Notification and Record-Keeping Manual Based on the Pet Food Safety Act

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Animal Products Safety Division
Food Safety and Consumer Affairs Bureau
Ministry of Agriculture, Forestry and Fisheries
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This manual summarize the following information important for pet food producers, importers and sellers:
(1) matters to be considered when producing, importing and selling pet food,
(2) appropriate methods of fulfilling notification requirements and
(3) appropriate methods of generating and retaining records.
Please direct any questions to a Regional Agricultural Administration Office, etc.
This manual will be revised as needed to make it easier for pet food business operators to understand.

For inquiries about the Pet Food Safety Act, please contact a Regional Agricultural Administration Office, etc.
I. Introduction
1. Overview of the Pet Food Safety Act
   (1) Background to the establishment of the Act
   In March 2007, many dogs and cats in the United States experienced health problems after consuming melamine-contaminated pet food. Because the product concerned had been exported to Japan, it was recalled by the responsible parties and pet food safety issues received a great deal of coverage in newspapers and other media outlets. In response to these incidents and to ensure pet food safety and protect pets from health issues, the “Act on Ensuring the Safety of Pet Animal Food” (Act No. 83 of 2008) (commonly known as the “Pet Food Safety Act”) was enacted in June 2008 and came into effect on June 1, 2009.
   
   (2) Outline of the Act
   The Pet Food Safety Act is outlined in the diagram below. Pet food producers, importers and sellers (hereinafter referred to collectively as “pet food business operators”) are required to comply with the pet food standards and specifications provided by the Japanese government (i.e., the Minister of Agriculture, Forestry and Fisheries and the Minister of the Environment). Please note that “pet animal food” as defined in the Act refers to food for dogs and cats. In addition, pet food business operators are required to fulfill notification and record-keeping requirements.
① Requirements related to pet food production, import and sale

To ensure pet food safety, the Pet Food Safety Act stipulates that the Japanese government is authorized to:

i) establish standards for pet food production methods and labeling as well as pet food component specifications and prohibit illegal pet food production, import and sale (Articles 5 and 6),

ii) prohibit pet food production, import and sale in case of emergency (Article 7),

iii) order pet food recall/disposal (Article 8) and

iv) request that pet food business operators provide information and conduct on-site inspections of their facilities (Articles 11 and 12).

② Notification and record-keeping responsibilities

To enable the Japanese government to obtain information about pet food business operators in advance and promptly order them to recall/dispose of their pet food products as needed, the Pet Food Safety Act requires pet food producers and importers to fulfill:

i) notification requirements (Article 9) and

ii) record-keeping requirements (except for retailers who sell pet food directly to consumers) (Article 10).

③ Responsibilities to be fulfilled by pet food business operators

The Pet Food Safety Act provides requirements for pet food business operators and the Japanese government to ensure pet food safety.

Specifically, pet food business operators have the primary responsibility to ensure pet food safety by acquiring knowledge and skills related to pet food safety, ensuring the safety of pet food ingredients and recalling pet food products as needed (Article 3). In addition, the Japanese government shall strive to collect and provide appropriate information to ensure pet food safety (Article 4).

To ensure pet food safety, it is extremely important that governmental administrative agencies, pet food business operators, pet owners and veterinarians, etc. share information regularly.
II. Important notes for pet food producers, importers and sellers

The Pet Food Safety Act stipulates that standards for pet food production methods and labeling as well as pet food component specifications shall be established by the Japanese government after consultation with the relevant advisory panels to protect pets from pet food-related health problems. Once these standards and specifications are established, production, import and sale of pet food which does not comply with them will be prohibited. In addition, during emergency situations in which pet food products contaminated with harmful substances are found to have been distributed, the Japanese government is authorized to prohibit production, import and sale of the products. When prohibited pet food products are found to have been distributed, the government is empowered to order their recall and disposal.

The Japanese government and the Food and Agricultural Materials Inspection Center (FAMIC) request that pet food business operators provide information and conduct on-site inspections of their facilities in order to ensure compliance with the required standards and specifications.

We ask pet food business operators to comply with these standards and specifications and to cooperate during on-site inspections.

Note: FAMIC (the Food and Agricultural Materials Inspection Center) is an independent administrative agency responsible for performing inspections and analysis of food and feed products.

III. Notification requirements for pet food business operators

1. Purpose

When pet food products are found to violate standards and specifications established by the Japanese government after their production and/or shipment, the government is authorized to prohibit their further production and order their recall and disposal.

For the government to prepare for these situations, it needs to ascertain in advance the locations at which pet food products are produced/imported and types of products produced/imported. To facilitate this process, pet food producers and importers are required to promptly submit business-related information, such as their names and locations, to the Regional Agricultural Administration Offices, etc. in prefectures in which their offices are located.

For inquiries about the Pet Food Safety Act, please contact a Regional Agricultural Administration Office, etc.

2. Pet food business operators subject to notification requirements

Business operators are required to provide notice before producing or importing commercial pet food products. Those meeting the conditions specified in (1) and (2) below are required to provide written notification. Business operators intending to both produce and import pet food need to provide separate notification for each activity.

Business operators responsible for ensuring the safety of pet food products must coordinate the recall and/or disposal of such products in the event of accidents, etc. regardless of the notification requirements.

Terms used in this section are defined below.
① Sale
   Unless otherwise noted, “sale” includes wholesale and retail sale and the distribution of free samples.

② Commercial pet food
   “Commercial pet food” refers to food intended for consumption by dogs and cats packaged in bags, cans, retort pouches, etc. for sale. Pet food produced and fed to dogs in “dog cafes” (a type of cafe in Japan which allows people to bring in their pet dogs) is not considered to be a commercial product. However, pet food produced and packaged in dog cafes which is then consumed elsewhere is considered to be a commercial product.

③ Ingredients
   Materials to be processed (e.g., ground, mixed, heated, shaped and dried) into pet food products

④ Final product
   An edible portion of a commercial pet food product

⑤ Production
   Processes by which ingredients are converted into final products and packaged for sale (in bags, cans, retort pouches, etc.). During packaging, final products come into direct contact with handlers. The definition also includes the division of an already produced or imported commercial pet food product into smaller portions and repackaging of it for sale as a different product.

⑥ Distribution processing
   Refers to supplemental processes applied to commercial pet food products which are not considered to be production processes (i.e., processes which do not fundamentally alter the shapes and properties of final products).
   (Examples) labeling, mending and reinforcing packaging materials and combining various products into an assortment

⑦ Import
   Refers to “import” as defined in Article 2, paragraph (1), item (i) of the Customs Act (Act No. 61 of 1954) and means reception of goods in Japan which were shipped from other countries. Goods required to pass through a bonded area are considered to be received in Japan after this process is completed.

⑧ Business operators
   Individuals and corporations which intend to produce, import or sell products on a continuous basis. Even where said individuals and corporations have actually engaged in these activities only once, they are considered to be business operators if they intend to do so continuously.

(1) Commercial pet food producers
   Business operators who produce all or part of their commercial pet food in Japan. They are considered to be commercial pet food producers even if they export all of their commercial pet food products.
As described in “1. Purpose” above, the notification requirements were established to help the Japanese government identify locations at which pet food products are produced and types of products produced. Notification requirements for pet food business operators vary depending on the specific conditions listed below (please also refer to the flow chart below).

1 Business operators that engage in any of the following activities are required to register as pet food producers.
   a. Purchase and processing of ingredients and packaging of products for sale
   b. Packaging of individual or mixed pet food products (in particles or in another form) produced by other business operators
   c. Production of pet food for other business operators (e.g., original equipment manufacturers (OEMs))
   d. Production of commercial pet food by repackaging food intended for human consumption (e.g., nimoshi (a small fish boiled and then dried) and bolo (a type of confection))
   e. Conversion of already produced or imported pet food into different types of commercial pet food (e.g., products containing smaller amounts of pet food) through various packaging processes
   f. Division into smaller portions, repackaging and sale of already produced or imported pet food

2 Business operators are not required to register as pet food producers where they:
   a. produce pet food exclusively overseas;
   b. produce only ingredients;
   c. commission other business operators (e.g., original equipment manufacturers (OEMs)) to produce all of their pet food;
   d. specialize in distribution processing, such as labeling, mending and reinforcing packaging materials and combining various products into assortments;
   e. produce pet food at the locations of their own shops, dog cafes, pet hotels (boarding kennels), etc., to be fed to pet animals at the locations (producing pet food for consumption elsewhere requires registration as a pet food producers); or
   f. sell a portion of already produced or imported pet food products at their shops (including portions which are wrapped casually for consumption elsewhere).

(2) Commercial pet food importers
   This category includes business operators who import commercial pet food to Japan. They fall under this category even if they later export all of the imported pet food.
   As with pet food producers, the notification requirements for pet food importers were established to enable the Japanese government to ascertain locations at which pet food products are imported and types of products imported. Notification requirements for pet food business operators vary depending on the specific conditions listed below (please also refer to the flow chart below).

1 Business operators are required to register as pet food importers where they:
   a. import pet food produced at their factories overseas for sale in Japan (i.e., goods importers); or
b. import bulk or packaged pet food produced or sold overseas (including pet food sellers who import the goods they sell).

② Business operators are not required to register as pet food importers where they:
   a. import only ingredients used to produce pet food in Japan (producers of commercial pet food are also required to register as pet food producers in addition to registering as pet food importers);
   b. are freight forwarders, etc. specialized in import customs clearance;
   c. are transport and warehousing specialists who handle imported commercial pet food at the request of pet food importers; or
   d. are import agents (e.g., import companies) that import commercial pet food produced or sold overseas at the request of pet food sellers in Japan and that are not considered to be importers of goods for customs clearance purposes.

**Questions to Determine Pet Food Business Operator Notification Requirements**

(1) For pet food producers

- Do you produce only ingredients?  
  - Yes: Notification not required  
  - No

- Do you process ingredients and perform all or part of the packaging process (including division into smaller portions)?  
  - Yes: Notification required
  - No: Please inquire about your specific situation.

- Do you produce pet food by repackaging food intended for human consumption?  
  - Yes: Notification not required
  - No

- Do you only perform processes which do not fundamentally alter final products (e.g., labeling, mending of packaging materials)?  
  - Yes: Notification not required
  - No

*Overseas pet food business operators (manufacturers and exporters) are NOT required to make a notification.*
3. Types of information to be submitted

The notification form to be submitted by commercial pet food producers and importers (Form 1) can be downloaded from the “Pet food safety” page of the MAFF site (http://www.maff.go.jp/e/policies/ap_health/petfood/index.html). Example answers are provided in Form 1.

Business operators who both produce and import pet food are required to submit separate notifications for each activity. The types of information to be submitted are described in detail below (please also consult the examples of completed forms found from p. 9 onward).

① Name and address

If you represent a corporation, please submit your notification along with one of the following forms (photocopies are acceptable) enabling us to confirm the corporation name, the title and name of the representative person and the name and address of the main office (i.e., the registered headquarters): certificate of registration, extract of the certificate of registration, certificate of all (partial) present matters or certificate of all (partial) historical matters.

If you are an individual business operator, please submit notification along with one of the following forms (photocopies acceptable) enabling us to confirm your name and address: official transcript of the residence certificate, official transcript of the family register, extract of the family register, certificate of all family register matters, certificate of personal matters or official copy of
the foreign resident registration ledger.

Each of the abovementioned forms used to confirm your name and other information is hereinafter referred to as a “registration certificate, etc.”

Where the address provided in the notification form (i.e., the address of the headquarters and branch offices, etc. of a corporation or the home address of an individual business operator) differs from the address provided in the registration certificate, etc., please submit notification accompanied by the registration certificate, etc.

Please enclose a cover letter correctly formatted in accordance with the requirements for submission of notification (for submissions by mail), a business card or notes, etc. on which the name, phone number, fax number and email address of the representative person are written to facilitate our review of information submitted by business operators and to enable us to obtain contact information in cases of emergency.

② Name and address of pet food production facility (applicable only to pet food producers)

Where more than one pet food production facility exists, please list all production facilities on the same notification form. Where facilities do not have names, please indicate what they are generally called (e.g., the main factory, etc.).

③ Addresses of shops and pet food storage facilities

Where multiple shops and pet food storage facilities exist in different locations, (e.g., the main shop, branch shops and business offices, etc.), please list them in the manner described in ②.

“Shops” refers to places of business operated on a for-profit basis.

Pet food is stored in storage facilities, such as commercial warehouses. A pet food storage facility may be owned by a pet food producer or a contractor. Where pet food producers and importers outsource packaging and distribution processing to other parties, these parties’ facilities are considered to be pet food storage facilities.

Where a regularly used warehouse becomes temporarily unavailable due to an accident or renovation, business operators are allowed to use unregistered storage facilities without submitting notification. However, business operators are responsible for ensuring proper management of such temporary facilities.

④ Types of pet animals for which pet animal food products are produced or imported

Pet food products should be appropriately labeled with the type of animal they are intended for the consumption of (e.g., “dogs” or “cats”). For example, where a corporation both produces and imports pet food for dogs, but only imports pet food for cats, please write “dogs” in the notification form for producers and “dogs and cats” in the notification form for importers.

⑤ Date on which production or import is initiated

Please write the date scheduled for initiating production or import for business purposes.

⑥ Pet animal food produced for export

If none of the pet food produced is for export, please write, “No products for export.”

If any or all pet food produced is for export, please write, “some products are for export,” or, “all products are for export,” accordingly. This arrangement allows us to track cases in which pet food products produced in Japan and exported to other countries are imported back into Japan.
4. Submission deadlines

(1) Those intending to produce or import pet food

Please submit notification before engaging in these activities.

(2) Those intending to modify previously submitted information, cease engaging in business or assume the business of another

Business operators may encounter the following situations after submitting notification of the production or import of pet food (as in (1) above), modifying information previously submitted or assuming the business of another:

i) information submitted requires further updating

ii) the business operator ceases engaging in business

iii) the business operator assumed the business of another as a result of the transfer, inheritance, merger or demerger of business.

Business operators experiencing any of these situations are requested to submit notification along with a registration certificate, etc. within 30 calendar days after the day following the day of their occurrence (e.g., when an event takes place on April 1, the submission deadline is May 1). Please find examples of completed forms from p. 9.

Business operators that have already submitted notification of the intention to produce or import pet food and are considering another business involving the production or importation of pet food are requested to submit another notification before engaging in these activities as described in (1) above.

5. Where to submit your information

Please submit your information to the Regional Agricultural Administration Office, etc. in the prefecture in which your main office (e.g., headquarters) is located.

Please mail the original document and one copy of the original document (a photocopy is acceptable). If you would like to receive a copy for your records, please enclose another copy and self-addressed stamped envelope with the original document. Alternatively, you can physically deliver these documents to the office.

For inquiries about the Pet Food Safety Act, please contact a Regional Agricultural Administration Office, etc.


(Note) If you are unable to meet a submission deadline, please consult beforehand with the Regional Agricultural Administration Office, etc. to which you intend to submit your information.
IV. Generating and retaining records

1. Purpose
As described in III-1 above, when pet food products are found to violate standards and specifications after shipment, the Japanese government is authorized to order their recall and disposal. For pet food business operators to prepare for these situations, they need to retain records related to their production, import and sales activities.

2. Conditions that require record-keeping
   ① Pet food producers/importers are required to keep records of the production/import of commercial pet food.
   ② Pet food producers, importers and sellers are required to keep records of transfers of commercial pet food to other pet food producers, importers or sellers.
   “Transfer” under ② above means sales to other producers, importers or sellers. This definition is valid even when intermediate parties—such as transport/warehouse service providers and trading companies that pay on behalf of sellers—are involved. The movement of products to and between intermediate parties does not constitute “transfer,” but transferors should establish a system enabling them to trace the movement of products between intermediate parties to prepare for potential recalls. Reception of a product by the intended recipient marks the completion of a “transfer.”
   “Pet food sellers” refers to business operators that sell, but do not produce or import, commercial pet food. They include wholesalers, home improvement retailers, supermarkets and veterinarians that carry commercial pet food.
   Pet food sellers are required to keep records of transfers of commercial pet food to other pet food sellers (e.g., a transfer between wholesalers, from a home improvement retailer to a supermarket or between veterinarians). Pet food sellers are not required to keep records of sales to customers (i.e., transfers of products to consumers).
   Sales of pet food ingredients and the sending of pet food to packaging service providers do not constitute “transfer.”

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**Where the Ledger is Necessary**

- Manufacturer/Importer
- Warehouse
- Carrier
- Distributor
- Wholesaler
- Retailer
- Pet owner

- Transfer: O: Ledger is necessary, X: Ledger is unnecessary
- Payment
- E.g., Commission agent
- Transfer (selling) among wholesalers
- The date of transfer is the timing at which the distributor receives the product.
3. Types of records to be kept

(1) When producing pet food (applicable only to pet food producers)
   ① Pet food name, quantity and production date
      A. Name
         Brand name (e.g., “X pet food for adult dogs containing small fish, 1 kg”)
      B. Quantity
         Quantity of each lot (e.g., “X kg,” “X number of X-kg bags”)
      C. Production date
         Date on which pet food was produced

   ② Names and amounts of ingredients
      Please provide the names and amounts of ingredients used to produce pet food products indicated in ① above. Ingredients should be recorded in a manner enabling easy comparison with product labels in the event of accidents or other emergency situations.
      Delivery slips, etc. may be used as records of ingredient usage. Even if the slips provide abbreviated or other generic forms of ingredient names, their use is acceptable as long as these names are easily comparable with the ingredients listed on product labels.
      When you use ingredients which were transferred to you (i.e., ingredients purchased from another business operator), please record names and amounts of said ingredients as well as the purchase dates and names of the vendors.
      Although no legal obligation to keep records of ingredient producers and countries of origin exists, it is desirable for pet food producers to do so to facilitate investigation into the causes of product-related problems.

(2) When importing pet food (applicable only to pet food importers)
   ① Name, quantity, production date and packaging appearance of imported pet food
      To properly record the names and quantities of imported pet food products, please refer to (1)① above. The date of import is the same as the import approval date provided on an issued import permit.

   ② Country and source from which pet food was imported
      The import source is the same as the exporter provided on an issued import permit.

   ③ Country in which imported pet food was produced, producer and ingredients of imported pet food
      Please record “country in which imported pet food was produced” and “ingredients of imported pet food” in the manner described in (1)② above to enable easy comparison of these records with the country of origin and ingredients written on product labels. You may use delivery slips, etc. as records of this information. Use of such slips is acceptable even where they only provide abbreviated or generic names if these names are easily comparable with the country of origin and ingredients provided on product labels.

(3) When transferring pet food products to other pet food producers, importers or sellers (applicable to all pet food business operators)
   ① Name and quantity of transferred pet food
      A. Name
Brand name (e.g., “X pet food for adult dogs containing small fish, 1 kg”)

B. Quantity
Quantity involved in each transaction (e.g., “X kg,” “X number of X-kg bags”)

② Name of the pet food transferee, date of transfer and appearance of transferred pet food packaging
Please record this information as described under ① above for each pet food transfer. “Date of transfer” refers to the date on which the intended producer, importer or seller received transferred pet food products.

③ When distributing free samples
Records are required to be kept of free samples distributed to pet food sellers (including veterinarians, etc.). It may be difficult to maintain records of free samples distributed where no delivery slips are issued. If delivery slips are not issued, this record-keeping requirement may be satisfied by preparing a list of pet food sellers to which free samples may be distributed and retaining it at the business office. When products are transferred from a warehouse to a business office, leading to issuance of a delivery slip, a record of the transfer is required to be kept using the usual record-keeping procedure.

4. Record-keeping methods, record retention period, etc.
In principle, records should be kept using notebooks or computers. Alternatively, the record-keeping obligations can also be met by retaining various documents related to business operations, such as ingredient specification documents, product specification documents, ingredient delivery slips, product sales slips, product receipts, import permits and invoices.
Hardcopy and electronic records are required to be retained for two years.
In principle, hard copies of records are required to be retained at every office and facility. If some facilities (e.g., a public warehouse used to store imported goods) are unsuitable for the retention of records, they may be retained at the business office or headquarters with authority over the facility. In such a case, please inform FAMIC, etc. of your record-keeping practices and locations at which records are retained when it conducts on-site inspections.
On-site inspections of pet food business operator facilities

—Responsibilities of business operators—

The Japanese government or the Food and Agricultural Materials Inspection Center (FAMIC) inspects the facilities of pet food business operators to determine whether their pet food production, import and/or sales activities are in compliance with the relevant standards and specifications. Please be aware of the following concerning the inspection procedure.

- On-site inspections based on the Pet Food Safety Act are carried out without advance notice.
- An observer—who should be familiar with specifics of pet food production, import and/or sales activities—is required to be present during the inspection.
- The observer will be asked to sign and affix his/her seal to inspection reports.
- Compensation equivalent to market prices, etc. will be paid for pet food products sampled during on-site inspections. If you choose to decline compensation, please submit an application form.
- Test results for pet food samples taken during on-site inspections will be publicized, including the name and address of the pet food business operator, types and names of pet food products, test results and violations, if any.