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(Provisional Translation)

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Food Safety and Consumer Affairs Bureau No. 2236

Nature Conservation Bureau Notice No. 090529009

May 29, 2009

Amendment

Food Safety and Consumer Affairs Bureau No. 5294

Nature Conservation Bureau Notice No. 1402241

February 24, 2014

To: Directors of the relevant organizations

Director-General, Food Safety and Consumer Affairs
Bureau, Ministry of Agriculture, Forestry and Fisheries

Director-General, Nature Conservation Bureau, Ministry
of the Environment

Concerning the Enforcement of Act on Ensuring the Safety of Pet Food

Act on Ensuring the Safety of Pet Food (Act No. 83 of 2008, hereinafter the “Act”) has been enacted, and is to be enforced on June 1, 2009 together with the Government Ordinance Pursuant to Act on Ensuring the Safety of Pet Food (Government Ordinance No. 366 of 2008, hereinafter the “Government Ordinance”), the Ministerial Ordinance for Enforcement of the Pet Food Safety Act (Ordinance of Ministry of Agriculture, Forestry and Fisheries and Ministry of the Environment No. 2 of 2009, hereinafter the “Regulations”), the Ministerial Ordinance on Specifications and Standards of Pet Food (Ordinance of Ministry of Agriculture, Forestry and Fisheries and Ministry of the Environment No. 1 of 2009, hereinafter the “Ministerial Ordinance on Specifications and Standards”), the Ministerial Ordinance Concerning on-the-Spot Inspections, Etc., and Reports Stipulated in Article 13 of Act on Ensuring the Safety of Pet Food (Ordinance of Ministry of Agriculture, Forestry and Fisheries No. 31 of 2009, hereinafter the “FAMIC Ministerial Ordinance”), the Enforcement Ordinance Concerning the Use of Information Technology for the Storage, Etc., of Documents by Private Operators Related to Act on Ensuring the Safety of Pet Food (Ordinance of Ministry of Agriculture, Forestry and Fisheries and Ministry of the Environment No. 3 of 2009, hereinafter the “Information Technology Enforcement Ordinance”), the Ministerial Ordinance Providing for the Delegation of Authority to the Director-General of the Regional Agricultural Administrative Office Stipulated in Paragraph 1 of Article 16 of Act on Ensuring the Safety of Pet Food (Ordinance of Ministry of Agriculture, Forestry and Fisheries No. 32 of 2009, hereinafter the “Ministerial Ordinance on Delegation to Director-General of Agricultural Administrative Office”), and the Ministerial Ordinance Providing for the Delegation of Authority to the Director of the Regional Environment Office Stipulated in Paragraph 2 of Article 16 of Act on Ensuring the Safety of Pet Food (Ordinance of Ministry of the Environment No. 5 of 2009, hereinafter the

“Ministerial Ordinance on Delegation to the Director of the Environment Office).

In consideration of the aims of the new framework based on the Act and ordinances, the work of enforcing the Act shall be handled with the following being used as a reference. Please make members of your organization aware of this notice.

I. Aim of the Enactment of the Act

1. With the number of pets rising every year, reports of the health damage to pet animals caused by the use of pet food have increased in foreign countries, and there have also been cases of large-scale product recalls by pet food manufacturers outside Japan.
2. In Japan, ensuring the safety of pet food has also become a major issue in conjunction with the expansion of the pet food market. However, until now there have not been any laws or regulations. Therefore, the identification of causes and the resolution of problems were left up to voluntary measures in the pet food industry, and no effective measures had been developed for emergencies. Consequently, the damage to pets caused by pet food overseas could just have easily occurred in Japan.
3. Therefore, the Ministry of Agriculture, Forestry and Fisheries and the Ministry of the Environment jointly established the Study Group for Ensuring the Safety of Pet Food, at which the current situation of ensuring the safety of pet food and the need for a systematic response to ensuring safety was discussed. As a result, it was proposed that the necessary laws and regulations should be introduced covering each of the stages of manufacturing, importing and selling. Moreover, the results of a Japanese public attitude survey concerning the safety of pet food also supported the establishment of regulations on pet food, so the Act was enacted as a new Act for ensuring the safety of pet food.

II. Objectives and Definitions, Etc.

1. Objectives
The Act regulates the manufacturing, importing and selling of pet food by stipulating the specifications for the constituents of pet food as well as the standards for the methods of pet food manufacturing and labeling in view of the damage to pets' health caused by pet food that has arisen overseas. Through these regulations, the Act aims to ensure the safety of pet food, thus protecting the health of pets and contributing to animal welfare (Act , Article 1).
2. Pets
“Pet” refers to an animal specified by Cabinet Order that is taken care of for the purpose of being a pet (Act , Article 2, Paragraph 1). In relation to the need for regulations from the perspective of ensuring the safety of pet food, this refers specifically to dogs and cats in consideration of the proportion of pet food shipment volumes that each type accounts for (Government Ordinance, Article 1).
3. Pet Food
“Pet food” refers to that which is used for the purpose of providing nutrition to pets

(Act , Article 2, Paragraph 2). Mineral water, raw meat, snacks, gums, and supplements, etc., used for pets for this purpose are included in the definition of pet food.

Notwithstanding that drugs stipulated under Article 2, Paragraph 1, Items 2 and 3 of the Pharmaceutical Affairs Act (Act No. 145 of 1960) or quasi-drugs stipulated in Paragraph 2 of the same Article included under those recognized as used exclusively for animals (veterinary pharmaceuticals) shall not be covered by the Act . Items that an animal put in its mouth such as toys or pet food containers are not included as pet food because they do not provide nutrition to pets.

4. Manufacturers, Importers and Sellers

- (1) “Manufacturer” refers to a person engaged in the business of manufacturing pet food (includes compounding and processing) (Act , Article 2, Paragraph 3). “Includes compounding and processing” refers to processing pet food from raw materials through to final products and the process of filling the product into containers (bags, cans, retort pouches) for sale. Consequently, it also includes packaging process by opening and repacking manufactured or imported pet food to convert to other type of packages, such as subdividing into smaller volume products.
- (2) “Importer” refers to a person engaged in the business of importing pet food (Act , Article 2, Paragraph 3) “Importing” refers to taking charge of freight that is imported or arrives in Japan from a foreign country (arrives in Japan via a bonded area for items that pass through a bonded area) as stipulated in Article 2, Item 1 of the Customs Act (Act No. 61 of 1954)
- (3) “Seller” refers to a person engaged in the business of selling pet food who is not a manufacturer or an importer (Act , Article 2, Paragraph 3). “Person engaged in the business of selling pet food” refers to a person engaged in the business of transferring ownership rights to another person for a financial consideration and does not include a person engaged only in such acts as free distribution.
- (4) “Business” refers to a person intentionally engaging in the specified act (manufacturing, importing, or selling) repeatedly, and does not require the objective of profit. Moreover, there shall be no distinction between an individual person and a corporation.

5. Responsibility of Operators

The Act imposes regulations on operators, including the manufacturers, etc., of pet food, in order to ensure the protection of the health of pets. However, to truly secure product safety, it is not enough for operators to passively observe the bare minimum of the stipulated regulations. It is important that operators themselves bear the awareness and responsibility for taking timely and proactive measures to secure safety. The Act stipulates that the operators bear the primary responsibility for ensuring the safety of pet food (Act , Article 3).

Consequently, operators must carry out the manufacturing of pet food with adequate expertise and technology to ensure that harmful substances are not produced at the manufacturing stage. In the event that harmful pet food goes into distribution, operators must recall pet food and take other measures as soon as possible to prevent damage to the health of pets.

These measures are representative examples of the measures that operators should take. As the kind of measures that should be taken will vary depending on the business content of the operator, measures should, in principle, be implemented based on the independent judgment of each operator. Moreover, this is not to imply that measures other than these measures are not required.

6. Responsibility of the National Government

While it is important for operators themselves to proactively ensure the safety of pet food, the national government must also endeavor to collect, organize, analyze and provide information concerning the safety of pet food (Act , Article 4).

As pet food has not been regulated hitherto in Japan, the collection, etc., of information concerning the actual status of pet food manufacture and distribution in Japan and accidents caused by pet food, etc., has been inadequate. It is necessary for the smooth implementation of the Act that the national government proactively collects, organizes and analyzes information in and outside Japan and provides that information to manufacturers, importers and sellers of pet food as well as Japanese pet owners.

III. Regulation of Manufacturing, Etc., of Pet Food

1. Establishment of Standards and Specifications, Etc.

The establishment of standards and specifications forms the basis for ensuring the safety of pet food. From the perspective of preventing damage to the health of pets caused by the use of pet food, the Minister of Agriculture, Forestry and Fisheries and the Minister of the Environment may lay down standards for the methods of pet food manufacturing and labeling and specifications for the constituents of pet food, hearing the opinions of the Agricultural Material Council and the Central Environment Council (Act , Article 5).

In order to ensure the safety of pet food, it is first important that the manufacturers, importers, and sellers of pet food conduct the manufacture, import and sale of pet food in observance of the standards and specifications in the Ministerial Ordinance on Specifications and Standards.

2. Coverage of Standards and Specifications

From the perspective of preventing damage to the health of pets due to the circulation of pet food that contains harmful substances, standards and specifications shall be established for pet food for sale that is widely distributed.

“Pet food for sale” refers to pet food that is supplied for sale (refers to sale as specified in Item 1, Article 6 of the Act), and the following pet food shall be excluded (Ministerial Ordinance on Specifications and Standards, Appendix 1)

- (i) Pet food manufactured by a person for the purpose of supplying it to that person’s own pet.
- (ii) Pet food used by a pet at the site where the pet food is manufactured.

Description in (ii) above means that pet food supplied at a so-called dog café, etc., is not covered as it is not widely distributed.

3. Notes to the Ministerial Ordinance on Specifications and Standards

(1) Specifications for constituents of pet food (Ministerial Ordinance on Specifications and Standards, Appendix 1)

A person who manufactures, imports or sells the pet food for sale listed in Appendix 1 of the Ministerial Ordinance of Standards shall manage manufacturing rigorously to ensure that the pet food does not contain the substances listed in the same Appendix in excess of the stipulated content.

(2) Standards for methods of manufacturing of pet food (Ministerial Ordinance on Specifications and Standards, Appendix 2)

The following must be observed when manufacturing pet food for sale.

(i) Ingredients that contain harmful substances, that are contaminated with microbes, or that are suspected of any of these problems, shall not be used. “Harmful substances” and “microbes” refer to those that may damage the health of pets in relation to their properties or volume of content or contamination. “Harmful substances” could include mycotoxins, pesticides, heavy metals, and other harmful chemical substances while “microbes” may include pathogenic bacteria, etc.

(ii) In case of applying heat to or drying pet food for sale, the process shall be sufficiently effective to eliminate any microbes that are originated from raw materials, and then are present and can grow in the pet food. In this case, the proper temperature and time for heating, etc., must be used, taking into consideration the ingredients and containers or packaging of the pet food for sale.

(iii) Propylene glycol shall not be used in manufacturing pet food for sale for cats. Propylene glycol that originates in the raw materials for pet food for sale in a volume that is not expected to damage the health of cats shall not be covered by the regulations.

(3) Standard for labeling of pet food (Ministerial Ordinance on Specifications and Standards, Appendix 3)

Pet food for sale must be labeled with the items listed below. Of these, (a) through (c) shall be labeled from the perspective of preventing damage to the health of pets, and (c) through (e) shall be labeled from the perspective of identifying the product in the case of a problem arising. The items must be labeled in the Japanese language.

(a) Name of pet food

This refers to the product name of the pet food for sale, and it shall clarify whether the pet food is for dogs or cats.

(b) Ingredients names

In addition to the word “Ingredients,” all the ingredients (including additives) shall, in principle, be listed.

Ingredients other than additives may be labeled according to the category names listed in Appendix 1 of this document. Moreover, the individual names of the ingredients may be listed in parentheses following category names. In this case, ingredients that may change temporarily due to the adjustment of nutritional constituents, etc., can be abbreviated to “other” or “etc.”

All additives used as ingredients shall be listed as ingredients with the exception of processing aids. Processing aids refer to substances which are added to pet food during the processing process and which are removed before the completion of the pet food or which are changed by some of the raw materials of the pet food into ingredients such as those generally contained in the pet food without causing an evident increase in the total quantity of the ingredients, or ingredients whose quantity is so small as to have little impact on the pet food.

Moreover, additives used as substances listed in Appendix 2 of this document shall also be listed with the name for use listed in the same Appendix.

Notwithstanding that additives used as substances listed in Appendix 3 of this document may also be labeled with the collective names listed in the same Appendix.

The individual names of vitamins and minerals as nutritional supplement may be listed as a group in parentheses following the word “Vitamins” and “Minerals” respectively. Regarding the vitamin, either vitamin names or material (chemical) names may be labeled. Regarding the mineral, names of elements intended to add or material (chemical) names may be labeled.

In the case of can products with a content volume of 100g less and products with an available area for labeling of 120cm² (approx. 18 square inches) or less, nutritional supplement names can be abbreviated to vitamins, minerals and amino acids.

(c) Best before date

“Best before date” shall mean a date expressing the time period until the end of which all expected quality of the product is expected to be maintained. However, there may be some cases in which that quality is maintainable beyond the relevant term. In addition to the words “Best before date,” the day, month and year, or the month and year shall be labeled. In the case of labeling the month and year, quality must be maintainable until the final day of the relevant month.

A manufacturer or other operator who has accurately assessed data on pet food for sale, shall establish the “best before date” properly based on scientific and reasonable grounds. In the case that a seller, etc., opens the container or packaging of pet food for sale, the relevant seller, etc., shall respond in an appropriate manner by considering whether it is necessary to change the best before date of the relevant pet food for sale.

(d) Name and address of manufacturer, importer or seller

The label shall include the category of the operator as well as the name and address of the person with the responsibility for the content of labeling. The labeling of the operator category shall be “manufacturer,” “importer,” or “seller.”

(e) Country of origin

In addition to the words, “Country of origin,” the country where the final process of the manufacturing process of the pet food for sale was completed shall be labeled. Final process does not include acts that do not cause substantial change on the pet food for sale such as packaging or assorting. In the case that the country of origin of the pet food is Japan, it may also be only labeled made in Japan (*kokusan*).

4. Prohibition on Manufacture

- (1) No person shall manufacture, etc., pet food that does not meet the standards and specifications (Act , Article 6). No one is exempt from the regulations, and they are not limited to manufacturers, importers and sellers. This means that in order to ensure the safety of pet food, even if actions do not come under the definition of business, or one-off manufacture, etc., without the intention of repetition, things that do not meet the relevant standards and specifications must be regulated.
- (2) The manufacture of pet food by a method that does not meet the relevant standards in order to supply it for sale shall be prohibited from the perspective of preventing its distribution.

The definition of “sale” includes supply other than by sale to unspecified or a number of persons (Act , Article 6, Paragraph 1). Such supply is conducted on a regular basis, and has to be covered by the regulations to eliminate the possibility of the widespread distribution of harmful pet food.

Supply included in sale refers to the following.

- (i) Supply other than sale to unspecified or a number of persons, including the widespread free distribution of new products for purposes of promoting the new products of manufacturers through such channels as appointed retail stores, etc., of the manufacturer.
- (ii) Supply stipulated by Ordinance of Ministry of Agriculture, Forestry and Fisheries and Ministry of the Environment as equivalent to (i), which is supply to specified persons. This includes the following:
 - (a) A case where the supply of the pet food is for sale, and the relevant pet food is manufactured, processed, and transferred to a manufacturer or seller, etc. based on the commission from them.”
 - (b) A case where the supply of the pet food is for supply other than sale to unspecified or a number of persons, and the relevant pet food samples are manufactured, processed, and transferred to a manufacturer or seller, etc. based on the commission from them.”
- (3) In addition to prohibiting the domestic manufacture of pet food to supply for sale by a method that does not meet the relevant standards, it is also necessary to prohibit import of pet food that does not meet the relevant standards, to ensure it will never enter the distribution chain. Therefore, the sale and the import for sale of pet food manufactured by a method that does not meet the relevant standards is also prohibited (Act , Article 6, Item 2).
- (4) The sale of pet food without labeling that meets the relevant standards, and the sale of, or the manufacture or import for sale of pet food that does not meet the relevant standards is prohibited (Act , Article 6, Items 3 and 4).

5. Prohibition on the Manufacture of Pet Food that Contains Harmful Substances, Etc.

- (1) When the Minister of Agriculture, Forestry and Fisheries and the Minister of the Environment deem it necessary to prevent the health of pets from being damaged, they may prohibit manufacturers, importers, or sellers from manufacturing, importing, or selling pet food (Act , Article 7). The pet food covered by such prohibition is: (i) pet

food containing or suspected of containing harmful substances (Act , Item 1, Paragraph 1, Article 7), and (ii) pet food contaminated or suspected to be contaminated with microbes (Act , Article 7, Paragraph 1, Item 2). Such pet food could conceivably include, for example, food adulterated with harmful chemical substances, or contaminated with pathogenic microorganisms, etc., due to a faulty manufacturing process or other accident.

- (2) Furthermore, when prohibiting manufacturing, etc., scientific and expert opinion concerning the harmful substance or microbes will be needed, so the Minister of Agriculture, Forestry and Fisheries and the Minister of the Environment shall hear the opinions of the Agricultural Material Council, which possesses expertise regarding animal feed, and the Central Environment Council, which possesses expertise concerning animal welfare (Act , Article 7, Paragraph 1).
- (3) The regulations concerning pet food shall in principle address the setting of the standards and specifications provided for in Article 5 of the Act . However, substances whose possible use in pet food is not envisaged at the time when standards and specifications have been set may be contained in a product due to causes that include accidents. It is anticipated that the need to urgently prevent damage to the health of pets through the use of such pet food will arise, but it is difficult to anticipate such emergencies and set comprehensive standards and specifications in advance. Therefore, in an emergency, the manufacture, import, or sale of pet food may be prohibited as an emergency measure not based on the details of the standards and specifications.
- (4) When the Minister of Agriculture, Forestry and Fisheries and the Minister of the Environment make a prohibition under the provision of Paragraph 1, it must be published in the official gazette (Act , Article 7, Paragraph 2). This is intended to prevent the distribution of the pet food to which the prohibition relates and the manufacture, etc., of the same pet food by ensuring widespread public dissemination of the relevant prohibition.

6. Order for Destruction, Etc.

- (1) The manufacture and sale, etc., of pet food that does not meet the relevant standards and specifications and pet food containing harmful substances is prohibited (Act , Articles 6 and 7). However, if such pet food is distributed despite the relevant prohibition, when the Minister of Agriculture, Forestry and Fisheries and the Minister of the Environment deem it particularly necessary to prevent the health of pets from being damaged, they may, to the extent necessary, order manufacturers or other operators to destroy or recall the relevant pet food and take other necessary measures (Act , Article 8).
- (2) “Deem it particularly necessary” is intended to limit the implementation of measures to cases in which there is judged to be a particularly high necessity in consideration of the objective it is hoped to achieve through the implementation of the relevant measures and the means. In addition, the decision on whether it is particularly necessary requires individual and concrete examination into whether the health of pets is being damaged by the sale, etc., of the relevant pet food. Furthermore, “to the extent necessary” is intended to limit an order for destruction or recall to cases in which it is made in order to prevent the health of pets being damaged due to the use of pet food.
- (3) “Other necessary measures” could vary due to such factors as the extent, etc., of the harmful substances contained in the pet food covered by the measures. Such necessary measures may include methods such as sterilization of harmful microorganisms,

detoxification by chemical treatment, and the removal of harmful substances.

IV. Other

1. Notification by Manufacturers, Etc.

(1) Coverage and timing of notification

- (i) The Act prohibits the manufacture, etc., of pet food that does not meet the relevant standards and specifications in order to ensure the safety of pet food (Act , Article 6). However, when pet food with safety issues has been manufactured, it is necessary to quickly prohibit the manufacture or import of the relevant pet food (Act , Article 7) or to implement an order for its destruction, etc., (Act , Article 8). Therefore, the Minister of Agriculture, Forestry and Fisheries and the Minister of the Environment impose a duty of notification on manufacturers or importers of pet food for which standards and specifications have been established (Act , Article 9) in order to allow prompt measures to be taken through access to data concerning manufacturers and importers, which are the particular starting points for distribution. Pet food for sale refers to pet food for the purpose of selling, but operators who manufacture pet food used on site, such as that supplied in a dog café, etc., are not covered by the duty of notification (Ministerial Ordinance on Specifications and Standards, Appendix 1).
- (ii) Excluded from application of the duty of notification shall be those persons stipulated by Ordinance of the Ministry of Agriculture, Forestry and Fisheries and Ministry of the Environment (Act , Article 9, Paragraph 1), and manufacturers and importers whose businesses are to manufacture and to import pet food and who do not have the intent to market pet food (“to market” refers to supplying of pet food for sale stipulated in Article 6, Item 1 of the Act), as stated in the Regulations (Regulations, Article 3). As the pet food relating to the manufacture or import is not generally distributed, there is little need to impose a duty of notification for assessment. Thus, such pet food is excluded from the application of the duty of notification.
- (iii) With regard to the timing of notification, a manufacturer or importer of pet food must notify the Minister of Agriculture, Forestry and Fisheries and the Minister of the Environment of the matters including its name and address prior to commencing that business (Act , Article 9, Paragraph 1).
- (iv) A manufacturer or an importer of pet food for which standards and specifications were hitherto not established and for which new standards and specifications have been established must provide notification promptly after the standards and specifications have been established. With regard to the timing of notification, the permissible limit for retrospective notification based on similar provisions in other laws shall be that the notification must be made within thirty (30) days of the date of the establishment of the standards or specifications (Act , Article 9, Paragraph 2).
- (v) A person who manufactures or imports pet food for which standards and specifications are actually established at the time of the enforcement of the Act falls under the category of a person who has become a manufacturer or importer of pet food for which new standards and specifications have been established and so must provide notification within thirty (30) days of date of the establishment of the

standards and specifications. (Consequently, no special interim measures have been established for such persons.)

- (vi) When there is a change to the notified matters or the business is terminated, an operator who has given notification (hereinafter “operator giving notification”) must give notification of the change or termination. The timing of the notification must be within thirty (30) days (Act , Article 9, Paragraph 3).
- (vii) When an operator giving notification transfers all of the business to which the notification related, or when there has been a succession, merger or spin off relating to the operator giving notification, the position of the operator giving notification shall be inherited (Act , Article 9, Paragraph 4). The operator who has inherited the position of the operator giving notification must give notification within thirty (30) days of the date of the succession, attaching documents (copy of registration ledger, etc.,) that give evidence of that fact (Act , Article 9, Paragraph 5).

(2) Matters for notification

Manufacturers and importers are required to give notification of the matters below.

- (i) Name and address (name, name of representative, and address of principal business office for a corporation) (Act , Article 9, Paragraph 1, Item 1)
- (ii) Name and address of the business premises that manufacture the relevant pet food for a manufacturer (Act , Article 9, Paragraph 1, Item 2)
- (iii) Address of business premises to sell and store the relevant pet food (Act , Article 9, Paragraph 1, Item 3)
- (iv) The kind of pet that pet food pertaining to manufacturing or importing is used for (dogs or cats) (Regulations, Article 4, Item 1)
- (v) Starting date of manufacturing, importing or marketing of pet food (Regulations, Article 4, Item 2)
- (vi) When the pet food is manufactured or imported for the purpose of export, it must be notified accordingly (Regulations, Article 4, Item 3)

Moreover, notification must be submitted using the notification form in attachment No. 1 to the Regulations (Regulations, Article 2). A corporation must attach a copy of its registration book and an individual must attach a copy of his/her resident’s card when making the notification.

Pet food is mainly individually packaged and sold to consumers. Therefore, there is little possibility of adulteration with harmful substances at the stage of the seller. An order for destruction, etc., may be made to sellers by accessing data through manufacturers and importers who have a duty of notification. Thus, the duty of notification is not imposed on sellers (Act , Article 9, Paragraph 1).

2. Keeping of Books

In order to ensure the safety of pet food, the Act stipulates establishing standards and specifications of pet food, and prohibition of the sale, etc., of pet food that does not meet the standards and specifications (Act , Article 6), and prohibition of the sale, etc., of pet food that contains harmful substances (Act , Article 7). In addition, the Minister of Agriculture, Forestry and Fisheries and the Minister of the Environment may order the

destruction, etc., of pet food as an emergency measure when pet food prohibited from sale is sold despite the prohibition (Act , Article 8).

In order to implement these measures in a timely and appropriate manner, it is necessary to facilitate the assessment of the actual circumstances of the distribution of pet food. Therefore, a manufacturer, importer, or seller of pet food must keep a book and record pet food transactions (Act , Article 10).

(1) Items to be recorded in the book

(i) Keeping of books in the case of manufacture or import (Act , Article 10, Paragraph 1)

There is a need to keep track of the pet food that is manufactured or imported by manufacturers or importers, which form the starting point, in order to understand the distribution channels for pet food. A manufacturer or importer of pet food for which standards and specifications have been established must keep a book, record the following items, when manufacturing or importing the relevant pet food, and retain the book (Regulations, Article 5, Paragraph 1).

Items to be recorded in the book by manufacturers

- (a) The name and volume of the pet food (Act , Article 10, Paragraph 1)
- (b) The date of manufacturing of the pet food (Regulations, Article 5, Paragraph 1, Item 1)
- (c) The names and quantities of raw materials used to manufacture the pet food (Regulations, Article 5, Paragraph 1, Item 2, Sub-item (a))
- (d) When a raw material used to manufacture pet food is obtained by transfer, the date of transfer and the name of the transferee (Regulations, Article 5, Paragraph 1, Item 2, Sub-item (b))

Items to be recorded in the book by importers

- (a) The name and volume of the pet food (Act , Article 10, Paragraph 1)
- (b) The date of importing of the pet food (Regulations, Article 5, Paragraph 1, Item 1)
- (c) The name of the country from which the pet food is imported and the name of the supplier (Regulations, Article 5, Paragraph 1, Item 3, Sub-item (a))
- (d) The type of packing of the pet food imported (Regulations, Sub-item (b), Item 3, Paragraph 1, Article 5)
- (e) The name of the country where the imported pet food was manufactured, the name of the manufacturer, and the names of the raw materials (Regulations, Article 5, Paragraph 1, Item 3, Sub-item (c))

(ii) Keeping of books in the case of transfer (Act , Article 10, Paragraph 2)

In order to further clarify the channels by which manufactured or imported pet food reaches consumers, a manufacturer, importer or seller of pet food for which standards and specifications have been established must keep a book, record the following items, when transferring the relevant pet food to a manufacturer, importer

or seller, and retain the book (Regulations, Article 5, Paragraph 2).

Items to be recorded in the book

- (a) The name and volume of the pet food (Act , Article 10, Paragraph 2)
- (b) The name of the other party in the transfer (Act , Article 10, Paragraph 2)
- (c) The date of transfer of the pet food (Regulations, Article 5, Paragraph 2, Item 1)
- (d) The type of packing of the pet food (Regulations, Article 5, Paragraph 2, Item 2)

(iii) Exemptions

When a manufacturer, importer, or seller sells pet food directly to a pet owner or receives pet food, there is no duty to record the sale or transfer in a book (Act , Article 10, Paragraph 2). This is because health damage to pet animals can be prevented by alerting pet owners who have purchased harmful pet food. Moreover, there is little need to be so rigid that the assessment of the distribution process is duplicated at the points of transferee and transferer.

(2) Format of books

The book must be in the form of a paper document, but measures are in place to enable entries and storage using electronic recording methods (Information Technology Enforcement Ordinance, Article 4).

Specifically, (1) the book may be created by storing them in files in a computer or on magnetic discs (Information Technology Enforcement Ordinance, Article 6), and (2) the electromagnetic records produced may be stored using files in a computer or on magnetic disc or CD-ROM, etc. (Information Technology Enforcement Ordinance, Article 4).

(3) Period for retaining books

- (i) The shelf life for pet food varies substantially depending on such factors as the type of animal the food is for. Further, the categories of pets that are covered may expand in the future, and cases in which a uniform standard is problematic are anticipated. Therefore, it is considered appropriate to enable the period of retaining books to be established in a flexible manner depending on the shelf life of pet food. Thus, the period for retaining books shall be as stipulated by ministerial ordinance (Act , Article 10)
- (ii) Specifically, in Article 1 of the Government Ordinance, dogs and cats are stipulated as pets, and considering the period that dog and cat food is in distribution on the market, the period for retaining books must be two years from the last date of entry in the book (Regulations, Article 5, Paragraph 3).

3. Collection of Reports and On-the-spot Inspections

(1) Coverage

In order to ensure the safety of pet food, the Minister of Agriculture, Forestry and Fisheries or the Minister of the Environment may, to the extent necessary for the enforcement of the Act , (1) request the necessary reports concerning operations from manufacturers, importers, or sellers as well as pet food freight and warehouse operators (Act , Article 11, Paragraph 1), and (2) have their officials conduct on-the-spot

inspections, question the parties concerned and conduct sampling (hereinafter “on-the-spot inspections, etc.”) with regard to the relevant operators (Act , Article 12, Paragraph 1). In on-the-spot inspections, etc., officials may enter the business premises, warehouses, sea vessels, vehicles and other locations concerned with pet food manufacturing, importing, retail, transport or storage operations of the operators.

In addition to the manufacturers, importers and sellers, which are directly covered by the regulations of the Act , pet food freight and warehouse operators are also covered by the collection of reports.

(2) Sampling of pet food (Act , Article 12, Paragraph 1)

Paragraph 1 of this Article allows the sampling of pet food and raw materials to the extent necessary for inspection. In the case of sampling, compensation based on the market price must be paid.

Pet food is commonly sold in the form of a retort or can, and even if the volume to be sampled is limited to the minimum necessary for inspection, the economic value of the product is lost as a result of the sampling. Therefore, compensation based on the market price must be paid.

(3) Publication of a summary of the results of inspection (Act , Article 12, Paragraph 5)

When the Minister of Agriculture, Forestry and Fisheries or the Minister of the Environment have had pet food or raw materials sampled and inspected, a summary of the results of the inspection must be published from the perspective of preventing the spread of further damage through the dissemination of the results.

(4) On-the-spot inspection, etc., by FAMIC

(i) In Paragraph 12 of the Act , the Minister of Agriculture, Forestry and Fisheries or the Minister of the Environment may conduct an on-the-spot inspection, etc. The inspection operation may be conducted efficiently and effectively through the utilization of a specialist body which possesses expertise with relation to the specialist and technical matters concerning the constituents, etc., of pet food.

Therefore, in order to make an on-the-spot inspection, etc., more efficient and effective, the Minister of Agriculture, Forestry and Fisheries may have the Food and Agricultural Materials Inspection Center (hereinafter “FAMIC”) conduct an on-the-spot inspection, etc (Act , Article 13). FAMIC has amassed a knowledge of inspections to ensure the safety of livestock feed and also possesses expertise regarding pet food, which is similar to livestock feed.

(ii) When pet food is sampled in an on-the-spot inspection conducted by FAMIC, compensation based on the market price must be paid as with an on-the-spot inspection by the Minister of Agriculture, Forestry and Fisheries or the Minister of the Environment stipulated in Paragraph 1, Article 12 of the Act (Act , Article 13, Paragraph 1). The inspection of pet food or raw materials based on the provisions of Paragraph 1, Article 12 of the Act or Paragraph 1, Article 13 of the Act must be by the method stipulated by the Director of FAMIC.

Moreover, when an on-the-spot inspection, etc., is carried out, the Minister of Agriculture, Forestry and Fisheries, the competent minister for FAMIC, shall give FAMIC instructions on carrying out the on-the-spot inspection, etc., indicating the date and location, etc., (Act , Article 13, Paragraph 2). After FAMIC has conducted

an on-the-spot inspection, etc., it must report the results to the Minister of Agriculture, Forestry and Fisheries in writing (Act , Article 13, Paragraph 3, and FAMIC Ministerial Ordinance, Article 1).

- (iii) When the Minister of Agriculture, Forestry and Fisheries has FAMIC carry out an on-the-spot inspection under the provision of Paragraph 1, Article 13 of the Act , the Minister, when deemed necessary to ensure the proper implementation of operations of the inspection, may give the needed orders to FAMIC concerning the relevant operations (Act , Article 14). The scope of the orders shall be limited to the scope necessary for the operation of the on-the-spot inspection, etc.

4. Exceptions Concerning Pet Food for Export

The Act aims to ensure the safety of pet food in order to protect the health of pets, and pet food manufactured and sold in Japan, and pet food imported into Japan are covered by the regulations.

On the other hand, pet food exported from Japan must meet the regulations of the country to which it is exported, and there are cases in which it is inappropriate to impose the same regulations as those imposed on pet food that is distributed in Japan. Therefore, partial exclusion from the application of the Act and other necessary exceptions relating to pet food for export may be defined by Cabinet Order (Act , Article 15), with measures to be taken in line with actual circumstances.

Specifically, Article 2 of the Government Ordinance exempts the manufacture, import and sale of pet food for export from the application of the provisions of Article 6 of the Act (prohibition on the manufacture, import or sale of pet food that does not meet the standards and specifications stipulated under the provision of Article 5 of the Act).

Pet food for testing and research is excluded from the application of the Act , which regulates manufacturing, etc., for selling purposes, although exceptions may not be established by Cabinet Order.

5. Delegation of Authority

When the Minister of Agriculture, Forestry and Fisheries or the Minister of the Environment orders the destruction or recall, etc., of harmful pet food, the collection of reports and the on-the-spot inspection, etc., are essential measures for assessing the circumstances of manufacturing, importing, or selling of the relevant pet food, and it is important that the operation be conducted accurately and promptly.

Therefore, the authority of the Minister of Agriculture, Forestry and Fisheries or the Minister of the Environment may be partially delegated to the Director-General of the Regional Agricultural Administration Office or the Director of the Regional Environment Office (Act , Article 16) based on the respective judgment of each. Specifically, the authority for the collection of reports under the provision of Paragraph 1, Article 11 of the Act and the on-the-spot inspection, etc., under the provision of Paragraph 1, Article 12 of the Act is to be delegated to the Director-General of the Regional Agricultural Administrative Office and the Director of the Regional Environment Office (Ministerial Ordinance on Delegation to Director-General of Agricultural Administrative Office and Ministerial Ordinance on Delegation to the Director of the Environment Office).

Appendix 1

Category Name
Cereals
Potatoes
Starches
Sugars
Nuts and seeds
Pulses
Vegetables
Fruits
Mushrooms
Algae
Fishery products
Meats
Eggs
Dairy products
Fats and oils

Notes

1. Items other than those above must be labeled with the individual name.
2. For “Fishery products,” when raw materials derived from fish only are used, they may be labeled “Fish.”
3. “Meats” may be labeled “Domesticated animal meats.” In addition, when raw materials derived from poultry only are used, they may be labeled “Poultry.”

Appendix 2

Name for Use
Sweetener
Color
Preservative
Thickening stabilizer
Antioxidant
Color fixative

Notes

1. For “Color,” when the name of the material used for the additive includes the character “color,” the labeling of the name for use (i.e., color) may be omitted.

2. Concerning the “Thickening stabilizer”, when a number of polysaccharides are used, they may be labeled collectively as “Thickener polysaccharides” and each name of the additives may be omitted.

Appendix 3

Collective Name
Yeast food
Kansui (Alkaline preparations for Chinese noodles)
Enzymes
Glazing agent
Flavoring agent
Acidifier
Seasoning
Coagulant for soybean curd
Bittering agent
Emulsifier
Acidity regulator
Raising agent