Date obtained

7. Management protocols and corresponding records maintained at the Petfood Factory

Management Aspects	Management protocols/records maintained
1. Equipment and facilities	
1.1. Hygiene management on the premises of the factory	
1.2. Hygiene management of equipment and facilities; pest control measures	
1.3. Management of maintenance and calibration of equipment and facilities	
1.4. Hygiene management of drainage, sewage and waste	
1.5. Hygiene management of water for production	
1.6. Management of cleaning agents, toxic or hazardous materials	
2. Personnel	
2.1. Staff's vocational proficiency; the quality control team	
2.2. Training plan for the staff	
2.3. Physical checkup program for the staff	
3. Production operation and management system	
3.1 the HACCP system	
3.2 Standard operating procedure (SOP) for production	
3.3 Storage management processes of materials, semi-finished and final products	
3.4 Product traceability system	
3.5 Assessment of suppliers of materials/packing products etc.; acceptance tests for their goods.	
3.6 Customer complaint handling procedure	
3.7 Product recall system	
4. Heat treatment and product testing	
4.1 Heat treatment specifications	
4.2 Testing specifications for semi-finished and final products	

Stamp of the factory

Stamp of the person-in-charge

Date:

Annex II

**Hygiene Assessment Criteria for Inclusion in the Petfood Factory Register
for Exporting to the EU**

Vendors should the EU rules -- Regulation (EC) No 183/2005 for feed hygiene and businesses, also Regulations (EC) No 1069/2009 and Regulation (EU) No 142/2011 for hygiene requirements for production with animal-derived materials -- to ensure fulfilling the following requirements:

1. Equipment and facilities		EU Regulations
1.1 Hygiene management on the premises of the factory	1.1.1 Production area must be separated from the living space or the office.	183/2005 Annex II
	1.1.2 At the factory, entrances/exits, doors/windows, ventilation holes and other openings should be kept clean and equipped with measures to prevent and control pest invasion.	183/2005 Annex II
	1.1.3 Factory ceiling or overhead fixtures on the inside of the roof should be constructed and finished to prevent the accumulation of dirt, to reduce condensation and the growth of molds, and to prevent foreign objects from falling into petfood causing contamination.	183/2005 Annex II
	1.1.4 The factory should have adequate lighting, ventilation, automatic temperature recording, alarms and fire-fighting equipment installed in compliance with fire safety regulations.	183/2005 Annex II
1.2 Hygiene management of equipment and facilities; pest control measures	1.2.1 At the factory, equipment and facilities for production and storage (for heating, drying, freezing, temperature control, etc.), lockers, vehicles and the surrounding areas should be kept clean. A pest control program (against rodents, flies, mosquitos, cockroaches, and birds etc.) should be formulated and carried out.	183/2005 Annex II
	1.2.2 At the factory, the operation areas, facilities and equipment (e.g. for heating, drying, freezing, and temperature control) as well as the warehouse must be properly designed and must allow adequate cleaning and disinfection to minimize contamination and risk of food quality concerns. After cleaning and disinfection traces of detergent and disinfectant should be minimized and be dried off.	183/2005 Annex II
1.3 Management of maintenance and calibration of equipment and	1.3.1 Facilities and equipment for production (e.g. for heating, drying, freezing, temperature control, etc.) should be inspected and maintained regularly to ensure proper operation. Measuring tools like weighing scales	183/2005 Annex II

facilities	and meter gauges should be tested and calibrated on a regular basis.	
	1.3.2 Mixing equipment for production should be appropriate for the range of weights or volumes being mixed, and should be capable of achieving effective homogeneity.	183/2005 Annex II
1.4 Hygiene management of drainage, sewage and waste	1.4.1 The sewage system must be designed to avoid risks of petfood contamination, and should be cleaned frequently to stay free-flowing and without odor.	183/2005 Annex II
	1.4.2 The factory should have proper procedures to temporarily store and dispose of waste, sewage as well as rainwater. The procedures must not negatively impact the production equipment or petfood quality. Vector control measures must be implemented.	183/2005 Annex II
1.5 Hygiene management of water for production	Water for petfood production must come from the tap (municipal water). Pipes should be made of materials that will not affect water quality.	183/2005 Annex II
1.6 Management of cleaning agents, toxic or hazardous materials	Cleaning agents, toxic or hazardous materials should be stored at a designated cabinet and managed by designated personnel.	183/2005 Annex II
2 Personnel		
2.1 Staff's vocational proficiency; the quality control team	2.1.1 The production and quality control personnel hired by the factory must be equipped with knowledge and expertise related to products made at the factory.	183/2005 Annex II
	2.1.2 The factory must set up a quality control team, and clearly state the team members' titles, responsibility, education background, training and experience.	183/2005 Annex II
2.2 Training plan for the staff	The factory should have training plans for its staff.	183/2005 Annex II
2.3 Physical checkup program for the staff	The factory should have physical checkup programs for the staff.	183/2005 Annex II
3. Production operation and management system		
3.1 the HACCP system	3.1.1 The factory should carry out procedures based on the Hazard Analysis and Critical Control Points (HACCP) system.	183/2005 Article 6
	3.1.2 The factory should set up a quality control system based on the HACCP principle, also develop self-inspection controls based on risk analysis and maintain the records.	183/2005 Article 7
	3.1.3 The factory should monitor for the presence of substances and other contaminants harmful to human	183/2005 Annex II

	or animal health, also develop proper control strategies to minimize the risk.	
3.2 Standard Operating Procedure (SOP) for production	The factory should formulate the standard operating procedure (SOP) document for production, carry out production operations based on the SOP document, and keep the production records for at least 5 years.	183/2005 Annex II
3.3 Storage management processes of materials, semi-finished and final products	3.3.1 To avoid cross contamination, raw materials, semi-finished products and final products should be packed in proper packing materials with clear labels and stored at separate locations.	183/2005 Annex II
	3.3.2 The factory should provide proper storage conditions in respective spaces for materials, semi-finished products and final products in order to avoid quality deterioration. These spaces should have proper vector control measures.	183/2005 Annex II
3.4 Product traceability system	3.4.1 The factory should set up a product traceability system for every stage of the product life -- from material purchasing to product sales -- and keep relevant records for at least five years.	183/2005 Annex II
	3.4.2 A product samples collection procedure should be developed to ensure traceability: how the samples are collected, sealed, and labeled. Samples must be stored under conditions which prevent any abnormal change in the compositions of the sample or any adulteration. The factory should, when necessary, be able to provide the sample to the competent authority.	183/2005 Annex II
3.5 Assessment of suppliers of materials/packing products etc.; acceptance tests for their goods	3.5.1 For raw materials and packing products used, the factory should set up an assessment system for qualified vendors, as well as an acceptance test system for the goods.	183/2005 Annex II
	3.5.2 Animal-derived materials used in producing petfood should comply with the European Union regulations.	1069/2009 Article 14
3.6 Customer complaint handling system	A customer complaint handling system should be set up.	183/2005 Annex II
3.7 Product recall system	A product recall system should be set up.	183/2005 Annex II
4. Heat treatment and product testing		
4.1 Heat treatment specifications	4.1.1 Canned petfood must be subject to heat treatment to a minimum Fc value of 3 -- namely heating at 121°C for 3 minutes -- then be enclosed in a sealed container free from microbial contamination.	142/2011 Annex XIII
	4.1.2 Non-canned petfood must be subject to either of the following heat treatments: (A) more than 90°C throughout the substance of the final product; (B) more	142/2011 Annex XIII

	than 90°C on all animal-derived ingredients.	
	4.1.3 Final products of dental chews must be subject to heat treatment of over 90°C.	142/2011Annex XIII
4.2 Testing specifications for semi-finished products or final products	4.2.1 Regarding non-canned petfood and dental chews, five or more random samples should be taken to verify compliance with the following standards: (A) Salmonella should be absent from all samples at 25 grams each, (B) Enterobacteriaceae should meet either of the two standards: (B.1) bacterial count is no more than 10/gram in all samples, or (B.2) none of the sample show a bacterial count of more 300/gram, AND more than 60% of the samples show a bacterial count of no more than 10/gram.	142/2011Annex XIII
	4.2.2 After heat treatment, every precaution should be taken to prevent microbial contamination.	142/2011Annex XIII

Annex III

**Hygiene Assessment Checklist for Inclusion in the Petfood Factory Register
for Exporting to the EU**

I. Information of the Applicant

Factory name : _____

Person-in-charge: _____

Factory address: _____

Management representative: _____

Contact number: _____

Assessment date: _____

II - Criteria for Hygiene Assessment Inspection

Criteria for Hygiene Assessment Inspection		compliant	non-compliant	not applicable	Findings
1. Equipment and facilities					
1.1 Hygiene management on the premises of the factory	1.1.1 Production area must be separated from the living space or the office.				
	1.1.2 At the factory, entrances/exits, doors/windows, ventilation holes and other openings should be kept clean and equipped with measures to prevent and control pest invasion.				
	1.1.3 Factory ceiling or overhead fixtures on the inside of the roof should be constructed and finished to prevent the accumulation of dirt, to reduce condensation and the growth of molds, and to prevent foreign objects from falling into petfood causing contamination.				
	1.1.4 The factory should have adequate lighting, ventilation, automatic temperature recording, alarms and fire-fighting equipment installed in compliance with fire safety regulations.				
1.2 Hygiene management of equipment and facilities; pest control measures	1.2.1 At the factory, equipment and facilities for production and storage (for heating, drying, freezing, temperature control, etc.), lockers, vehicles and the surrounding areas should be kept clean. A pest control program				

Criteria for Hygiene Assessment Inspection		compliant	non-compliant	not applicable	Findings
	(against rodents, flies, mosquitos, cockroaches, and birds etc.) should be formulated and carried out.				
	1.2.2 At the factory, the operation areas, facilities and equipment (e.g. for heating, drying, freezing, and temperature control) as well as the warehouse must be properly designed and must allow adequate cleaning and disinfection to minimize contamination and risk of food quality concerns. After cleaning and disinfection traces of detergent and disinfectant should be minimized and be dried off.				
1.3 Management of maintenance and calibration of equipment and facilities	1.3.1 Facilities and equipment for production (e.g. for heating, drying, freezing, temperature control, etc.) should be inspected and maintained regularly to ensure proper operation. Measuring tools like weighing scales and meter gauges should be tested and calibrated on a regular basis.				
	1.3.2 Mixing equipment for production should be appropriate for the range of weights or volumes being mixed, and should be capable of achieving effective homogeneity.				
1.4 Hygiene management of drainage, sewage and waste	1.4.1 The sewage system must be designed to avoid risks of petfood contamination, and should be cleaned frequently to stay free-flowing and without odor.				
	1.4.2 The factory should have proper procedures to temporarily store and dispose of waste, sewage as well as rainwater. The procedures must not negatively impact the production equipment or petfood quality. Vector control measures must be implemented.				
1.5 Hygiene management of water for production	Water for petfood production must come from the tap (municipal water). Pipes should be made of materials that will not affect water quality.				

Criteria for Hygiene Assessment Inspection		compliant	non-compliant	not applicable	Findings
1.6 Management of cleaning agents, toxic or hazardous materials	Cleaning agents, toxic or hazardous materials should be stored at a designated cabinet and managed by designated personnel.				
2 Personnel					
2.1 Staff's vocational proficiency; the quality control team	2.1.1 The production and quality control personnel hired by the factory must be equipped with knowledge and expertise related to products made at the factory.				
	2.1.2 The factory must set up a quality control team, and clearly state the team members' titles, responsibility, education background, training and experience.				
2.2 Training plan for the staff	The factory should have training plans for its staff.				
2.3 Physical checkup program for the staff	The factory should have physical checkup programs for the staff.				
3. Production operation and management system					
3.1 the HACCP system	3.1.1 The factory should carry out procedures based on the Hazard Analysis and Critical Control Points (HACCP) system.				
	3.1.2 The factory should set up a quality control system based on the HACCP principle, also develop self-inspection controls based on risk analysis and maintain the records.				
	3.1.3 The factory should monitor for the presence of substances and other contaminants harmful to human or animal health, also develop proper control strategies to minimize the risk.				
3.2 Standard Operating Procedure (SOP) for production	The factory should formulate the standard operating procedure (SOP) document for production, carry out production operations based on the SOP document, and keep the production records for at least 5 years.				

Criteria for Hygiene Assessment Inspection		compliant	non-compliant	not applicable	Findings
3.3 Storage management processes of materials, semi-finished and final products	3.3.1 To avoid cross contamination, raw materials, semi-finished products and final products should be packed in proper packing materials with clear labels and stored at separate locations.				
	3.3.2 The factory should provide proper storage conditions in respective spaces for materials, semi-finished products and final products in order to avoid quality deterioration. These spaces should have proper vector control measures.				
3.4 Product traceability system	3.4.1 The factory should set up a product traceability system for every stage of the product life -- from material purchasing to product sales -- and keep relevant records for at least five years.				
	3.4.2 A product samples collection procedure should be developed to ensure traceability: how the samples are collected, sealed, and labeled. Samples must be stored under conditions which prevent any abnormal change in the compositions of the sample or any adulteration. The factory should, when necessary, be able to provide the sample to the competent authority.				
3.5 Assessment of suppliers of materials/packing products etc.; acceptance tests for their goods	3.5.1 For raw materials and packing products used, the factory should set up an assessment system for qualified vendors, as well as an acceptance test system for the goods.				
	3.5.2 Animal-derived materials used in producing petfood should comply with the European Union regulations.				
3.6 Customer complaint handling system	A customer complaint handling system should be set up.				
3.7 Product recall system	A product recall system should be set up.				
4. Heat treatment and product testing					

Criteria for Hygiene Assessment Inspection		compliant	non-compliant	not applicable	Findings
4.1 Heat treatment specifications	4.1.1 Canned petfood must be subject to heat treatment to a minimum Fc value of 3 -- namely heating at 121°C for 3 minutes -- then be enclosed in a sealed container free from microbial contamination.				
	4.1.2 Non-canned petfood must be subject to either of the following heat treatments: (A) more than 90°C throughout the substance of the final product; (B) more than 90°C on all animal-derived ingredients.				
	4.1.3 Final products of dental chews must be subject to heat treatment of over 90°C.				
4.2 Testing specifications for semi-finished products or final products	4.2.1 Regarding non-canned petfood and dental chews, five or more random samples should be taken to verify compliance with the following standards: (A) Salmonella should be absent from all samples at 25 grams each, (B) Enterobacteriaceae should meet either of the two standards: (B.1) bacterial count is no more than 10/gram in all samples, or (B.2) none of the sample show a bacterial count of more 300/gram, AND more than 60% of the samples show a bacterial count of no more than 10/gram.				
	4.2.2 After heat treatment, every precaution should be taken to prevent microbial contamination.				

Recommendations:

1. _____
2. _____
3. _____
4. _____
5. _____

III. Outcome of the Hygiene Assessment Inspection

Inspection passed

Inspection conditionally passed :

The factory is advised to submit by (the date) _____ the following supplementary information and/or a report on corrective actions performed, for review and approval by the Department of Animal Welfare of the Ministry of Agriculture:

- 1.
- 2.
- 3.
- 4.
- 5.

Inspection failed

Remarks :

1. A petfood factory will be deemed failing the hygiene assessment inspection when the factory is non-compliant with 10 or more inspection criteria in the checklist.
2. This report is to be signed by the Assessment Team and the representative of the factory. The original will be kept on file at the Department of Animal Welfare of the Ministry of Agriculture; a photocopy will be kept by the factory.

The Signature Page

Members of the Assessment Team :	Representative of the petfood factory and other participants:
<p>Experts :</p> <p>Animal and Plant Health Inspection Agency (APHIA) of the Ministry of Agriculture :</p> <p>Competent authority from the _____ Municipality (special, city or county):</p> <p>Department of Animal Welfare, Ministry of Agriculture :</p>	

Date of Hygiene Assessment: