

For Pet Food Business Operators

In Order to Supply Safe Pet Foods

— Measures based on the Pet Food Safety Act —

Final revision: January 15, 2015
Ministry of Agriculture, Forestry and Fisheries
Food Safety and Consumer Affairs Bureau
Animal Products Safety Division

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1. Introduction

The Act on Ensuring of Safety of Pet Food (Act No. 83 of 2008, hereinafter referred to as the “Pet Food Safety Act”) was enacted in June 2009.

This Act aims to protect the health of pet animals (hereinafter referred to as “pets”) and contribute to the protection of animals by regulating matters related to the production of feed for pet animals (hereinafter referred to as “pet foods”).

The national government sets the production methods, labeling standards, and compositional specifications of pet foods based on the provisions of this Act. It grasps the details of business based on the notifications submitted from the relevant business operators, and confirms the compliance of the relevant business operators with the regulation and the applicability of the compositional specifications of distributed pet foods by conducting on-site inspections and the collection and testing of pet foods. When the distribution of any harmful pet foods becomes evident, the government takes measures such as the prohibition of manufacturing, destruction, and collection in order to securely prevent health damage to pets.

In order to prevent health damage to pets, it is highly important that the business activities are implemented based on the understanding of all business operators including importers, manufacturers and wholesalers of pet foods such as (i) recognizing one’s primary responsibility on securing the safety of pet foods, (ii) securing the safety of pet foods and ingredients by obtaining knowledge and skill on securing safety and sharing them mutually among business operators, and (iii) implementing measures such as immediate collection through cooperation of business operators in the chance event where the distribution of harmful pet foods becomes evident.

Particularly among manufacturers, the responsibility for securing the safety of pet foods is significant, and it is important to implement adequate sanitary control, manufacturing management, and risk management.

According to the purport above, this document presents the items that business operators should abide by in terms of engagement and management, in order to manufacture, import and sell safe pet foods based on the Act. Business operators are required to prevent the distribution of harmful pet foods and to take all possible measures to minimize health damage to pets, using this document as a reference.

2. Basic measures to secure safety

Business operators are required to try to secure the safety of pet foods, prevent the distribution of harmful pet foods, and to take all possible measures to minimize health damage to pets, using the below as a reference.

In order to do so, it is important to summarize important items in each stage from the

manufacturing to distribution of pet foods in documents (written standards, working manual, etc.) and make the necessary information accessible anytime, as well as to record the situation of implementing measures and to archive them adequately. Such records are highly useful also for confirming how the pet foods are manufactured, and to investigate the causes once any problem occurs.

The following efforts are examples of business management methods and others, so please utilize them for self-inspection of management methods according to the actual situation of each workplace. Please refer to the “Checklist for Manufacturing Management and Quality Control Methods” upon implementing the self-inspection.

2-1. Manufacturers

Upon the manufacturing of pet foods for commercial use, utilize Exhibit 1. Checklist for Manufacturing Management and Quality Control Methods (Examples) to work to secure the safety of pet foods.

1) Understanding the outline of manufacturing business

Manufacturers should work to understand the following when considering safety management.

- Manufactured item
- Manufactured volume
- Manufacturing process
- Structure (layout of manufacturing workplace)
- Equipment instrument (type, number, specification, capacity, etc.)
- Organization (manufacturing management system, quality control system, etc.)

2) Collecting information and acquiring knowledge/skill on safety

Manufacturers should work to collect information on the safety of pet foods and acquire knowledge/skills that are required upon manufacturing. They should also work to develop human resources in charge of safety management as needed.

3) Preparation of product standard document

Set standards necessary for safety management and document them.

4) Manufacturing management

Manufacturers should work to maintain process management complying with the standards/specifications, such as setting management criteria and work procedures for processes requiring safety management.

5) Quality control

Manufacturers should put effort into quality control, including the confirmation of the management of processes requiring safety management and the confirmation of the properties of ingredients, interim products and end products, conducted as needed.

6) Ledger management

Manufacturers should work to confirm that work instructions, work records, order forms and other forms in all processes from accepting ingredients to manufacturing and shipment are all mutually related and can be used as records with which one can trace all the way to ingredients from the product.

Also, specify the ledger and documents among them that are required to be recorded, equipped and stored under law, and confirm that the details of the records and their retention period (two years) comply with the law.

7) Labeling management

Manufacturers should prepare labels based on the labeling standards specified under law.

Also keep in mind the labeling regulations other than for the safety of pet foods.

- The Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices

Labeling that makes it seem like pharmaceuticals, such as showing a disease name or advocating efficacy/effect, is not allowed.

(It is risky to directly translate the labeling into a foreign language and affix it without examining the details.)

- Act Against Unjustifiable Premiums and Misleading Representations
Misleading labeling such as showing the product or service to be much better than in actuality is not allowed.
- Pet Food Fair Competition Code, etc.

8) Reactions to be taken in case of an accident

Manufacturers should take actions to minimize health damage to pets when any accidents, such as accidents caused by the use of the pet food or the contamination of harmful substances in ingredients, occur.

Set forth the procedure for submitting notification to the Ministry of Agriculture, Forestry and Fisheries, and for the collection of products, in advance.

- Delay in initial reaction may result in aggravating the damage.
- Call for the attention of pet owners promptly, widely and accurately.
- Take necessary measures with collected products such as storing and disposing by clearly differentiating products.

2-2. Importers

Upon the import of pet foods for commercial use, utilize Exhibit 2. Examples of Checklist for Imported Pet Foods for Commercial Use to work to secure the safety of pet foods.

1) Understanding the outline of import business

Manufacturers should work to understand the following when considering safety management.

- Imported item
- Imported volume
- Business operators from which items are imported
- Products storage facilities
- Organization (import management system, safety management system, etc.)

2) Collecting information and acquiring knowledge/skill on safety

Importers should work to collect and streamline information on the safety of pet foods and acquire knowledge/skills that are required upon importing. They should also work to develop human resources in charge of safety management as needed.

3) Manufacturing management/quality control of production at the workplace from which items are imported

Importers should understand the situation of manufacturing management/quality control of production at the workplace from which items are imported.

Cautions when imported products are manufactured and managed under the standards of the exporter country

- The threshold of the standards in Japan may be lower (stricter) than that of the exporter country.
- When the inspection method taken at the exporter country differs from the “Inspection Method for Pet Foods” mandated by the President of FAMIC (hereinafter referred to as the “Official Method”), the value obtained as a result may be lower (more optimistic) than the result of the Official Method.

4) Ledger management

Importers should work to confirm that work instructions, work records, order forms and other forms in all processes from accepting products to shipment are all mutually related and be able to identify the product.

Also, specify the ledger and documents among them that are required to be recorded, equipped and stored under law, and confirm that the details of the records and their retention period (two years) comply with the law.

5) Labeling management

Importers should prepare labels based on the labeling standards specified under law.

Also keep in mind the labeling regulations other than for the safety of pet foods.

- The Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices
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Importers should take actions to minimize health damage to pets when any accidents, such as accidents caused by the use of the pet food or the contamination of harmful substances in ingredients, occur.

Set forth the procedure for submitting notification to the Ministry of Agriculture, Forestry and Fisheries, and for the collection of products, in advance.

- Delay in initial reaction may result in aggravating the damage.
- Call for the attention of pet owners promptly, widely and accurately.
- Take necessary measures with collected products such as storing and disposing by clearly differentiating products.

2-3 Distributors (wholesalers)

1) Understanding the outline of sales business

Distributors (wholesalers) should work to understand the distribution items and sales volume.

They should also work to understand that there is labeling provided for in laws applied to the items they handle.

Distributors (wholesalers) who market private-brand products through manufacturing contracts with other companies should prepare labels based on the labeling standards specified under law.

2) Collecting information and acquiring knowledge on safety

Distributors (wholesalers) should work to collect/streamline information on the safety of pet foods and acquire knowledge that is required upon marketing.

3) Ledger management

Distributors (wholesalers) should work to confirm that forms in all processes from accepting products to shipment are all mutually related and be able to identify the product.

Also, specify the ledger and documents among them that are required to be recorded, equipped and stored under law, and confirm that the details of the records and their retention period (two years) comply with the law.

4) Reactions to be taken in case of an accident

Distributors (wholesalers) should cooperate with relevant business operators and take actions to minimize health damage to pets when any accidents, such as accidents caused by the use of the pet food or the contamination of harmful substances in ingredients, occur.

2-4. Distributors (retailers)

1) Understanding the outline of sales business

Distributors (retailers) should work to understand the distribution items and sales volume.

They should also work to understand that there is labeling provided for in laws applied to the items they handle.

Distributors (retailers) who market private-brand products through manufacturing contracts with other companies should prepare labels based on the labeling standards specified under law.

2) Collecting information and acquiring knowledge on safety

Distributors (retailers) should work to collect/streamline information on the safety of pet foods and acquire knowledge that is required upon marketing.

It is also important to disseminate and raise awareness on the appropriate way of feeding pets.

- There are cases where owners feed pet foods for particular nutritional purposes on their own judgment, causing health damage.

(Diagnosis by veterinarians and feeding according to their instruction becomes necessary.)

- Feeding appropriate amount, etc.

3) Reactions to be taken in case of an accident

Distributors (retailers) should cooperate with relevant business operators and take actions to minimize health damage to pets when any accidents, such as accidents

caused by the use of the pet food or the contamination of harmful substances in ingredients, occur.

Major Requisites of Pet Food Safety Laws to be Complied with

I. Standards and specifications

The national government specifies standards for the manufacturing methods/labeling of pet foods and their compositional standards by hearing opinions from the Council, from the perspective of preventing health damage to pets caused by pet foods. Please refer to the brochure “For Securing Safety of Pet Foods”

(http://www.maff.go.jp/e/policies/ap_health/petfood/attach/pdf/index-1.pdf).

II. Ledger equipment

When any violation of standards/specifications becomes evident after the shipment of pet foods, the national government may order the disposal or the collection of pet foods already manufactured/shipped. It is necessary that business operators keep the record of manufacturing, import and sales, in case such an incident occurs.

Cases to be stated in the ledger are as follows:

- (i) Where the manufacturer or importer manufactures or imports pet foods for commercial use
- (ii) Where the manufacturer, importer or distributor transfers pet foods for commercial use to manufacturers, importers or distributors.

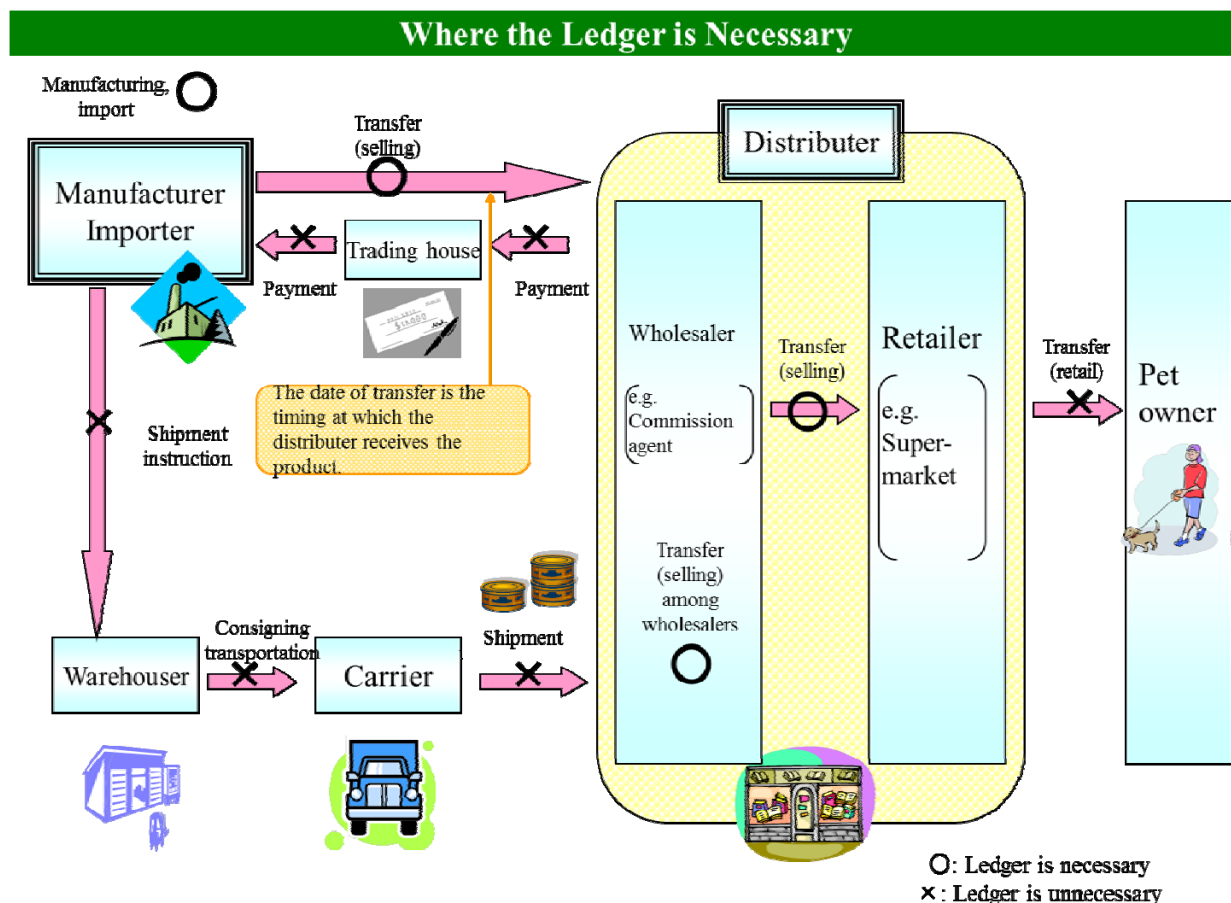
“Transfer” in (ii) above means to sell the products to manufacturers, importers or distributors. Even if there is a middleman between the counterpart of such transfer, including carriers and warehouse operators handling the transportation of products or trading houses who pay the price, the term “transfer” refers to the sales of products to the counterpart to whom the products are ultimately handed over, and delivery to or by middlemen are not included in “transfer.”

In addition, “transfer” is completed when the counterpart receives the products. (However, in case the collection of products becomes necessary, business operators should prepare a system with which data regarding the logistics of such middlemen that are necessary for the traceability of products can be obtained under the responsibility of manufacturers, importers and distributors.)

“Distributors” are those who are engaged in the business of selling pet foods for commercial use (excluding manufacturers and importers), including commission agents, home centers, supermarkets and veterinary hospitals, who sell pet foods for commercial use.

When pet foods for commercial use are transferred from distributors to other distributors (such as wholesale among commission agents and sale from a veterinary hospital to another veterinary hospital), it is necessary to state the transaction in the ledger. However, in the case of retail (= direct sales to consumers), stating in the ledger is not mandatory.

Further, sale of the ingredients of pet foods and the handing of contents in order to outsource only the package to packers do not fall under “transfer.”



[Matters to be stated]

1. When pet foods are manufactured (only for manufacturers)

(i) Name, volume, and manufacturing date of the manufactured pet food

a. Name

State the trade name of the pet food, for instance “XX Pet Food for Adult Dogs Containing Small Fish, 1kg Bag Type.”

b. Volume

State the volume of the product for each lot, for instance “xx kg,” “yy bags of zz kg-pack.”

c. Manufacturing date

State the date the products are manufactured.

(ii) Name and volume of ingredients

Name and volume of ingredients used for manufacturing should be stated for each product name stated according to (i) above. The names of the ingredients should correspond to the “names of ingredients ” used for the labeling of pet

foods, in order to confirm whether the ingredients are used as labeled in case any incident occurs.

For utilizing the invoice, etc. of the existing ingredients, abbreviated names and other names normally used are also accepted, as long as they clearly show the names of the ingredients shown on the products.

Further, if such ingredients are those being transferred (that is, purchased from other business operators), state the date of purchase and the name of the person/operator from which the material was purchased, in addition to the name and volume of the material.

Although it is not mandatory under the law, it is desirable to specify the manufacturer and the country of origin of the ingredients, so that the cause can be investigated promptly if there are any problems in the product.

2. When pet foods are imported (only for importers)

(i) Name, volume, imported date, and the form of package of the imported pet food

Stated the name and volume according to method as explained in (1) (i) above. The imported date is the import permit date specified in the import permit notification.

(ii) Name of the country from which the pet food is imported, name of the person/operator who is the counterpart exporter

The counterpart exporter is the exporter specified in the import permit notification.

(iii) Name of the country in which the pet food is manufactured, name of the person/operator of the manufacturer, name of ingredients.

The name of the country of manufacture and the name of ingredients should correspond to the “country of origin” and “names of ingredients ” used for the labeling of pet foods, so as to confirm whether they are consistent with the information labeled, as explained in (1) (ii) above. For utilizing the invoice, etc. of the existing ingredients, abbreviated names and other names normally used are also accepted, as long as they clearly show the country of origin and the names of the ingredients shown on the products.

3. When pet foods are transferred to manufacturers, importers or distributors (for all business operators)

(i) Name and volume of the transferred pet food

a. Name

State the trade name of the pet food, for instance “XX Pet Food for Adult Dogs Containing Small Fish, 1kg Bag Type.”

b. Volume

State the volume of the product for each lot, for instance “xx kg,” “yy bags of zz kg-pack.”

(ii) Name of the person/operator to whom the pet food is transferred, date of transfer,

and form of package

Specify for each name of the transferred pet food in (i) above. The date of transfer is the date the manufacturer, importer or distributor that received the product.

(iii) Distribution of samples free of charge

Even if samples free of charge are distributed to distributors (including veterinary hospitals), it is necessary to state it in the ledger. However, if the samples are distributed without order forms and is difficult to state in the ledger afterwards at the office, the statement of transfer may be substituted by the office equipping the list of places where such samples may be distributed (transfer with order forms from warehouse to office requires the ordinary style of the statement of transfer).

[Method of stating in the ledger and storage period]

Information in the ledger should be recorded in a notebook or computer as a general rule. However, when information to be stated is included in the business management documents, for instance material specification, product specification, ingredients delivery form, product sales form, product receipt, import permit notification, or invoice, the statement in the ledger may be substituted by keeping such documents.

Regarding the ledger, the recorded ledger or electronic data should be stored for at least two years.

The ledger should be equipped in each business base as a general rule. However, as for business bases where there is difficulty in retaining a ledger, such as an import (marketing) warehouse, it is acceptable to equip the ledger in the office or headquarters having jurisdiction over said business base. In such case, it is necessary to clearly show the statement in the ledger and the situation of equipment at each business base when there is an on-site inspection by FAMIC, etc.

Points to Consider upon the Use of Additives

[Point]

Use additives only where necessary and keep the use to the minimum necessary amount.

1. What are additives?

The term “additives” used in the Pet Food Safety Act shall mean substances which are used by being added, mixed or infiltrated into pet food or by other methods in the process of producing food or for the purpose of processing or preserving food.

For your information, the definition in Codex and Food Sanitation Act is as follows.

In the Codex General Standard for Food Additives, food additives are defined as “any substance not normally consumed as a food by itself and not normally used as a typical ingredient of the food, whether or not it has nutritive value, the intentional addition of which to food for a technological (including organoleptic) purpose in the manufacture, processing, preparation, treatment, packing, packaging, transport or holding of such food results, or may be reasonably expected to result (directly or indirectly), in it or its byproducts becoming a component of or otherwise affecting the characteristics of such foods.”

In Paragraph 2, Article 4 of Food Sanitation Act, additives are defined as “substances which are used by being added, mixed or infiltrated into food or by other methods in the process of producing food or for the purpose of processing or preserving food.”

In Paragraph 3, Article 2 of Act on Safety Assurance and Quality Improvement of Feeds, feed additives are defined as “substances which are used by being added, mixed or infiltrated into feed or by other methods for the purpose of preventing quality deterioration and other use provided for in Order of the Ministry of Agriculture, Forestry and Fisheries, and those that are designated by the Minister of Agriculture, Forestry and Fisheries by hearing opinions from the Agricultural Materials Council.”

Reference: Additives used for pet foods

Additives used for foods and feeds are mainly used also for pet foods. Such additives are confirmed as not damaging human or animal health through the implementation of safety tests or with the past record of their actual use.

(i) Food additives (Food Sanitation Act)

- General information on food additives
http://www.mhlw.go.jp/seisakunitsuite/bunya/kenkou_iryoku/shokuhin/syokuten/index.html
 - List of designated additives
<http://www.ffcr.or.jp/zaidan/MHWinfo.nsf/a11c0985ea3cb14b492567ec002041df/407593771b8750e94925690d0004c83e?OpenDocument>
 - List of additives utilization criteria
<http://www.ffcr.or.jp/zaidan/MHWinfo.nsf/a11c0985ea3cb14b492567ec002041df/980837ba5d9b0d28492575d6000785e6?OpenDocument>
- (ii) Feed additives (Act on Safety Assurance and Quality Improvement of Feeds)
- List of feed additives
http://www.famic.go.jp/ffis/feed/sub3_feedadditives.html
- (iii) Feed additives in the U.S.
- The Official Publication by the AAFCO (Association of American Feed Control Officials) includes the list of substances provided for in the federal law by the Department of Health and Human Services as “Additives & GRAS Substances*.”
 * GRAS Substances: Generally recognized as safe Substances
 - 21CFR 573, Department of Health and Human Services (Food Additives Permitted in Feed and Drinking Water of Animals)
<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=573>
 - 21CFR 582, Department of Health and Human Services (Substances Generally Recognized as Safe)
<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=582>
- (iv) Feed additives in EU (EC) No.1831/2003
- http://ec.europa.eu/food/food/animalnutrition/feedadditives/legisl_en.htm (Outline)
 - http://ec.europa.eu/food/food/animalnutrition/feedadditives/comm_register_feed_additives_1831-03.pdf

2. Adequacy of the use of additives

Based on the Codex General Standard for Food Additives, the use of food additives is justified only when such use has an advantage, does not present an appreciable health risk to consumers, and serves the technological functions including processing and storage, and the needs set out below, and only where these objectives cannot be achieved by other means:

(1) To preserve the nutritional quality of the food

Example: nutrient enhancement (vitamin and mineral), essential amino acids, essential fatty acid, omega-3 unsaturated fatty acid, etc.

(2) To provide necessary ingredients or constituents for foods manufactured for groups of

consumers having special dietary needs

Example: additives by use (minerals), dietary fiber for foods for cat furball care (those having physical effect such as cellulose)

- (3) To enhance the keeping quality or stability of a food or to improve its organoleptic properties(Provided that this does not change the nature, substance or quality of the food so as to deceive the consumer)

Example: gelator, thickener, antioxidant, preservatives, essence (flavor), seasoning, acidulant, emulsifier, pH adjuster, inflating agent, moisturizer, coloring substances, etc.

- (4) To provide aids in the manufacture, processing, preparation, treatment, packing, transport or storage of pet foods (Provided that the additive is not used to disguise the effects of the use of faulty ingredients or of undesirable practices or techniques during the course of any of these activities.)

This includes the processing aid in the case of food production (for example, antifoam agent used for making tofu). It is hardly used in the case of ordinary pet foods.

3. Points of notice for adequate manufacturing

- (1) Amount of the use of additives for which standards/specifications are unspecified under the Pet Food Safety Act should be set at the minimum amount necessary for obtaining the effect that is the purpose of use in the pet food.
- (2) Confirm that the additives used are of quality adequate for use in pet foods, and in the case of additives mixed with other ingredients, adjust so that they are mixed thoroughly and evenly.
- (3) Use by measuring the prescribed necessary amount for each manufacturing, and record the state of adding in the work (manufacturing) records.

* As for compositional specifications and manufacturing standards regarding additives, please refer to the brochure “For Securing Safety of Pet Foods”

(http://www.maff.go.jp/e/policies/ap_health/petfood/attach/pdf/index-1.pdf).

How to use "Checklist for Manufacturing Management/Quality Control Methods"

This checklist is merely an exemplification of the method of manufacturing management, quality control, etc. Please use the document as a reference for establishing a management system and for self inspection according to the reality of each company and working place. Examples are shown in the case of a manufacturer. As for importers and distributors, please use the document as a reference for establishing a management system and for self inspection in terms of common work contents.

Checklist for Manufacturing Management/Quality Control Methods

How to use

This document.

Here is the explanation on the structure of the checklist and how to use it.

Understanding the outline of manufacturing business

The manufacturer should understand and streamline the situation of manufactured item, manufactured volume, manufacturing process, structure (layout of manufacturing office), equipment instrument, and organization (manufacturing and management system, quality control system, etc.).

- [Outline of business]:	In addition to items such as the number of employees, understand and streamline the outline of the business base according to Annex 1-5 below, and at the same time understand the situation of the preparation of written standards and manuals
- [Annex 1. Organization/system chart]:	Understand and streamline the organization and system related to safety management
- [Annex 2. Overall view of the factory]:	Understand and streamline the structure and layout of factory related to safety management.
- [Annex 3. List of facilities]:	Understand and streamline facilities related to safety management.
- [Annex 4. List of ledger documents]:	Understand and streamline ledger and documents related to safety management.
- [Annex 5. List of products]:	Understand and streamline the manufactured item and the form of package.
- [Statement of process control]:	Understand and streamline the processes requiring safety management.
- [Statement of quality control]:	Understand and streamline the items requiring quality control.
- [Manual for the receipt and payment of ingredients]:	Understand and streamline the procedures for each process with process management criteria or quality control criteria.
- [Manual for reactions to be taken against incidents]:	Understand and streamline the procedures for ledger management, labeling management, reactions to be taken in case of an accident, and education and

— Collecting information and acquiring knowledge/skill on safety

Implement education and training for the purpose of collecting and streamlining information and acquiring knowledge on the safety of pet food that becomes necessary for manufacturing.

— Product standard document

Set specifications and standards necessary for safety management and document them.

— Manufacturing management

As for processes where safety management is required, manage the manufacturing according to the manufacturing management standards and work procedures at each process set forth in advance, and record the result.

— Quality control

As for items where safety management is required, control the quality according to the quality control standards and quality control procedure, and record the result.

— Ledger management

Make records so that it can be confirmed that work instructions, work records, order forms and the ledger in all processes from accepting raw materials to manufacturing and shipment are all mutually related and can be used to identify by tracing all the way to raw materials from the product. Also, specify the ledger and documents among them that are required to be recorded, equipped and stored under law, and keep them for the retention period specified under the law (two years).

— Labeling management

Prepare labeling based on the labeling standards specified under law.

— Manual for reactions to be taken against incidents

In case any accidents caused by the use of the pet food or the contamination of harmful substances in pet foods or raw materials occur, take reactions to minimize the health damage to pets.

Outline of business	Creation date	
	Confirma- tion date	

☐ 1. Understanding the outline of business

- No. of employees
About _____ persons

- Days of operation
About _____ days

- Hours of operation
AM : _____ - PM : _____

- No. of brands manufactured
About _____ brands

- Manufactured volume(select each unit)
Monthly production _____ kg ☐

☐ Daily production About _____ ton ☐

- Organizational chart As in the organization/system chart of Annex 1
- Overall view of the factory As in the overall view of the factory of Annex 2
- List of facilities As in the list of facilities of Annex 3
- List of ledger document As in the list of ledger documents in Annex 4
- List of products As in the list of products in Annex 5

☐ 2. Statement/manual of process control (adequate inadequate)

- Manufacturing plan (adequate inadequate)
- Receipt and payment of ingredients (adequate inadequate)
- Manufacturing (adequate inadequate)
- Shipment (adequate inadequate)
- Quality control (adequate inadequate)
- Labeling (adequate inadequate)

☐ 3. Statement/manual of quality control (adequate inadequate)

- Management of facilities and instruments (adequate inadequate)
- Management of ingredients (adequate inadequate)
- Product management (adequate inadequate)

☐ 4. Manual for ledger management (adequate inadequate)
 ☐ 5. Manual for labeling management (adequate inadequate)
 ☐ 6. Manual for reactions to be taken against incidents (adequate inadequate)
 ☐ 7. Manual for education and training (adequate inadequate)

Outline of business base (organization/system chart)	Creation date	
	Updated date	

Director and
Factory Manager

General Administration Division

Manufacturing Division
(Official responsible for manufacturing management)

Quality Control Division
(Official responsible for quality control)

Person in charge of ingredients acceptance

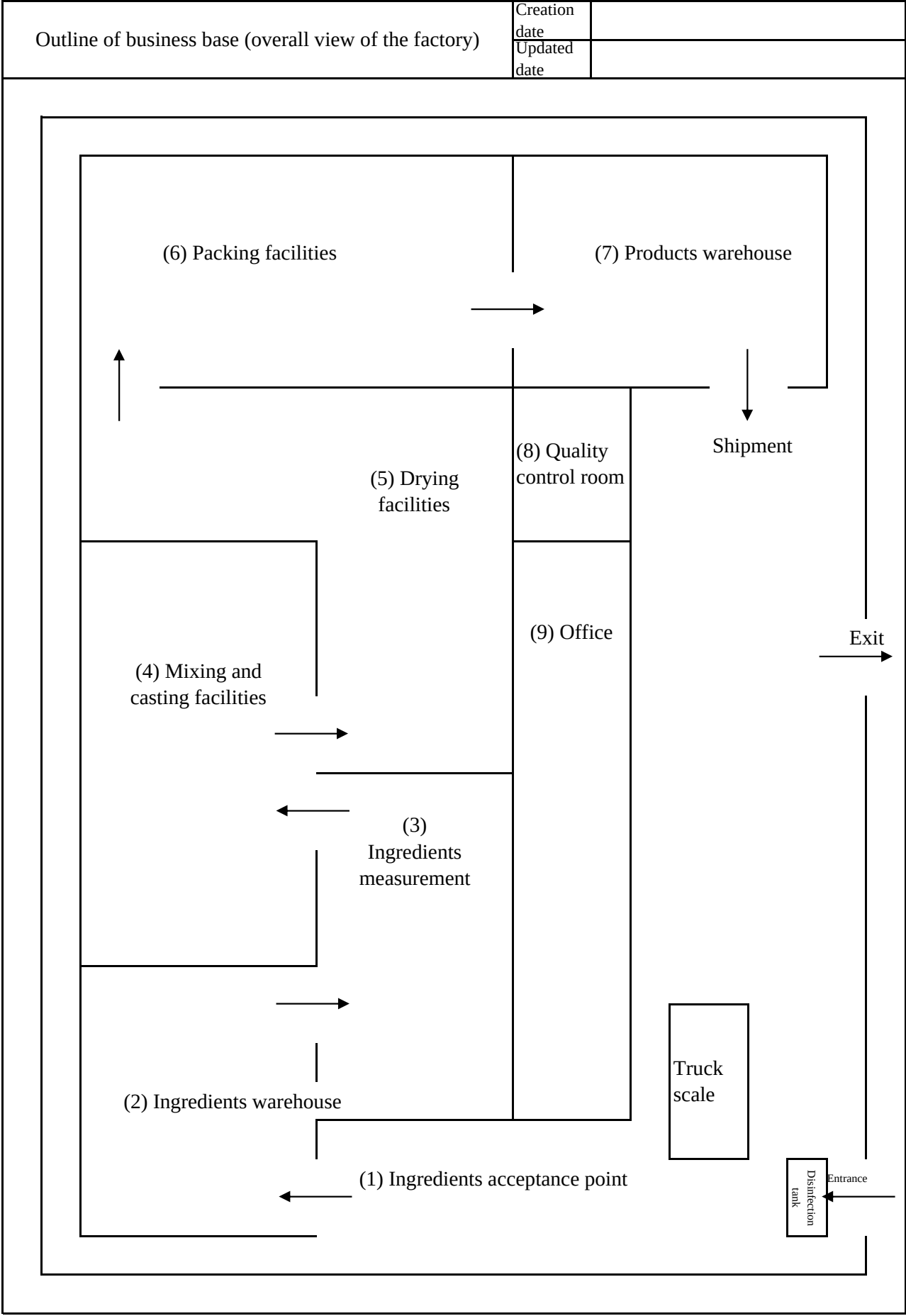
Person in charge of ingredients inspection

XXX, person in charge

XXX, person in charge

XXX, person in charge

XXX, person in charge



Outline of business base (list of facilities)			Creation date	
			Updated date	
Process	Name of facility	Specification, ability, set value	Administrator	Management method
(1) Ingredient s acceptanc e	Disinfection tank			Checkup of antiseptic solution amount at the opening time, replacement of antiseptic solution every Friday
	Truck scale	XX tons at maximum Error ± xx kg		Statutory inspection once every X months
(2) Storage of ingredien ts	Refrigerator	0 - 20°C, <u>10°C</u>		Checkup of temperature at the opening time
	Freezer	-20 - 0°C, <u>-5°C</u>		Checkup of temperature at the opening time
(3) Ingredien ts measure- ment	Measuring apparatus 1	Manufactured by XX Company, 20kg		Extraction check at the opening time and statutory inspection once every X months
	Measuring apparatus 2	Manufactured by XX Company, 500g		Extraction check at the opening time and statutory inspection once every X months
(4) Mixing and casting	Mixing machine	1 cubic meter		Regular inspection once every X months
	Casting facilities			Regular inspection once every X months
(5) Heating facilities	Heating facilities			Regular inspection once every X months
(6) Packing facilities	Packing facilities			Regular inspection once every X months
(7) Products storage	Refrigerator	0 - 20°C, <u>10°C</u>		Checkup of temperature at the opening time
	Freezer	-20 - 0°C, <u>-5°C</u>		Checkup of temperature at the opening time
(8) Quality control	Instrument			Regular inspection once every X months
	Storage of specimens	0 - 20°C, <u>10°C</u>		Checkup of temperature at the opening time

Outline of the business base (list of ledger documents)				Creation date	
				Updated date	
Process	Name of ledger documents	Storage space	Period (covered by law)	Affiliation and name of the person in charge	
Production plan	Specification for ingredients acceptance Determination of ingredients supplier Packing materials Manufacturing design (formula design) Manufacturing design (manufacturing method)	Bookshelf A in the office	Two years (law)	Manufacturing Division, XX	
Receipt and payment of ingredients	Confirmation at the time of accepting raw materials Disposal of non-conforming products				
Manufacturing	Management of production facilities Written manufacturing instructions				
Shipment					
Quality control					
Labeling					

Outline of business base (products list)		Creation date	
		Updated date	
Name	Type	Packing format	Labeler
XX Pet Food for Adult Dogs Containing Small Fish, 1kg Bag Type	Dry	1kg PP bag	XX Pet Co., Ltd.

Statement of process control		Creation date	
		Updated date	
Process	Details of business	Process control criteria	
Production plan	Determination of specification for accepting ingredients Determination of ingredients supplier Packing materials Manufacturing design (formula design) Manufacturing design (manufacturing method)	Set ingredients specifications that comply with the standards/specifications of the Pet Food Safety Act. Confirm that specifications for ingredients acceptance are fulfilled. Confirm that the labeling complies with the standards of the Pet Food Safety Act. Confirm that the design complies with the standards/specifications of the Pet Food Safety Act. Also, confirm that additives for which standards/specifications are unspecified under the Pet Food Safety Act should be set at the minimum amount necessary for obtaining the effect that is the purpose of use in the pet food. Confirm that the manufacturing method (conditions of heating treatment, etc.) complies with the standards of Pet Food Safety Act.	
Receipt and payment of ingredients	Confirmation at the time of accepting ingredients Disposal of non-conforming products	Ingredients are accepted by checking the supplier and acceptance specification. Ingredients that are not compatible with acceptance specification are disposed as non-conforming products.	
Manufacturing	Management of production facilities Written work instructions Work records	Confirm the temperature conditions, time, etc. of heating treatment facilities, and record them in work records.	
Shipment			
Quality control			
Labeling			

Statement of quality control		Creation date	
		Updated date	
Process	Details of business	Quality control criteria	
Checkup of facilities and instruments	Checkup of testing facilities		
	Checkup of testing instruments		
Management of ingredients	Collection of specimen		
	Test implementation method		
	Test implementation frequency		
	Judgment standard/record		
Management of products	Storage of specimen		
	Collection of specimen		
	Test implementation method		
	Test implementation frequency		
	Judgment standard/record		
	Storage of specimen		

Manual for the receipt and payment of ingredients		Creation date	
		Confirmation date	
Result of the checkup of facilities at the opening time		Result of the checkup of ledger, work instruction, and records	
☐ Disinfection tank (adequate inadequate) ☐ Refrigerator (adequate inadequate) ☐ Freezer (adequate inadequate) ☐ Measuring apparatus 1 (adequate inadequate) ☐ Measuring apparatus 2 (adequate inadequate)		☐ List of ingredients (adequate inadequate) ☐ Invoice (adequate inadequate) ☐ Record of items inspection (adequate inadequate) ☐ Warehouse acceptance form (adequate inadequate) ☐ (adequate inadequate)	
Work procedures for the receipt and payment of ingredients			
Operation procedure	Details of business	Person in charge	Related forms
Acceptance	- Issuance of the list of ingredients acceptance	(in full name)	List of ingredients acceptance
	- Checking the list of raw materials acceptance, invoice, and ingredients	(in full name)	Invoice, ingredients specification
Items inspection	- Issuance of sampling directions	(in full name)	Sampling directions
	- Items inspection	(in full name)	Record of items inspection
	- Carry-in to warehouse	(in full name)	Lot label
Withdrawal	- Issuance of the list of ingredients withdrawal	(in full name)	List of ingredients withdrawal
Report			
Reactions to be taken at the time of malfunction			
If any malfunction arises during the process, the details of the malfunction are reported to the official responsible for manufacturing management to receive instruction. - Details of malfunction - Instruction After taking reactions according to the instruction, report the details to the official responsible for manufacturing management. - Record of the result of reaction			

*** Prepare procedure manual for each process.**

Manual for reactions to be taken against incidents		Creation date	
		Confirmation date	
Result of the checkup of ledger, work instruction, and records			
☐ (adequate inadequate) ☐ (adequate inadequate) ☐ (adequate inadequate) ☐ (adequate inadequate) ☐ (adequate inadequate)			
Work procedures for reactions to be taken at the time of malfunction			
Operation procedure	Details of business	Person in charge	Related forms
Occurrence of incident	- Confirm the details of the incident	(in full name)	
Report	- Report to the official responsible for manufacturing management * Promptly contact the administrative agency in case of a grave incident	(in full name)	
Confirm	- Identify the lot in question	(in full name)	
Treatment	- Discontinuation of use and selling, collection, and storage - Information provision and request to relevant parties - Installation of consultation desk	(in full name) (in full name) (in full name)	
Cause investigation	- Cause investigation, consideration of remediation measures	(in full name)	
Report	- Report to the administrative agency	(in full name)	

Examples of Checklist for Pet Foods Importers

Do not start the import procedure or selling before the confirmation by the responsible officer.

1. Outline of imported product

Product name	
Country from which the product is imported	
Country of origin (country where the finishing process making substantial change was completed)	

2. Items to be confirmed before import

		Responsible officer	Division head in charge	Person in charge
	Items to be confirmed	Date	Confirmed by	Remarks
Ingredients	Ingredients including harmful substances or being contaminated by pathogenic microorganisms, or having a risk of including or being contaminated by them are unused.			
	In the case of foods for cats, propylene glycol is unused as a ingredients.			
	Ingredients do not include components that exclusively fall under pharmaceuticals (when it cannot be determined, make inquiries to prefectures.			
Production method	When being heated or dried, a method having sufficient effect in removing microorganisms coming from ingredients, etc. that may exist and develop in the pet food is taken.			
	Confirm the product specification or production flow chart used by the manufacturer and confirm the outline of the production method.			
Labeling	Product name (make distinctions between for dogs and for cats)			

	Name of the ingredients (State all ingredients used. Be careful not to omit showing the purpose of additives.)			
	Best-before date (When the product is repacked, the repacking business operator should make adequate labeling based on a scientific and rational basis.)			
	Name and address of the manufacturer, importer or distributor (“co-packed by” or “sold by” are not allowed)			
	Name of the country of origin (country where the finishing process making substantial change was completed)			
	Other (Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices, Act against Unjustifiable Premiums and Misleading Representations, Pet Food Fair Competition Code, etc.)			
End product	Fulfills the standards/specifications based on analysis made according to the “Inspection Method for Pet Foods” (21 Food and Agricultural Materials Inspection Center No. 1764, Notification by the President of FAMIC: hereinafter referred to as the “Official Method”)			
	Fulfills the standards/specifications based on analysis other than those according to the Official Method (requires separate confirmation by the Official Method)			
	Inquiries to Regional Agricultural Administration Offices, etc. on the labeling standards under the Pet Food Safety Act (where necessary)			
	Inquiries to the Animal Products Safety Division (Pharmaceutical Affairs Inspection Team) of the Ministry of Agriculture, Forestry and Fisheries on the labeling regarding the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices (where necessary)			
	Other (necessity of animal quarantine and plant quarantine, etc.)		With or without	

3. Items to be confirmed after import

Responsible officer	Division head in charge	Person in charge

Items to be confirmed	Date	Confirmed by	Remarks
Confirmation of conformity to quality standards (in-house standards)			
Frequency of inspection by the Official Method to confirm the conformity to standards/specifications under the Pet Food Safety Act (schedule)	○ By each lot		
Confirmation of conformity to labeling standards (Product name, names of ingredients, best-before date, name and address of the business operator, name of the country of origin)			

* Includes mainly the items necessary based on the Pet Food Safety Act. Please use by adding check items related to other laws as necessary.

Please also refer to the brochure of the Pet Food Safety Act and Q&A available on the website.
http://www.maff.go.jp/e/policies/ap_health/petfood/index.html

Examples of Checklist for Pet Foods Distributers

Business operators engaged only in the sales of pet foods do not have the obligation to submit notification under the Pet Food Safety Act. However, they must sell pet foods that fulfill labeling standards, compositional standards and standards for production methods.

Please also refer to the brochure of the Pet Food Safety Act and Q&A available on the website.

(<http://www.maff.go.jp/j/syouan/tikusui/petfood/>)

It is necessary to submit notification as a manufacturer for unpacking pet foods and selling them after re-packing in small portions.

Checking items

	Items to be confirmed	Date	Confirmed by	Remarks
Time of	Confirm that the product fulfills the compositional standards and standards for production method under the Pet Food Safety Act. (E.g. Confirm with production specification)			
Labeling of packaging materials	Product name (make distinctions between for dogs and for cats)			
	Name of the ingredients			
	Best-before date			
	Name and address of the manufacturer, importer or distributor			
	Name of the country of origin			
	Other (Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices, Act against Unjustifiable Premiums and Misleading Representations, Pet Food Fair Competition Code, etc.)			

* Includes mainly the items necessary based on the Pet Food Safety Act.

Please use by adding check items related to other laws as necessary.