

Matters to Set Out the Manufacturing Standards for Feeds and Feed Additives Derived from Recombinant DNA Technology based on the provisions of the Ministerial Ordinance on the Specifications and Standards of Feeds and Feed Additives

Ministry of Agriculture, Forestry and Fisheries Notification No. 1782 of November 26, 2002

Ministry of Agriculture, Forestry and Fisheries Notification No. 362, partially revised on February 28, 2005

Ministry of Agriculture, Forestry and Fisheries Notification No. 1007 of July 23, 2014

Ministry of Agriculture, Forestry and Fisheries Notification No. 971 of June 20, 2025

Based on the provisions in 1 (2) L of Appended Table 1 and 3 (8) of Appended Table 2 of the Ministerial Ordinance on the Specifications and Standards of Feeds and Feed Additives (Ordinance of the Ministry of Agriculture and Forestry No. 35 of 1976), the manufacturing standards for feeds and feed additives derived from recombinant DNA technology shall be stipulated as follows.

(Application)

Article 1 The manufacturing standards prescribed in 1 (2) J of Appended Table 1 and 3 (8) of Appended Table 2 of the Ministerial Ordinance on the Specifications and Standards of Feeds and Feed Additives (Ordinance of the Ministry of Agriculture and Forestry No. 35 of 1976) shall be governed by the provisions of this public notice.

(Manufacturing Standards)

Article 2 Standards specified by the Minister of Agriculture, Forestry and Fisheries as prescribed in 1 (2) J of Appended Table 1 and 3 (8) of Appended Table 2 of the Ministerial Ordinance on the Specifications and Standards of Feeds and Feed Additives (hereinafter referred to as “Manufacturing Standards”) shall be as set forth in Appended Forms 1 and 2.

(Application for Confirmation)

Article 3 Those who intend to obtain the confirmation set forth in 1 (2) J of Appended Table 1 and 3 (8) of Appended Table 2 of the Ministerial Ordinance on the Specifications and Standards of Feeds and Feed Additives shall submit a written application pursuant to Appended Form 1 to the Minister of Agriculture, Forestry and Fisheries for each workplace, attaching a document proving that the relevant workplace conforms to the Manufacturing Standards.

(Confirmation)

Article 4

- 1 When a written application is submitted pursuant to the provisions of the preceding Article, the Minister of Agriculture, Forestry and Fisheries shall confirm whether the workplace conforms to the Manufacturing Standards.
- 2 A manufacturing workplace in a foreign country that the Minister of Agriculture, Forestry and Fisheries finds to be controlled by standards equal to or higher than the Manufacturing Standards shall be deemed to have been confirmed by the Minister of Agriculture, Forestry and Fisheries under the preceding paragraph.

(Change of Facilities, Etc., at Workplace)

Article 5 It shall proceed as directed in the provisions of Article 3 and paragraph (1) of the preceding Article as to changes to facilities, etc., at workplaces that have been confirmed by the Minister of Agriculture, Forestry and Fisheries under the said paragraph.

(Revocation of Confirmation)

Article 6 If the Minister of Agriculture, Forestry and Fisheries finds that a workplace has ceased to conform to the Manufacturing Standards, the Minister shall revoke the confirmation set forth in Article 4, paragraph (1).

(Report)

Article 7

- 1 Those who have obtained the confirmation set forth in Article 4, paragraph (1) shall report to the Minister of Agriculture, Forestry and Fisheries the status of production at each workplace in accordance with Appended Form 2 at the beginning and end of the production of feeds or feed additives derived from recombinant DNA technology and at the end of each fiscal year.
- 2 Manufacturers shall promptly report to the Minister of Agriculture, Forestry and Fisheries any occurrence that affects the safety of feeds or feed additives derived from recombinant DNA technology in the manufacture thereof.

Appended Form 1

Month Date Year

To the Minister of Agriculture, Forestry and Fisheries

Address (location of principal office
in the case of a corporation)

Name (name of the corporation and its representative
in the case of a corporation)

Based on the Manufacturing Standards for Feeds and Feed Additives Derived from Recombinant DNA Technology (Ministry of Agriculture, Forestry and Fisheries Notification No. 1782 of November 26, 2002), we will apply for the confirmation of compliance with the manufacturing standards of the following items in the attachment:

Feeds derived from recombinant DNA technology

Feed additives derived from recombinant DNA technology

(Notes)

- 1 The paper size shall be Japanese Industrial Standards A4 size.
- 2 Characters shall be clearly written in standard style using ink, etc.

Appended Form 2

Status of production of feeds or feed additives derived from recombinant DNA technology

| | | Month | Date | Year |
|--------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------|----------------|------|------|
| Manufacturer | Address | (Postal code) | | |
| | Name | (Tel) | | |
| | Title and name of the representative | | | |
| Manufacturing workplace | Address | (Postal code) | | |
| | Name | (Tel) | | |
| Name of manufactured item (generic name) and manufacturing quantity | | | | |
| Title and name of manufacturing control manager | | | | |
| Title and name of manufacturing safety supervisor | | | | |
| Title and name of the chairperson of the Manufacturing Safety Committee | | | | |
| Overview of manufacturing | | | | |
| Manufacturing start date | | Month | Date | Year |
| Status of holding Manufacturing Safety Committee's meetings | | | | |
| Whether or not there has been any problem in manufacturing, and if there has been a problem, the condition thereof and the measures taken at the time. | | | | |
| Others | | | | |

(Notes)

- 1 The paper size shall be Japanese Industrial Standards A4 size.
- 2 Characters shall be clearly written in standard style using ink, etc.
- 3 If it is not possible to describe all of the matters to be entered in the entry column, it shall be written as "as shown in Attachment ()" in the relevant column, and an attachment shall be included.
- 4 Any part that has changed since the last submission shall be marked with *.

Appended Form 1 (Re: Article 2)

Standards for Facilities, Equipment, and Apparatus

When manufacturing feeds or feed additives using recombinants (hosts (in recombinant DNA technology, referring to living cells into which DNA is transferred; the same shall apply hereinafter) containing recombinant DNA), facilities, equipment, and apparatus that satisfy the following requirements shall be used:

- 1 Work areas (areas where recombinants are directly handled to conduct manufacturing operations; the same shall apply hereinafter) shall be provided.
- 2 Work areas shall be separated from other areas and shall have culture and fermentation apparatus for the production of feeds or feed additives using recombinants.
- 3 Equipment for testing and inspecting the biological properties of recombinants and the quality of feeds or feed additives shall be provided.
- 4 The following equipment shall be provided:
 - (1) Storage equipment, such as freezers and refrigerators, capable of storing recombinants and non-recombinant products separately
 - (2) Equipment for hygienically preparing media, etc.
 - (3) Equipment capable of cleaning and sterilizing machinery and instruments, containers, etc., used for manufacturing or testing and inspection
- 5 Equipment capable of producing feeds or feed additives without unintentionally mixing recombinants shall be provided.
- 6 Equipment that does not generate unsafe impurities in the manufacturing processes or that prevents them from being mixed into feeds or feed additives shall be provided.
- 7 Other equipment and apparatus deemed necessary for handling recombinants shall be provided.

Appended Form 2 (Re: Article 2)

Standards for Officials and Organizations

- 1 A person who performs the following operations (hereinafter referred to as “manufacturing control manager”) shall be appointed for each manufacturing workplace.
 - 1 A manual describing the matters related to the management of equipment and apparatus, handling of recombinants, and handling of feeds or feed additives derived from recombinant DNA technology (hereinafter referred to as the “Manufacturing Control Manual”) shall be prepared.
 - 2 A manufacturing plan for feeds or feed additives derived from recombinant DNA technology shall be designed, and a manual describing the matters related to the

manufacture of feeds or feed additives derived from recombinant DNA technology and the prevention of contamination by recombinants shall be prepared (hereinafter referred to as “Manufacturing Operation Manual”).

- 3 A manual describing countermeasures against accidents, such as spillage of culture fluid containing recombinants, and operation procedures in emergency (hereinafter referred to as the “Emergency Response Manual”) shall be prepared.
- 4 The following matters shall be recorded and stored for five years from the day when the manufacture of feeds or feed additives derived from recombinant DNA technology is completed.
 - (1) Name of the recombinant and the number affixed to the container thereof
 - (2) Status of storage and passage of the recombinant such as storage location, storage conditions, number of passages, person in charge of storage, and start date of storage
 - (3) Biological properties of the recombinant and the date of testing and inspection
 - (4) Name and address of the supplier of the recombinant, the date of the transfer, and the name of the transferee
 - (5) Records of periodic inspections of equipment and apparatus and manufacturing records
 - (6) Records of testing and inspections of feeds or feed additives derived from recombinant DNA technology
- 5 An inventory of stored articles, including recombinants, shall be prepared and stored.
- 6 Appropriate overall control and supervision of manufacturing operations shall be conducted.
- 7 Persons engaged in manufacturing operations (hereinafter referred to as “manufacturing workers”) shall be familiarized with the Manufacturing Operation Manual in advance, and education and training on the following matters shall be provided to them before engaging in manufacturing operations:
 - (1) Knowledge of the safety of recombinants, including the origin, manufacturing process, and properties
 - (2) Skills for safe handling of recombinants used in manufacturing
 - (3) Knowledge of equipment and apparatus and skills to handle them
 - (4) Knowledge of sanitary control during manufacturing processes, prevention of contamination, etc.
 - (5) Knowledge of measures to be taken in the event of an accident, such as familiarity with the Emergency Response Manual
- 8 The committee for ensuring safety in the manufacture of feeds or feed additives derived from recombinant DNA technology (hereinafter referred to as the “Manufacturing Safety Committee”) shall be requested to investigate and deliberate on ensuring the safety of operations related to the manufacture of feeds or feed additives derived from recombinant DNA technology.
- 9 Other matters necessary for ensuring the safety of feeds or feed additives derived from recombinant DNA technology shall be implemented.

- 2 A person who performs the following operations (hereinafter referred to as “manufacturing safety supervisor”) for each manufacturing workplace shall be appointed from among those who are highly proficient in the knowledge and skills required for hygiene management during the manufacturing processes and for ensuring the safety of feeds or feed additives derived from recombinant DNA technology.
 - 1 It shall be confirmed that the manufacture of feeds or feed additives derived from recombinant DNA technology is carried out properly in accordance with this public notice.
 - 2 The manufacturing control manager shall be assisted in recombinant DNA technology.
 - 3 Other matters necessary for ensuring the safety of feeds or feed additives derived from recombinant DNA technology shall be implemented.

- 3 A Manufacturing Safety Committee that satisfies the following requirements shall be established for each manufacturing workplace:
 - 1 The Manufacturing Safety Committee shall be composed of persons from appropriate fields, with due considerations to the requirement of highly specialized knowledge and skills, and judgment from a broad perspective.
 - 2 At the request of the representative of the manufacturer or the head of the manufacturing workplace and the manufacturing control manager, the Manufacturing Safety Committee shall investigate and deliberate on the following matters, provide necessary advice or recommendations to the representative of the manufacturer or the head of the manufacturing workplace and the manufacturing control manager, and keep the record of deliberations for five years.
 - (1) Conformity of the Manufacturing Control Manual and the Manufacturing Operation Manual with this public notice
 - (2) Status of implementing safety education and training and health management for manufacturing workers
 - (3) Suitability of the Emergency Response Manual
 - (4) Necessary measures and improvement actions in the event of an accident
 - (5) Other matters necessary for ensuring the safety of feeds or feed additives using recombinant DNA technology

- 4 A manual on the implementation of periodic medical examinations shall be prepared for manufacturing workers involved in the production of feeds or feed additives derived from recombinant DNA technology, and the results of the periodic medical examinations shall be kept for five years.