

Guidelines for Preventing the Contamination of Feed Products with Toxic Substances

I. Purpose

From the standpoint of the fundamental principle of prevention of adverse effects on the health of citizens as established by Article 5 of the Food Safety Basic Law (Law No. 48, 2003), the Ministry of Agriculture, Forestry and Fisheries institutes measures, for example by determining specifications and standards concerning feed and related products (“feed products”) pursuant to Article 3 of the Law Concerning Safety Assurance and Quality Improvement of Feed (Law No. 35, 1953; “Feed Safety Law”). For their part, importers and manufacturers of feed products ensure safety by fulfilling their responsibilities of food-related businesses operators under Article 8 of the Food Safety Basic Law. In view of the fact that Japan depends on imports for most ingredients used to manufacture feed products, it is difficult for individual feed product manufacturers to prevent contamination of feed products with toxic substances on their own, necessitating a broad-based effort on the part of importers and other companies as well as concerned parties and institutions, including the Ministry of Agriculture, Forestry and Fisheries. These Guidelines are provided from the perspective of making all possible efforts to ensure the safety of feed products in order to both prevent contamination with toxic substances from the ingredient stage and deal with the circumstances of contamination and the scenarios in which it may occur by making reasonable assumptions about their nature.

II. Definition

In addition to terms defined by the Feed Safety Law, these Guidelines make use of the following terms:

1. Toxic substances
Chemical substances including residual pesticides, mold, and heavy metals that may have an adverse impact on the health of humans or animals.
2. Ingredients
Ingredients and materials used to manufacture feed and feed additives.
3. Feed products
Feed, feed additives, and their respective ingredients.
4. Products
Manufactured feed and feed additives, including intermediate products.
5. Surveillance

Investigations carried out to assess the extent or circumstances of feed product issues.

6. Monitoring

Investigations carried out to assess trends characterizing feed product issues from the standpoint of determining whether corrective measures are necessary.

III. Action by the Ministry of Agriculture, Forestry and Fisheries

The Ministry of Agriculture, Forestry and Fisheries has established Basic Guidelines for Dealing with Food Safety Emergencies (“Basic Guidelines”) as a blueprint for responding to situations requiring emergency action related to food safety (“food safety emergencies”). These Basic Guidelines describe the Ministry’s basic approach to dealing with food safety emergencies. In the event of a food safety emergency triggered by a feed product-related cause, the Ministry shall take action as necessary in accordance with the Action Guidelines for Dealing with Food Safety Emergencies Caused by Products Manufactured or Produced by the Agriculture, Forestry, and Fisheries Industry (“Action Guidelines”). These Guidelines generally follow the Action Guidelines in describing actions taken by the Ministry of Agriculture, Forestry and Fisheries.

1. Action during ordinary times

- (1) The Ministry shall gather and analyze information concerning feed products and enact the following regulations pursuant to the Feed Safety Law:
 - i. Establishment of specifications and standards relating to feed product safety (Article 3)
 - ii. Testing and labeling of feed products (Article 5)
 - iii. Prevention of the distribution of feed products containing toxic substances (injunctions prohibiting the manufacture, import, and sale of toxic feed products or requiring their destruction, etc.) (Articles 23 and 24)
 - iv. Establishment of the manufacture, distribution, etc., of appropriate feed products at manufacturing, sales, and other facilities (notification of manufacturers and sellers, obtaining reports, spot inspection, sampling of feed products, etc.) (Articles 50, 55, 56, and 57)
- (2) The Ministry shall provide for the use of industry companies templates and/or examples of specifications, procedures and other documents adopted on a voluntary basis by importers, manufacturers, and other

industry companies in accordance with these Guidelines.

2. Response to food safety emergencies

(1) Food safety emergencies caused by feed products are assumed to comprise cases such as the following where food safety may be compromised by the use of feed products, accidents, or other occurrences:

- i. Cases involving food contamination and harm to or adverse effects on humans and animals on a large scale or throughout a widespread area
- ii. Cases involving food contamination due to causes about which there is insufficient scientific knowledge and harm to or adverse effects on humans and animals, or where such is deemed possible
- iii. Cases other than those described in III-2-(1)-(i) and III-2-(1)-(ii) above where the Ministry determines that emergency action is necessary based on a consideration of social repercussions

(2) Initial response to food safety emergencies

- i. The Ministry's initial response to an incident or accident shall consist of communicating and coordinating action with the Food Safety Commission and government ministries with food safety responsibilities such as the Ministry of Health, Labour and Welfare based on an awareness of the fact that the most important imperative is the protection of citizens' health. At the same time, the Ministry shall seek to gather information from the Food Safety Commission; the Ministry of Health, Labour and Welfare; the Food and Agricultural Materials Inspection Center (FAMIC); feed product companies; and food manufacturers and distributors. It shall investigate whether the case comprises a food safety emergency by analyzing this information.
- ii. In the event that the Ministry determines that the case comprises a food safety emergency, it shall set up a Ministry of Agriculture, Forestry and Fisheries Food Safety Emergency Task Force ("Ministry Task Force") in accordance with the Basic Guidelines.
- iii. After setting up the Ministry Task Force, the Ministry shall set up a communication system and immediately undertake the following countermeasures:
 1. It shall consider, execute, and issue instructions for any countermeasures that need to be taken immediately.

2. It shall provide information to companies involved with the feed products in question.
 3. It shall gather, organize, and analyze information and other data concerning the region in which the food safety emergency occurred.
 4. It shall share information concerning the emergency, and communicate and coordinate with the Food Safety Commission and government ministries with food safety responsibilities such as the Ministry of Health, Labour and Welfare.
 5. It shall establish a website and make information available to the public through a media office.
- iv. The Ministry shall dispatch FAMIC employees or employees from the Ministry or Regional Agricultural Administration Offices to the site of the emergency as necessary to conduct on-site inspections and collect samples of feed products for testing. At this time, the Ministry shall also request the cooperation of or advice from academic experts as necessary.
 - v. The Ministry shall release information to the news media in accordance with the Action Guidelines.
 - vi. In addition to consulting with and working to accommodate the opinions of consumers and other stakeholders, the Ministry shall set up a consultation office in the Regional Agricultural Administration Office. It shall also ask FAMIC to set up a coordinating office.

(3) Response when a feed product issue is discovered

Following the initial response to an incident or accident, the Ministry shall take the following actions when they are judged to be necessary from the standpoint of ensuring food safety in light of a comprehensive determination based on gathered information:

- i. The Ministry shall ask feed product importers, manufacturers, and distributors to halt shipments and recall affected products. Furthermore, the Ministry shall issue injunctions as necessary requiring the recall of problematic feed products in accordance with the Feed Safety Law.

The Ministry shall as necessary present methods for the analysis of toxic substances in order that importers of feed products and

other companies be able to implement an appropriate level of quality control.

- ii. The Ministry shall issue written guidance via prefectural governments; agriculture, forestry, and fisheries groups; and feed product manufacturers' groups so that livestock farmers and others do not use affected feed products. The Ministry shall strive through this guidance to provide information to a broad base via the news media.
- iii. Acting through Regional Agricultural Administration Offices and District Agriculture Offices, the Ministry shall directly contact livestock farmers and other potential users to provide guidance as necessary so that they do not use affected feed products.

IV. Collection and Sharing of Information

1. Collection of information concerning country/region of production from importers

Importers shall gather and organize information that is likely to impact the safety of feed products, for example unfavorable weather conditions such as droughts in countries or regions that produce feed products, or pesticide application in response to unusual contamination with mycotoxin or pest infestation during storage in warehouses or other facilities. Of this information, importers shall report that which is judged important from a feed product safety standpoint via FAMIC to the Animal Products Safety Division, Food Safety and Consumer Affairs Bureau, the Ministry of Agriculture, Forestry and Fisheries ("Animal Products Safety Division").

2. Inspections and dissemination of information by FAMIC

- (1) Surveillance and monitoring of toxic substances contained in feed products

FAMIC shall conduct systematic surveillance and monitoring inspections for toxic substances in feed products, including actions undertaken in accordance with the Annual Plan for the Surveillance and Monitoring of Toxic Substances Related to Food Safety as established by the Ministry of Agriculture, Forestry and Fisheries.

- (2) Dissemination of information

FAMIC shall regularly disseminate information provided in accordance with IV-1 above, surveillance and monitoring inspection results provided in accordance with IV-2-(1) above, and other information concerning

toxic substances in feed products to importers and manufacturers registered in accordance with IV-3 below.

(3) Emergency response

During emergencies where a food safety issue caused by feed products may occur, FAMIC shall move quickly to provide information to importers and other involved companies by email, fax, or other means in accordance with instructions from the Animal Products Safety Division.

3. Gathering of information concerning feed product safety by importers and manufacturers

Importers and manufacturers shall register their email addresses with FAMIC so that they can receive information from FAMIC.

Importers and manufacturers shall utilize information and other data obtained from FAMIC in accordance with IV-2 above to access breaking information deemed likely to have an impact on feed product safety.

V. Importation of Feed Products

Importers shall fulfill the following operational requirements:

1. Establishment of feed product specifications

Importers shall establish clear specifications for ensuring the safety of each imported feed product they handle based on the information provided by FAMIC in accordance with IV-2 above and in reference to the templates and examples provided by the Ministry of Agriculture, Forestry and Fisheries in accordance with III-1-(2) above.

2. Confirmation of compliance with feed product specifications

Importers shall take action to confirm safety of imported feed products, for example by signing agreements with suppliers to satisfy the specifications described in V-1 above, or take other action to have equivalent results. They shall also confirm compliance with such as necessary, for example by visiting overseas manufacturing plants and other facilities to assess the conditions under which feed products are manufactured, and record their findings.

3. Creation of procedures for quality control and other processes

Importers shall create procedures for quality control, complaint resolution, recall processing, and education and training based on the templates and examples described in III-1-(2) above in order to ensure that the operations stipulated in V-4 through V-7 below are carried out in an appropriate manner. They shall have previously designated individuals or companies perform these operations in accordance with the procedures.

4. Quality control

Importers shall perform the following operations related to quality control in accordance with the procedures concerning quality control created in V-3 above:

- (1) Collect the necessary samples at a self-determined frequency and create records of the same.
- (2) Test the collected samples as necessary in order to confirm compliance with the specifications described in V-1 above and create records of the same.
- (3) If any problems are discovered, for example analysis results that exceed standard values, report this fact to FAMIC.
- (4) In principle, records of the tests described in V-4-(2) above shall be stored for a period of at least 2 years from the date of their creation.

5. Complaint resolution

When they receive a complaint concerning the presence of one or more toxic substances in imported feed products from livestock farmers, manufacturers, or other companies, importers shall perform the following operations related to complaint resolution in accordance with the procedures concerning complaint resolution created in V-3 above:

- (1) Investigate the cause of the circumstances surrounding the complaint and take appropriate action.
- (2) Create a complaint resolution record describing the nature of the complaint, the results of the investigation of its cause, any corrective action taken, and any other relevant information. In principle, this record shall be stored for a period of at least 2 years from the date of its creation.

6. Recall processing

When recalling imported feed products, for example because they contain toxic substances in excess of standard values, importers shall perform the following operations related to recall processing in accordance with the procedures concerning recall processing created in V-3 above:

- (1) Investigate the cause that led to the recall and take appropriate action.
- (2) Process recalled feed products in an appropriate manner.
- (3) Create a recall processing record describing the nature of the recall and associated processing, the results of the investigation of its cause, any corrective action taken, and any other relevant information. In principle, this record shall be stored for a period of at least 2 years from the date of its creation.
- (4) In principle, whenever a recall is initiated, importers must report this fact

along with the underlying reason and circumstances of the recall to the Animal Products Safety Division via FAMIC.

7. Education and training

Importers shall perform the following operations related to education and training in accordance with the procedures concerning education and training created in V-3 above:

- (1) Systematically implement necessary education and training programs related to feed product safety for employees involved in import operations, for example by making use of training and other services provided by FAMIC.
- (2) Create records of implemented education and training programs. In principle, these records shall be stored for a period of at least 2 years from the date of their creation.

8. Cooperation with surveillance and monitoring

Importers shall cooperate with the collection of samples targeted for toxic substance surveillance and monitoring by FAMIC as described in IV-2 above.

VI. Acceptance of Ingredients at Manufacturing Plants

Manufacturers shall perform the following operations when accepting ingredients, or have them performed by previously designated individuals or companies as appropriate given the nature of the operations:

1. Establishment of ingredient specifications

Manufacturers shall establish clear specifications for ensuring safety for each ingredient they handle based on the information provided by FAMIC in accordance with IV-2 above and in reference to the templates and examples provided by the Ministry of Agriculture, Forestry and Fisheries in accordance with III-1-(2) above.

2. Confirmation of compliance with ingredient specifications

Manufacturers shall sign agreements with suppliers of ingredients requiring them to satisfy the specifications described in VI-1 above. They shall also confirm compliance with such as necessary, for example by visiting manufacturing plants and other facilities to assess the conditions under which ingredients are manufactured, and create records of their findings. Regarding imported ingredients, they shall confirm conditions at manufacturing plants through importers and other involved companies, and create records of their findings. In contract manufacturing arrangements where the contractor is to supply ingredients, the contractor shall be responsible for confirming the

compliance of ingredients with feed product specifications.

3. Cooperation with surveillance and monitoring

Manufacturers shall cooperate with the collection of samples targeted for toxic substance surveillance and monitoring by FAMIC as described in IV-2 above.

VII. Guidelines Concerning the Manufacture of Feed Products

Manufacturers shall perform the following operations when manufacturing feed products. Some of the following may be omitted when it is judged that the likelihood of contamination by a toxic substance during the manufacturing process is low.

1. Process control standards and quality control standards

- (1) Manufacturers shall create process control standards for each plant they operate describing manufacturing process control and other necessary information.
- (2) Manufacturers shall create quality control standards for each plant they operate describing sample collection methods, testing methods, test result judgment methods, and other necessary information.

2. Appointment of manufacturing control officers and quality control officers

- (1) Manufacturers shall appoint a manufacturing control officer and quality control officer for each plant they operate.
- (2) Manufacturing control officers shall possess knowledge related to manufacturing control.
- (3) In principle, quality control officers shall possess knowledge related to quality control.
- (4) In principle, the same person may not serve as a plant's manufacturing control officer and quality control officer at the same time. In the event that a given plant has a feed manufacturing manager as stipulated by Article 25 of the Feed Safety Law, the feed manufacturing manager may also serve as the manufacturing control officer.

3. Responsibilities of manufacturing control officers

Manufacturers shall have the manufacturing control officer of each plant perform the following operations related to product manufacturing control in accordance with process control standards and in an appropriate manner:

- (1) Officers shall create procedures related to manufacturing describing manufacturing process instructions, precautions, and other necessary information in order to prevent contamination with toxic substances.
- (2) Officers shall perform the following operations themselves, or have them

performed by previously designated individuals as appropriate given the nature of the operations:

- i. Manufacture products in accordance with manufacturing-related procedures.
- ii. Create product manufacturing records for each lot.
- iii. Inspect and maintain manufacturing equipment on a regular basis and create records of the same.
- iv. Perform other operations related to manufacturing control as necessary.

(3) Officers shall confirm that manufacturing control is being carried out in an appropriate manner and in accordance with process control standards.

(4) Officer shall store manufacturing-related records for a period of 8 years from the date of their creation in accordance with Article 52 of the Feed Safety Law. Additionally, they shall in principle store records related to manufacturing control for a period of at least 2 years from the date of their creation.

4. Responsibilities of quality control officers

Manufacturers shall have the quality control officer of each plant perform the following operations related to ingredient and product quality control in accordance with quality control standards and in an appropriate and systematic manner:

(1) Officers shall perform the following operations themselves, or have them performed by previously designated individuals as appropriate given the nature of the operations:

- i. Collect samples from ingredient and product lots at a frequency determined to be appropriate, and create records of the same.
- ii. Test collected samples as necessary in order to confirm compliance with the specifications established by VI-1 above and create records of the same. Timing of tests shall reflect a consideration of the chemical stability of the target toxic substances.
- iii. Store collected samples under appropriate storage conditions for a period of time that determined to be sufficient, even after testing.
- iv. Inspect and maintain testing equipment and instruments used to test samples on a regular basis and create records of the same.
- v. Perform other necessary operations related to quality control.

(2) Officers shall judge test results and report them in writing to the manufacturing control officer. If any problems are discovered, for example analysis results that exceed standard values, they shall report this fact to FAMIC.

(3) In principle, records of the tests described in VII-4-(1)-ii above shall be stored for a period of at least 2 years from the date of their creation.

5. Incident response and other procedures

Manufacturers shall create procedures for each plant they operate related to incident response, complaint resolution, recall processing, self-inspections, and education and training in reference to the templates and examples described in III-1-(2) above in order to ensure that the operations described in VII-6 to VII-10 below are performed in an appropriate manner.

6. Incident response

In the event of an incident involving product contamination with a toxic substance or the possibility of contamination as a result of an equipment accident or other event during a manufacturing process, manufacturers shall have the plant's manufacturing control officer perform the following operations related to incident response in accordance with the procedures concerning incident response created by VII-5 above:

(1) Investigate the cause of the incident and, if improvements to manufacturing control or quality control are necessary, take appropriate action.

(2) Process products for which an abnormality was detected in an appropriate manner.

(3) Create an incident response record as necessary describing the nature of the incident, the results of the investigation of its cause, and any corrective action taken. In principle, this record shall be stored for a period of at least 2 years from the date of its creation.

7. Complaint resolution

When they receive a complaint concerning the presence of one or more toxic substances in a manufactured product from livestock farmers or other companies, manufacturers shall have the manufacturing control officer or quality control officer at the plant in question perform the following operations related to complaint resolution in accordance with the procedures concerning complaint resolution created by VII-5 above:

(1) Investigate the cause of the circumstances surrounding the complaint and, if improvements to manufacturing control or quality control are

necessary, take appropriate action.

- (2) Create a complaint resolution record describing the nature of the complaint, the results of the investigation of its cause, any corrective action taken, and any other relevant information. In principle, this record shall be stored for a period of at least 2 years from the date of its creation.

8. Recall processing

When recalling manufactured products, for example because they contain toxic substances in excess of standard values, manufacturers shall have the manufacturing control officer at the plant in question perform the following operations related to recall processing in accordance with the procedures concerning recall processing created by VII-5 above:

- (1) Investigate the cause that led to the recall and, if improvements to manufacturing control or quality control are necessary, take appropriate action.
- (2) Process recalled products in an appropriate manner.
- (3) Create a recall processing record describing the nature of the recall and associated processing, the results of the investigation of its cause, any corrective action taken, and any other relevant information. In principle, this record shall be stored for a period of at least 2 years from the date of its creation.
- (4) In principle, whenever a recall is initiated, manufacturers must report this fact along with the underlying reason to the Animal Products Safety Division via FAMIC.

9. Self-inspections

- (1) In principle, manufacturers shall have the manufacturing control officer and quality control officer at each plant they operate perform the following operations related to self-inspections in accordance with the procedures concerning self-inspections created by VII-5 above:
 - i. Perform regular self-inspections to assess the state of manufacturing control and quality control for products at the plant in question in accordance with procedures related to self-inspections.
 - ii. Create records of self-inspection results. In principle, such records shall be stored for a period of at least 2 years from the date of their creation.
- (2) In the event that improvements to manufacturing control or quality

control are necessary, manufacturers shall take appropriate action based on the self-inspection results described in VII-9-(1)-i above and create records of the same. In principle, such records shall be stored for a period of at least 2 years from the date of their creation.

10. Education and Training

Manufacturers shall have a previously designated individual perform the following operations related to education and training in accordance with the procedures concerning education and training created in VII-5 above:

- (1) Systematically implement necessary education and training programs related to manufacturing control and quality control for employees involved in manufacturing and quality control operations, for example by making use of training and other services provided by FAMIC.
- (2) Report on the status of education and training programs in writing to the manufacturer.
- (3) Create records of implemented education and training programs. In principle, these records shall be stored for a period of at least 2 years from the date of their creation.

VIII. Guidelines Concerning the Transport and Storage of Feed Products

1. Creation of procedures concerning transport and storage

Importers, manufacturers, and distributors shall create procedures concerning the transport and storage of feed products in order to prevent contamination with toxic substances or increases in such.

2. Conduct of operations in accordance with procedures

Importers, manufacturers, and distributors shall transport and store feed products in accordance with predetermined procedures.

3. Management of operations by importers and warehouse providers

In the event that importers, manufacturers, and distributors opt to outsource transport and storage operations instead of performing them themselves, they shall confirm in writing as necessary that transport and warehouse providers manage operations in accordance with relevant procedures in order to prevent contamination with toxic substances or increases in the same.

IX. Response to the Possibility of Production of Toxic Animal Products

In the event that the Ministry of Agriculture, Forestry and Fisheries determines that there is a possibility that a toxic farm product has been produced or that livestock or other animals have been harmed, importers, manufacturers, and distributors shall take

the following actions:

1. When the manufacturing lot of feed products containing the toxic substances has been identified

Importers, manufacturers, and distributors shall investigate whether they have handled feed products belonging to the manufacturing lot in question. If so, they shall report this fact immediately to any companies or individuals to whom the product was shipped, request that the sale and use of the product be halted, and initiate a recall. They shall also report the situation to the Animal Products Safety Division and feed product supplier as quickly as possible and provide a summary of how the recalled feed product was processed to the Animal Products Safety Division via FAMIC.

Suppliers receiving this information shall immediately notify all buyers of the feed product in question, request that the sale and use of the product be halted, and initiate a recall. They shall also provide a summary of how the recalled feed product was processed to the Animal Products Safety Division via FAMIC.

Furthermore, in the event that the feed product in question has been shipped to livestock farmers or other users, importers, manufacturers, and distributors shall immediately set up consultation offices and work to ensure the safety of animal products.

2. When there is information indicating the country of manufacturer and feed product type for the contaminated feed product

In this case, importers, manufacturers, and distributors shall investigate whether they have handled the feed product in question. If so, they shall report this fact immediately to any companies or individuals to whom the product was shipped, request that the sale and use of the product be halted, and analyze the feed product in question for toxic substances. They shall also report the situation to the Animal Products Safety Division and feed product supplier as quickly as possible.

Suppliers receiving this information shall immediately notify all buyers of the feed product in question and request that the sale and use of the product be halted.

If a toxic substance is detected by the analysis, importers, manufacturers, and distributors shall immediately notify the Animal Products Safety Division and the supplier and initiate a recall of feed products from the same manufacturing lot as the feed product in question from companies or individuals to whom the product was shipped. They shall also provide an overview of how the recalled feed product was processed to the Animal Products Safety Division via FAMIC.

Furthermore, in the event that the feed product in question has been shipped to livestock farmers or other users, importers, manufacturers, and distributors shall immediately set up consultation offices and work to ensure the safety of animal products.

X. Reporting of Import and Manufacturing Volume

By July 31 each year, importers and manufacturers of feed products shall report the volume of feed products they imported or manufactured during the previous fiscal year to the Animal Products Safety Division using a separately documented form, to be sent by email, fax, or other means.

This report need not be filed if the importer or manufacturer already submits a similar report to the Ministry of Agriculture, Forestry and Fisheries.

*These Guidelines do not include the separately documented form.