

Establishment of the Guidelines of Good Manufacturing Practice (GMP) for Feed

(June 17, 2015, Sho-an 27 No. 1853, Notice of the Director-General of Food Safety and Consumer Affairs Bureau, Ministry of Agriculture, Forestry and Fisheries of Japan)

(Partial amendment: April 8, 2016, Sho-an 27 No. 6399)

To ensure the safety of feed, the Ministry of Agriculture, Forestry and Fisheries of Japan (hereinafter referred to as “MAFF”) has established the standards and specifications based on “[Act on Safety Assurance and Quality Improvement of Feeds](#)” (Act No. 35 of 1953), and business operators involved in importing, manufacturing and distribution (hereinafter referred to as “business operator”) have taken necessary measures, recognizing that they themselves have the primary responsibility to act on the food safety assurance, based on “[Food Safety Basic Act](#)” ([Act No. 48 of 2003](#)).

Recently, the approach to ensure the safety of food has been shifting from the conventional one relying on testing final products to the one putting emphasis on the process control system such as HACCP. For feed, as part of the food chain, it is important that business operators themselves introduce such a process control method in all steps from ingredients to final products to ensure feed safety more effectively and efficiently.

Therefore, the existing guidelines addressing feed safety issues in feed manufacturing have been integrated and the Guidelines of Good Manufacturing Practice (GMP) for Feed, as shown in [Attachment 1](#), has been established as a guide so that business operators themselves can introduce the basic safety control (GMP) in order to provide safe feed. Please notify the parties concerned about it.

Attachment 1

Guidelines of Good Manufacturing Practice (GMP) for Feed

I. Purpose

In terms of the preventive measures against adverse effects on the health of citizens, the fundamental principle in Article 5 of the [Food Safety Basic Act \(Act No. 48 of 2003\)](#), MAFF has taken measures for feed safety based on “[Act on Safety Assurance and Quality Improvement of Feeds](#)” (Act No. 35 of 1953, hereinafter referred to as “Feed Safety Act”). Such measures include establishing standards and specifications for feed. At the same time, business operators, which manufacture, import, distribute, and conduct business activities, have taken necessary measures in order to assure the feed safety, recognizing that they themselves have the primary responsibility to act on the food safety assurance, based on Article 8 of the Food Safety Basic Act.

Recently, the international approach to ensure the safety of food has been shifting from the conventional method relying on testing final products to that focusing on the process control. Introduction of the HACCP system, built upon the basic hygiene practices for the production of safe food such as Good Manufacturing Practices (GMP), analyzing hazard at each process, monitoring and recording control points in manufacturing process, has now become mainstream.

In light of this stream, it is also important that business operators of feed, as a part of the food chain, introduce such a method and more effectively and efficiently ensure the safety in the entire processes from the ingredients to final products. Specifically, business operators are required to implement hygiene measures and manage facility properly based on the GMP, as well as controlling various hazards through proper control of manufacturing process and quality control activities. More specifically, preventing contamination of harmful microorganisms, including salmonella, preventing contamination of foreign matters such as metal fragments, preventing contamination of harmful chemical substances such as mycotoxins, and physical separation of animal derived proteins as a measure against bovine spongiform encephalopathy (BSE). Moreover, with feed containing antimicrobial feed additives, establishing a system to ensure accurate weighing of additives and homogeneous blending is required.

The Good Manufacturing Practice (GMP) guidelines for feed, etc. (hereinafter referred to as “GMP guidelines”) is a guide so that business operators themselves can appropriately control the hazards, introduce GMP which is the basic safety control for providing safe feed, and, furthermore, introduce higher safety control based on the concepts of HACCP depending on their own actual business conditions.

II. Definitions

The definitions of the terms used in the GMP guidelines are as follows, including those specified in the [Feed Safety Act](#).

1. Ingredients

Ingredients and materials to manufacture feed and feed additives

2. Feed, etc.

Feeds, feed additives, ingredients, etc.

3. Product

Feed and feed additives manufactured, including intermediate products

4. Business operator

Those who manufacture, import, and distribute feed, etc.

5. Business site

Place handling feed, etc. out of the places where the business operator conducts its business.

6. Type A feed

Feed, etc. which is handled not to be contaminated with animal-derived protein, etc. because they are or may be fed to ruminants (cattle, sheep, goats, and deer; the same applies hereinafter) in a farm.

7. Type B feed

Feed other than Feed-A and Feed for fish.

8. Exclusive feed for fish

Feed manufactured in the manufacturing process, which is approved by the Minister of Agriculture, Forestry and Fisheries that meets the manufacturing standards for the feed for aquaculture which contain bovine blood meal or bovine meat and bone meal.

9. Animal-derived protein, etc.

The following substances and materials containing them, excluding milk, dairy products, eggs, and egg products; gelatin, collagen, and fat not derived from ruminants confirmed by the Minister of Agriculture, Forestry and Fisheries based on “[Ministerial Ordinance on the Specification and Standards of Feed and Feed additives](#)” (Ministry of Agriculture and Forestry Ordinance No. 35 of 1976, hereinafter referred to as “Ministerial Ordinance”); and special animal fat specified in the Ministerial Ordinance Appendix 1-5-(1).

- 1) Mammal derived protein
- 2) Poultry derived protein
- 3) Fish derived protein
- 4) Animal fat
- 5) Animal derived protein in food scraps
- 6) Feed additive containing substances corresponding substances 1) to 5)

10. Antimicrobial feed additives

Feed additives specified in the table in the [Ministerial Ordinance](#) Appendix 1-1-(1)-c

11. Antimicrobial formulation for feed additives

Single or combined formulation of antimicrobial substances to be incorporated in antimicrobial feed additives

12. Manufacturing instructions

Giving instructions to manufacturing section for manufacturing products, including the name of product to be manufactured, amount of manufacture, manufacturing sequence

13. Lot

A batch of products or ingredients, etc. manufactured to have homogeneity in a series of manufacturing processes in a certain manufacturing period

14. Non-conforming products

Products or ingredients, etc. which do not meet the specifications and standards specified in the [Ministerial Ordinance](#), etc.

15. Cleaning

Removal, and cleaning, as appropriate, or cleansing of residues attached to the facilities and equipment (including instruments; the same applies hereinafter) (cleansing indicates washing using detergents or other cleansing methods which are equally effective.)

16. Transportation

Movement of feed, etc. within the facility or between facilities using a conveyer

17. Hazard

Substances in feed, etc. or state of feed etc. which may cause adverse effects on human or livestock health (for example, microbiological factors such as harmful microorganisms, etc., chemical factors such as pesticide residues, mycotoxins, etc., physical factors such as foreign matter contamination)

18. Process control standard code

Documents specifying the control method to be taken on the hazards which are evaluated as important by the hazard analysis in order to ensure the safety of feed, etc..

III. Good manufacturing practices (GMP)

The business operator shall ensure the safety of feed, etc. by conducting the following management activities as appropriate according to the individual condition of the plant.

1. Organization and employees

(1) Establishment of the management system

- 1) The manufacturer shall designate both process control manager and quality control manager for each business site. For the business sites appointing the feed manufacturing manager specified in Article 25, paragraph 1 of the [Feed Safety Act](#), the feed manufacturing manager can concurrently serve as the process control manager.
- 2) The manufacturing and quality control managers shall not concurrently serve as either of the two.
- 3) The manufacturer shall establish the quality control section independent of the manufacturing section.
- 4) The importer and distributor shall designate the operation control manager to develop the plan for implementation of the following items and conduct verification of the implementation status and effectiveness.

(2) Education and training of employees

The business operator shall set up the procedure manual on education and training and direct the previously designated person to carry out followings concerning education and training.

- 1) Providing systematic training and education, including trainings provided by FAMIC, on hygiene control, process control, or quality control for the employees.
- 2) Creating the education and training record and store the record for at least two years from the date created.

2. Establishment and maintenance of facilities

The business operator shall establish the premises of the business sites, facilities, and equipment so that they meet the following standards, and direct the previously designated person to conduct the periodic inspection and maintenance so that they are maintained in the appropriate state. Also, the business operator shall create a record concerning inspection and maintenance and store the record for at least two years from the date created.

When the business operator outsources the transportation or storage operation, it shall confirm in writing that the facilities and equipment which the outsourcee use, including ships, vehicles, tanks, and carrying machines, meet the following standards (limited to those corresponding to such facilities and equipment).

(1) Premises and facilities

- 1) Premises including pave and shall be maintained appropriately so that habitats of pests are removed.
- 2) The structures and materials of the floors, interior walls, ceilings, etc. of the facilities shall be easy for hygiene control and maintenance.
- 3) The structure of the premises shall allow for adequate control of the entry of people to the facilities by,

for example, placing defined borders on the premises.

- 4) The premises and facilities concerning manufacturing, import, distribution, or storage of feed, etc. shall be designed to prevent cross-contamination among type A feed, type B feed and the dedicated aquaculture feed according to “[Guidelines for Prevention on cross-contamination of Animal Derived Proteins in Ruminant Feeds](#)” (Notification 15 Sho-an No.1570 of September 10, 2003 by the Director-General of Food Safety and Consumer Affairs Bureau, MAFF; hereinafter referred to as “Guidelines on ruminant feed”).
 - 5) The structure shall be designed to prevent environment-origin contamination in the area for the operation process exposed to the open air, such as receiving of ingredients and filling containers. (i.e. install a ceiling over such area)
 - 6) The facility shall have a separated area for eating and drinking by employees, as well as a restroom, and washroom.
- (2) Equipment and instruments
- 1) Equipment shall have adequate performance for the intended purpose and production volume. The structure and materials of the equipment shall be easy for hygiene control and maintenance.
 - 2) Facility shall be equipped for appropriate control of lighting, ventilation, temperature and humidity.
 - 3) Water used in the facility shall be microbiologically and chemically suitable for the purpose. Systems for supply and discharge such water shall be installed.
 - 4) Systems to appropriately dispose drainage water and waste shall be in place.
 - 5) Measures to prevent cross-contamination among type A feed, type B feed, and dedicated aquaculture feed shall be implemented according to the Guidelines on ruminant feed.
 - 6) The equipment in which antimicrobial feed additives or feed containing antimicrobial feed additives, etc. directly contact the feed not containing antimicrobial feed additives, etc. shall be exclusively used in principle. When both feeds containing and not containing antimicrobial feed additives, etc. are handled in the same equipment, the equipment shall be cleaned before handling the feed not containing antimicrobial feed additives. Effectiveness of the cleaning method in terms of removal of antimicrobial feed additives, etc. shall be validated in advance.
 - 7) Measuring and dosing instruments with the appropriate measurement range shall be calibrated periodically confirmed. The accuracy and effectiveness of the mixers with regard to homogeneity shall be checked periodically.

3. Management of incoming ingredients

The business operator shall implement, or direct the designated person to implement, the following measures regarding management of incoming ingredients, etc.

- (1) The business operator shall prepare clear specifications necessary to ensure the safety of feed for each incoming ingredient, etc. Contract to supply ingredients, etc. meeting such specifications shall be signed with the suppliers.
- (2) The business operator shall verify the safety of incoming ingredients, etc. and record the result of verification. The verification activities include assessing the compliance of suppliers with the GMP guidelines or the Good Agricultural Practices, etc. assessing the test results submitted by suppliers, conducting the survey or hearing on supplier’s management, or conducting tests on incoming ingredients as appropriate. When the business operator outsources the manufacturing of products and supplies ingredients, etc. to the outsourcee, the business operator shall confirm the safety of such ingredients, etc. and record the results.

4. Hygiene management

The business operator shall set up the procedure manual on the following items necessary to facilitate appropriate hygiene management (hereinafter referred to as “hygiene management manual”). The process control manager, the operation control manager or the designated person shall implement hygiene management activities based on hygiene management manual. Routine check-ups on those activities shall be carried out.

When the business operator outsources the transportation or storage operation, it shall ensure in writing to the outsourcee conducting the operations that the items corresponding to such operation in the hygiene management manual are satisfied.

- 1) Employees' health status shall be recognized and routine hand washing, wearing of clean working clothes, disinfection of shoes, etc. shall be enforced among employees.
- 2) Regular cleaning and maintenance of facilities and equipment shall be carried out to maintain cleanliness. Disinfection shall be implemented as appropriate. Especially for the process in which condensation may occur, a clean and dry state shall be maintained.
- 3) Storage of ingredients, etc. and products shall be kept clean and dry state.
- 4) Items directly contacting the ingredients, etc. and products during transportation, carrying, and storage such as tanks, truck cargos, containers, wrappings and conveyers shall be dry and clean. Immersion of water or contamination of foreign matters shall be avoided.
- 5) Pest control measures such as setting traps or fumigation shall be implemented. Measures to prevent birds from entering from the opening of the facility shall be taken. (i.e. installing a bird net)
- 6) Agent to be used in cleaning, disinfection, and pest control shall be used and stored in order not to remain in the equipment for handling feed, etc.
- 7) Waste and waste water shall be managed appropriately in order not to contaminate equipment for handling feed, etc. or becoming habitats for pests.

5. Process and quality controls

(1) The business operator shall direct the process control manager of the business site (the operation control manager for an importer and a distributor) to prepare the process control procedure manual including necessary items out of the following items necessary to facilitate appropriate process control (hereinafter referred to as “process control manual”). The process control manager, the operation control manager, or the designated person shall implement process control activities based on the process control manual. When the business operator outsources the transportation or storage operation, it shall confirm in writing that the outsourcee conducting the operations will conduct transportation or storage based on the process control procedure.

- 1) When receiving ingredients, the incoming ingredients shall be checked the conformity with the specification which have previously been contracted with the suppliers. Especially, ingredients for type A feed shall be confirmed to be managed in an appropriate manner. When receiving animal derived protein etc., it shall be confirmed to be managed in an appropriate manner by checking the label or the manifest.
- 2) Manufacturing plan, along with the manufacturing instructions and product formulation specifications, shall be prepared and products shall be manufactured according to the plan. For the manufacturing process of formula feed containing antimicrobial feed additives and antimicrobial feed additives premixtures, appropriate manufacturing sequence shall be specified in the manufacturing instructions.
- 3) In all the processes from receiving of ingredients to transport of finished products, the measures

against cross-contamination, including identification of ingredients and finished products using lot numbers, cleaning of the manufacturing line, air-cleaning of clothes, hands of workers, and appropriate disposal of residues shall be taken.

- 4) Quantity of stored antimicrobial feed additives premixtures shall be checked and recorded.
- 5) Rework of products with defects shall be carried out using the method for which the safety has been validated. Information on rework including lot numbers of reworked product shall be recorded.
- 6) The products shall be appropriately labelled. Measures against contamination during transport of type A Feed, type B feed and exclusive feed for fish shall be taken, according to the Contamination Prevention Guidelines.
- 7) The records on manufacture shall be provided based on Article 52 of the [Feed Safety Act](#), and kept for eight years based on Article 72 of “[Ministerial Ordinance for Enforcement of the Act on Safety Assurance and Quality Improvement of Feeds](#)” (Ministry of Agriculture and Forestry Ordinance No. 36 of 1976).

Moreover, the record on storage, receipt and shipments, and manufacturing control shall be kept for at least two years.

- (2) The manufacturers and importers shall develop the procedure manual on the tests, laboratory analysis and other operations on quality control which are required to confirm that the operations according to the GMP guidelines are appropriately conducted and the safety of the products is sufficiently ensured (hereinafter referred to as “quality control procedure manual”). The quality and operation control managers or the designated person shall conduct activities on quality control based on the quality control procedure manual.

6. Tests and laboratory analysis

The business operator shall develop the procedure manual on sampling methods, testing methods, interpretation of the results, and other necessary items including the following items (hereinafter referred to as “test and laboratory procedure manual”) in order to ensure safety of ingredients and the quality control operations specified in 5 (2). In case the business operator outsources the test and laboratory analysis, the business operator shall request the outsourcee to develop such manual. The designated person appointed by either the business operator or the outsourcee shall conduct activities on tests and laboratory analysis.

- 1) Collecting samples of ingredients or final products at defined intervals set by the business operator or outsourcer in line with the method stated in “[Operation Guide for Inspection of Feed, etc.](#)” (Notification 52-Chiku-B No.793 of May 10, 1977, by the Director General of Livestock Industry Bureau, Ministry of Agriculture and Forestry) and creating records of sampling. As for products containing antimicrobial feed additives, in principle, the samples shall be collected by a manufacturing lot.
- 2) Testing collected samples at business site or external laboratories. As for feeds containing antimicrobial feed additives, including salinomycin sodium and monensin sodium, etc. described in Article 2, 2 (3) (a), a, (b) of “[Concerning the administration of the Act on Safety Assurance and Quality Improvement of Feeds](#)” (12 Seichiku No.1826 of March 30, 2001), the samples shall be tested and analyzed by a manufacturing lot.
- 3) A record of the results of the tests and laboratory analysis shall be provided and kept for at least two years in principle.
- 4) For manufactures, the results of the test and laboratory analysis shall be informed to the person in charge of the feed manufacturing or the manufacturing control manager in writing.
- 5) When non-conforming products are detected in the tests and laboratory analysis, or when deviations

from the usual state are observed, the causes shall be investigated and the necessary measures for preventing recurrence shall be taken.

- 6) The manufacturer shall store the samples collected for the certain period which the manufacturer itself has specified in the test and inspection procedure under the appropriate storage conditions after the tests and inspections. As for the final products containing antimicrobial feed additives, twice the amount of the samples required for the prescribed tests and inspections shall be stored.
- 7) The facilities and instruments to be used for the tests and inspections shall be periodically inspected and maintained and a record of the inspection and maintenance shall be created.

7. Self-inspection (Internal audits)

- (1) The business operator shall develop the procedure manual concerning the self-inspection for each business site in principle, in order to check that the process and quality control are implemented steadily and effectively. The business operator shall make designated person to periodically perform the self-inspection based on such procedure. The results shall be recorded and the record for at least two years in principle.
- (2) The business operator, based on the results of the self-inspection in (1), shall take the remedial measures, when the control method is required to be improved, Activities for remedy shall be recorded and the record shall be stored for at least two years in principle.

8. Actions to be taken in response to irregularity

The business operator shall develop the procedure manual concerning actions to be taken in response to irregularities including the following items, in principle, for each plant. Such irregularities include manufacture of non-conforming products and products which may cause health hazards to humans and/or livestock or the case such products may be manufactured caused by equipment troubles in the manufacturing process. The business operator shall make the manufacturing, quality, or operation control manager to take actions in accordance with the manual.

- 1) The causes of occurrence of irregularity shall be investigated and the countermeasures shall be taken.
- 2) When required, measures to improve hygiene, process control or quality management shall be taken.
- 3) Information shall be shared with the relevant business operators, including suppliers of ingredients and distributors as appropriate.
- 4) Products and ingredients with abnormality shall be appropriately handled.
- 5) Irregularity incidents shall be recorded with a summary of the incident, results of investigation and the measures for improvement, as appropriate. The record shall be kept for at least two years in principle.

9. Management of customer complaints

The business operator shall develop the procedure manual concerning actions to be taken in response to customer complaints on products safety including the following items, in principle, for each plant. The business operator shall make the manufacturing, quality, or operation control manager to take actions in accordance with the manual.

- 1) The causes of complaints shall be investigated and the countermeasures shall be taken.
- 2) When required, measures to improve hygiene, process control or quality management shall be taken.
- 3) Information shall be shared with the relevant business operators, including suppliers of ingredients and distributors as appropriate.
- 4) Management of complaints shall be recorded with a summary of complaints, the results of investigation and the measures for improvement. The record shall be kept for at least two years in principle.

10. Recall operation

The business operator shall develop the procedure manual for recall operation including the following item in case non-conforming products were manufactured or products might cause health hazards to humans or livestock. The business operator shall make the manufacturing, quality, or operation control manager to take actions regarding recall in accordance with the manual.

- 1) The causes of the recall shall be investigated and the countermeasures shall be taken.
- 2) When required, measures to improve hygiene, process control, or quality control shall be taken.
- 3) Information shall be shared with the relevant business operators, including suppliers of ingredients and distributors as appropriate.
- 4) Recalled product shall be appropriately handled.
- 5) Recall incidents shall be recorded with a summary of the recall, the results of investigation and the measures for improvement. The record shall be kept for at least two years in principle.
- 6) Recall incidents shall be reported to the Animal Products Safety Division, Food Safety and Consumer Affairs Bureau, MAFF (hereinafter referred to as "Animal Products Safety Division"), in principle, through the FAMIC.

11. Cooperation with government administrations and the relevant organizations

In order to ensure feed safety or respond to the incidents in which feed may compromise food safety, the business operator shall cooperate with MAFF and the relevant organizations including the FAMIC as follows.

(1) Registration of business operators

The business operator shall register its e-mail address with the FAMIC in order to receive the information on the safety assurance of feed, etc. which the FAMIC will send.

(2) Reporting of the quantity of feed imported or manufactured

The importers and manufacturers shall report the previous year's quantity of feed imported or manufactured in the [appended form 1](#) or [2](#) to the Animal Products Safety Division by July 31 every year by e-mail, fax, etc.

When the report of such fiscal year has been already submitted to MAFF in some way, the above report shall not be required.

(3) Collection of information on production areas

The importer shall collect and organize the relevant information which may affect the feed safety.

Such information includes extreme weather (for example, drought) in the production area, occurrence of mycotoxins during the storage or usage of pesticide for massive insect pests. Information considered to be of special importance shall be reported to the Animal Products Safety Division through the FAMIC.

(4) Cooperation for surveillance and monitoring

When the FAMIC performs surveillance and monitoring based on the "annual plan of surveillance and monitoring of hazardous chemicals concerning the food safety," etc., the business operator shall cooperate with it for those activities, including providing samples.

(5) Providing the information on the results of tests and laboratory analysis.

When the results of the tests and laboratory analysis indicates a trend that feed safety issue might arise such as the problem might affect large area, the business operator shall provide the information to the Animal Products Safety Division or the FAMIC.

(6) Use the shared information

The business operator shall use the results of surveillance and monitoring and other information, etc. provided by the Animal Products Safety Division, ingredient suppliers to know the latest information which may affect the safety of feed. If necessary, ingredient suppliers, variety of ingredients, frequency

and targets of tests, etc. shall be reviewed.

IV. Process control based on the hazard analysis

The business operator is recommended to develop a control method base on the HACCP principle in order to effectively and efficiently reduce risks by the following procedures 1 and 2 in addition to the implementation of GMP. Control method might be selected corresponding to the manufacturing conditions including variety of ingredients, source of ingredients, variety of products, settings of establishments. This procedure can be replaced by the procedure for HACCP introduction specified in the Codex Alimentarius or the procedure specified by the food safety management systems which requires HACCP procedures.

1. Hazard analysis

The business operator should prepare the list including the specifications of ingredients and the table describing the results of hazard assessment for each site.

2. Process control in the critical control points

- (1) Based on the assessments provided in 1, the business operator should determine the major processes which are significant for controlling hazards and specify the control method in the process control standard code.
- (2) The business operator should establish the procedure so that the manufacture or operation control manager of such business site appropriately and smoothly perform the process control procedure specified in the process standard code and shall reflect such procedure in both the process and quality control procedure manuals specified in III. 5.
- (3) The business operator validates the appropriateness of the control method specified in (1) at sufficient frequencies.

V. Verification by FAMIC

If a FAMIC confirmed regarding implementing a management based on the third of GMP guidelines by an application from a manufacturer or an importer in accordance with [Attachment 2](#), a certificate of verification shall be issued.

VI. Manufacturing process control concerning formula feed containing antimicrobial feed additives and premixture of antimicrobial feed additives

The manufacturers manufacturing formula feed containing antimicrobial feed additives and premixture of antimicrobial feed additives are exempted from the analysis of every manufacturing lot specified in III. 6. 2), when the FAMIC confirms the control status, etc. of antimicrobial feed additives, according to [“Establishing the guidelines for manufacturing and quality control of formula feed containing antibacterial feed additives and compound preparation of antibacterial feed additives”](#) (Notification 18 Sho-an No. 13845 of April 10, 2007, by Notice of the Director-General of Food Safety and Consumer Affairs Bureau, MAFF) or when the FAMIC confirms the control status, etc. in accordance with GMP guidelines by V.

(Appended form 1)

Report of manufacturing quantity of feed, etc. (Fiscal Year YYYY)

Date: YYYY/MM/DD

To Person in Charge of Feed Inspection Instruction Group, Animal Products Safety Division, Food Safety and Consumer Affairs Bureau, Ministry of Agriculture, Forestry and Fisheries of Japan (FAX: 03-3502-8275)

Name of Company: _____
 Person in charge : _____
 Zip code : _____
 Contact Address : _____
 Phone : _____
 E-mail address : _____

Table 1 Feed

Category		Name of kind of feed	Manufacturing quantity (ton) ¹⁾
Single feed	Feed A ²⁾		
	Other than Feed A		
Mixed feed	Feed A ²⁾		
	Other than Feed A		
Formula feed	Feed A ²⁾		
	Other than Feed A		

Table 2 Feed Additives

Category	Name of kind of feed additives	Manufacturing quantity (ton) ¹⁾
Feed A ²⁾		
Other than Feed A		

<< Instructions for filling out the above >>

- 1) For manufacturing quantity, round off the figure if the accurate total figure has not been obtained.
- 2) "Feed A" means feed used for ruminant (cattle, sheep, goats, and deer) (including those shared for other livestock).
- 3) If the space for entry is not large enough, use an additional paper.

(Appended form 2)

Report of import quantity of feed, etc. (Fiscal Year YYYY)

Date: YYYY/MM/DD

To Person in Charge of Feed Inspection Instruction Group, Animal Products Safety Division, Food Safety and Consumer Affairs Bureau, Ministry of Agriculture, Forestry and Fisheries of Japan (FAX: 03-3502-8275)

Name of Company : _____
 Person in charge : _____
 Zip code : _____
 Contact Address : _____
 Phone : _____
 E-mail address : _____

Table 1 Feed (grass hay and main grain)

Category	Name of exporting country	Number imported	Import Quantity (ton) ¹⁾
Grass hay			
Corn			
Milo			
Rye			
Oats			
Other wheat and barley			

Table 2 Feed (Excluding those reported in Table 1)

Category		Item	Number imported	Name of exporting country	Import Quantity (ton) ¹⁾
Single feed	Feed A ²⁾				
	Other than Feed A				
Mixed feed	Feed A ²⁾				
	Other than Feed A				
Formula feed	Feed A ²⁾				
	Other than Feed A				

Table 3 Feed Additives

Category	Item	Number imported	Name of exporting country	Import Quantity (ton) ¹⁾
Feed A ²⁾				
Other than Feed A				

<< Instructions for filling out the above >>

- 1) For import quantity, round off the figure if the accurate total figure has not been obtained.
- 2) "Feed A" means feed used for ruminant (cattle, sheep, goats, and deer) (including those shared for other livestock).
- 3) If the space for entry is not large enough, use an additional paper.

Attachment 2

Verification procedure based on guidelines of Good Manufacturing Practice (GMP) for Feed

I. Verification procedure

1. The importer and the manufacturer for Feed, etc. (hereinafter referred to as “applicant”) shall apply for verification to the president of Food and Agricultural Materials Inspection Center (hereinafter referred to as “FAMIC”) when they want to be verified by the FAMIC that their management system is in accordance with III of the guidelines of Good Manufacturing Practice (GMP) for Feed (hereinafter referred to as “guidelines”). The manufacturer shall apply for each manufacturing site.
2. The applicant shall pay the necessary expenses to the FAMIC in accordance with the FAMIC regulations when applying for the above item 1.
3. When the above application is submitted by the applicant, the FAMIC conducts an on-site inspection to determine whether the business site of applicant complies with III of the guidelines.
The FAMIC notifies the applicant of the result of conformity judgment.
The FAMIC will issue a certificate of verification to the applicant if it verified that applicant’s business site is operating according to the guidelines.
For manufacturers, the FAMIC will perform on-site inspection, notification of the result of conformity judgment, and issuance of a certificate of verification for each manufacturing site.
If the FAMIC determines that it is clear that the applicant’s business site partially meets the guidelines, for example, the applicant has obtained a private certification for a food safety management system, the FAMIC may omit part of the on-site inspection for verification.
4. Business operator who has been verified to comply with the guidelines shall notify the FAMIC of non-conformance with the guidelines if they no longer comply with the guidelines, and shall return the a certificate of verification.
The same treatment shall apply if business operator doesn’t renew the certification before the validity period of the certification expires.
5. The FAMIC may cancel verification when a verified business operator no longer complies with the guidelines.
6. The validity period of verification is 3 years.

II. Intermediate verification

1. Business operator shall apply for intermediate verification to the FAMIC every year after first or renewed verification.
2. When the above application is submitted by the applicant, the FAMIC conducts on- site inspection to check records etc. to determine whether the business site of applicant maintain compliance with the guidelines. The FAMIC notifies the result of conformity judgment to the applicant.
3. The validity period shall expire when the business operator does not applicate for intermediate application based on II.1.

III. Standard of Verification

1. Organization and employees

III.1 (1), (2) of the guidelines and following requirements shall be met.

- (1) Establishment of Management system

- 1) Organizational chart that shows department, position, name and description of job about the person responsible and the person in charge shall be prepared. The responsibility and authority of process control manager, quality control manager and operation control manager in the organization shall be clarified.
 - 2) Process control manager, quality control manager, operation control manager or the designated person shall carry out the operation according to the guidelines.
- (2) Education and training of employees
- 1) In the procedure manual on education and training, purpose, contents, plans, method and recording method etc. of training shall be described. Also, planning document which identified target person for education and training shall be prepared.
 - 2) Process control manager, quality control manager and operation control manager or the designated person shall attend a Feed safety seminar held by outside once a year in principle.
2. Establishment and maintenance of facilities
- III.2. of the guidelines and following requirements shall be met.
- (1) Premises and facilities
- 1) The target of maintenance of the facility, method of maintenance, frequency, the person responsible and recording method shall be specified.
 - 2) The border of site, controlled access area of vehicle or/and human shall set when required in terms of prevention of contamination in the facility.
Also, when required, controlled area that is distinguished from other areas (hereafter referred to as "clean area") shall be set up to prevent biological contamination. The cleanliness of the clean area has been confirmed by periodic test inspections.
 - 3) The type of feed handled at each site in premises and facilities (type A feed, type B feed, or exclusive feed for fish) shall be identified.
 - 4) Operation process and sites where the feed etc. are exposed to the open air shall be identified to prevent environment-origin contamination.
- (2) Equipment and instruments
- 1) The target of maintenance of the equipment, method of maintenance, frequency, the person responsible and recording method shall be specified.
 - 2) If the clean area is set in the business site, among the equipment and instruments set up in clean area, the equipment that needs management in terms of prevention of microbiological contamination shall be identified.
 - 3) Equipment and site for water supply and drainage shall be identified. In the case of using water other than water supply, the using water shall be confirmed to be suitable for use by water quality test etc.
 - 4) Equipment and site for treating dispose drainage water and waste shall be identified.
 - 5) The type of feed handled in each equipment (type A feed, type B feed, or exclusive feed for fish) shall be identified.
 - 6) Equipment (including shared equipment) which contact antimicrobial feed additives or feeds containing antimicrobial feed additives, etc. directly shall be identified. Equipment which adds and mixes antimicrobial feed additives shall be confirmed to work properly at all times.
 - 7) Type, number, setting position, measurement range, measurement accuracy of measurement instruments shall be clarified and maintenance method shall be specified.
Type, number, setting position of blending machine shall be clarified and maintenance method shall be specified.

The mixing accuracy of the blending machine that mixes the antimicrobial feed additives shall be checked at least once a year.

3. Management of incoming ingredients

III.3 of the guidelines and following requirements shall be met.

- (1) Validity of specification of the incoming ingredients shall be confirmed periodically. Review of specification etc. and re-sign with the suppliers shall be conducted as appropriate.
- (2) A method of confirming the safety of incoming ingredients shall be specified. Also, the method of confirming the management conditions of ingredients suppliers shall be specified in advance. The status of compliance with the specifications of incoming ingredients shall be confirmed periodically by tests and laboratory analysis.

4. Hygiene management

(1) III.4 of the guidelines and following requirements shall be met.

- 1) In the hygiene management manual, a concrete control method, the person responsible, and a recording method, etc. shall be described.
 - 2) A control method of entrance and exit of people and materials, such as gowning and disinfection of shoes, etc. shall be specified according to hygienic conditions which is required by each work area.
 - 3) A process and a place which requires disinfections are identified and a disinfection method and a disinfectant shall be specified. In the process, the points where measures against condensation, hardened/left feeds, etc. are heavily implemented shall be specified, and a control method and a measure in order not to contaminate products with hardened/left and decayed feeds shall be specified. No occurrence of microbial contamination in such places shall be checked by a regular testing and inspection.
 - 4) A place which may be polluted by harmful animals and pests is identified and a control method, the person responsible, a recording method, a confirmation method of effectiveness of measures shall be specified.
 - 5) Agent to be used in cleaning, disinfection, and pest control shall be specified to prevent harmful materials from contaminating the feed. A method of the agent, a storage method, the person responsible, a recording method of the agent being used shall be specified. The agent shall be stored in a designated place by a designated method.
 - 6) A storage area and a method of storage for waste shall be specified to prevent waste and waste water from contaminating equipment for handling feed. Waste and waste water shall be stored in designated area and equipment.
- (2) The verification methods for hygiene management shall be specified in advance. Based on the verification results, the procedure manual shall be reviewed as necessary.

5. Process and quality controls

(1) III.5 (1) of the guidelines and the following requirements shall be met.

- 1) In the process control manual, the specific control method, the person responsible, the person in charge, and the recording method shall be described.
- 2) The confirmation procedure when receiving ingredients shall be specified.
- 3) The confirmation method shall be specified as follows: the method of preparation of manufacturing instructions and product formulation specifications, person responsible, the method of determination of the manufacturing sequence of feeds containing antimicrobial feed additives, and the method of confirmation that the product formulations meet the specifications/standards stipulated by law. The

prepared product formulation specifications shall meet the specifications/standards stipulated by the law.

- 4) The measures for cross-contamination of type A feed, type B feed, and exclusive feed for fish, cross-contamination of feeds with and without antimicrobial feed additives, and cross-contamination of ingredients and products shall be specified.
 - 5) The procedure for checking the quantity of stored antimicrobial feed additives, the person responsible, the person in charge, and the method of records shall be specified. The quantity of stored antimicrobial feed additives shall be checked every day.
 - 6) The confirmation method of safety when reworking shall be specified in advance.
 - 7) The procedure of creating labels, the person responsible, the method for checking whether the labels are appropriated or not, and the handling method for labels which are no longer needed shall be specified. The labels displayed on the products shall confirm to meet the labeling standards stipulated by the law.
 - 8) The receipt of ingredients, manufacture of products, and the status of shipments shall be described in the record books in relation to each other by lot numbers according to Article 52 of the Feed Safety Act.
- (2) III.5 (2) of the guidelines and the following requirements shall be met.
- 1) In the quality control procedure manual, the contents of work related to quality control, the person responsible, and the recording method shall be described.
 - 2) The procedure for creating the quality control plan that specifies the timing of implementation, the frequency, the target, and the method for the quality control including tests and laboratory analysis shall be specified.
 - 3) The content of antimicrobial feed additives in feeds shall be confirmed by periodical tests and laboratory analysis to meet the specifications/standards specified by the law.
 - 4) The effective functioning of measures against cross-contamination of type A feed, type B feed, and exclusive feed for fish, and cross contamination of feeds with and without antimicrobial feed additives, and cross contamination of ingredients and products shall be confirmed by periodical tests and laboratory analysis.
 - 5) When the process of pressurized heating treatment is included, the production of feeds containing antimicrobial feed additives shall be pre-checked for effects on the antimicrobial feed additives in products.
- (3) The verification methods for process control and quality control shall be specified in advance. Based on the verification results, the procedure manual shall be reviewed as necessary.

6. Tests and laboratory analysis

III. 6. of the guidelines and following requirements shall be met.

- (1) In the test and laboratory procedure manual, including a case of an outsourcing, a sampling method, a testing method, the person in charge, the person responsible, the method for interpretation of the results, the action to be taken based on the results, a storage method of the samples, a recording method, etc. shall be described.
- (2) Methods used for tests and laboratory analysis shall be validated in advance.

7. Self-inspection (internal audits)

III. 7. of the guidelines and following requirements shall be met.

(1) In the procedure manual concerning the self-inspection, the person responsible of the self-inspection, the person in charge, inspection contents, a timing of implementation, a recording method, etc. shall be described.

(2) Based on the self-inspection results, the procedure manual shall be reviewed as necessary.

8. Actions to be taken in response to irregularity

III. 8. of the guidelines and following requirements shall be met.

(1) In the procedure manual of actions to be taken in response to irregularity, criteria of the situation of irregularity to be applied to the manual, a contact and information sharing system when an irregularity has occurred, a handling method for products with abnormality, a system of the investigation of the causes, a recording method, etc. shall be described.

(2) As the measures for the improvement based on the results of the investigation of the causes, the procedure manual etc. are reviewed as needed.

9. Management of customer complaints

III. 9. of the guidelines and following requirements shall be met.

In the procedure manual of management of customer complaints, a response procedure for customer complaints, a contact system, a handling method of products etc. that were subject to customer complaints, a system of the investigation of the causes, a recording method, etc. shall be described.

10. Recall operation

III. 10. of the guidelines and following requirements shall be met.

In the procedure manual of recall operation, a response procedure for recall operation, a contact system, a methods for storage, identification and handling of recalled products, a recording method, etc. shall be described.

11. Cooperation with the government administrations and relevant organizations

III. 11. of the guidelines and following requirements shall be met.

Email address registered with the FAMIC shall be up-to-date.

IV. Exemption from control method of antimicrobial feed additives

The business sites manufacturing formula feed or premixture containing antimicrobial feed additives or premixture of antimicrobial feed additives which has received a certificate of verification from the director of the center FAMIC based on “the first” “I. Verification procedure” are exempted from the analysis of every manufacturing lot of feeds(*) specified in the following notifications.

(*) Feed which including Salinomycin sodium, Monensin sodium, Lasalocid sodium, Halofuginone polystyrene calcium sulfonate, Semduramicin sodium or Narasin.

- “Regarding enforcement of ministerial ordinance, etc. revising a part of Ministerial Ordinance on the Specification and Standards of Feed and Feed additives” (Joint notification 53-Chiku-B No.2173/ 53-Suishin No.464, by the Director General of Livestock Industry Bureau / the Director General of Fisheries Agency, MAFF of Japan, dated September 5, 1978)
- “Regarding enforcement of ministerial ordinance, etc. revising a part of Ministerial Ordinance on the Specification and Standards of Feed and Feed additives” (Notification 58-Chiku-B No.1676, by the Director General of Livestock Industry Bureau, MAFF of Japan, dated July 6, 1983)
- “Regarding enforcement of ministerial ordinance, etc. revising a part of Ministerial Ordinance on the Specification and Standards of Feed and Feed additives” (Joint notification 60-Chiku-B No.2928, by the

Director General of Livestock Industry Bureau/the Director General of Fisheries Agency, MAFF of Japan, dated October 15, 1985)

- “Regarding enforcement of ministerial ordinance, etc. revising a part of Ministerial Ordinance on the Specification and Standards of Feed and Feed additives” (Joint notification 62-Chiku-B No.3099, by the Director General of Livestock Industry Bureau/the Director General of Fisheries Agency, MAFF of Japan, dated December 25, 1987)
- “Regarding enforcement of ministerial ordinance, etc. revising a part of Ministerial Ordinance on the Specification and Standards of Feed and Feed additives” (Joint notification 3-Chiku-B No.1113, by the Director General of Livestock Industry Bureau/the Director General of Fisheries Agency, MAFF of Japan, dated June 3, 1991)
- “Regarding enforcement of ministerial ordinance, etc. revising a part of Ministerial Ordinance on the Specification and Standards of Feed and Feed additives” (Notification 6-Chiku-B No.1012, by the Director General of Livestock Industry Bureau, Ministry of Agriculture, Forestry and Fisheries of Japan, dated July 18, 1994)

[Note]

This English translation of this guidelines has been prepared up to the revisions of Notice 27 Sho-an No. 6399 of 2016.

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