

Voluntary Report – Voluntary - Public Distribution

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Report Number: JA2019-0020

Report Name: Japan Invites Comments for Feed Safety Guidelines on the Handling of Genome-edited Feeds and Feed Additives - Revised

Country: Japan

Post: Tokyo

Report Category: Biotechnology and Other New Production Technologies, Grain and Feed

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Report Highlights:

On September 11, 2019, Japan's Ministry of Agriculture, Forestry and Fisheries opened the public comment period for Feed Safety Guidelines on the Handling of Genome-edited Feeds and Feed Additives. The public comment period will close on October 10, 2019.

On September 11, 2019, Japan's Ministry of Agriculture, Forestry, and Fisheries (MAFF) opened a 30 day public comment period for the Feed Safety Guidelines on the Handling of Genome-edited Feeds and Feed Additives. Comments must be submitted in Japanese and should contain the following information.

- Name (personal or corporate names)
- Address
- Contact information (telephone number and/or email address)

MAFF may use this information to confirm the details and/or meaning of comments. MAFF also may share this information with other MAFF divisions and/or other Japanese Government ministries depending on the contents of the comments. Also, please note that the filed comments may be released to the public with the name of the commenter.

Comments can be sent via one of three methods indicated below by October 10, 2019.

How to Submit Comments

1. Japanese Government's "e-Gov" system

Comments can be sent electronically via the "e-Gov" system which enables electronic submission of comments on regulatory proposals by the Japanese Government. The site for commenting on the proposed regulatory policy for the handling of food products derived from genome editing technology can be found at:

<https://search.e-gov.go.jp/servlet/Public?CLASSNAME=PCMMSTDETAIL&id=550002965&Mode=0>

2. Mail

Comments can be mailed to the address below:

Genetically Engineered Feed Group
Animal Products Safety Division
Food Safety and Consumer Affairs Bureau
Ministry of Agriculture, Forestry and Fisheries
1-2-1, Kasumigaseki, Chiyoda-ku Tokyo 100-8950 Japan

3. Facsimile

Comments can be sent via fax to the number indicated below:

Facsimile number: 03- 3502-8275 (from outside Japan, +81-3- 3502-8275)

Genetically Engineered Feed Group
Animal Products Safety Division
Food Safety and Consumer Affairs Bureau
Ministry of Agriculture, Forestry and Fisheries

The original documents, in Japanese, can be found at the site below.

<https://search.e-gov.go.jp/servlet/Public?CLASSNAME=PCMMSTDETAIL&id=550002965&Mode=0>

A provisional translation of MAFF's proposed draft for "Feed Safety Guidelines on the Handling of Genome edited Feeds and Feed Additives" can be found below.

Feed Safety Guidelines on the Handling of Genome-edited Feeds and Feed Additives (Draft)

1. Definition

(1) Genome-editing Technology

Genome-editing technology is defined as technology that modifies a specific site of a base sequence using an enzyme recognizing specific base sequences on a chromosome in order to add a specific function. In addition, in case foreign genes or fragments of such genes are contained in the end, it shall fall under recombinant DNA techniques.

(2) Genome-edited Feeds

Genome-edited Feeds shall fall under any of the following.

[1] Whole or part of a living organism obtained by genome-editing technology

[2] Those containing the whole or part of the concerned organism

[3] Those produced using microorganisms obtained by genome-editing technology or those containing the concerned microorganism

(3) Genome-edited Feed Additive

A Genome-edited feed additives are defined as additives produced using living organism obtained by genome-editing technology or containing the concerned materials.

In addition, among the genome-edited feed additives, in case the end product is a highly purified non-protein additive, such as an amino acid and vitamin, and meets requirements [1] and [2] described below, it shall be handled as a "highly purified feed additive" like feed additives produced using recombinant DNA technology.

[1] The purity of the product is equal to or greater than existing feed additives.

[2] Compared to conventional additives, the content of existing non-active ingredients have not increased significantly in said additive to a level that could cause a safety issue, and no new non-active ingredients suggested to be harmful are included.

2. Genome-edited Feeds Subject to Notification

Among Genome-edited Feeds, in case a feed is;

- the whole or part of a living organism obtained by genome-editing technology,
- produced using microorganisms obtained by genome-editing technology, wherein no foreign genes or fragments of such genes remain, and those of which results in deletion of base(s), substitution and insertion of a few bases caused by cleavage by an enzyme recognizing specific base sequences, and the consequent insertion of mutations of one to several bases due to failure of repair at the cleavage site of an artificial restriction enzyme, shall be subject to notification.

Therefore, feed products manufactured and processed by using the notified genome-edited feeds do not require notification.

In addition, those excluded from the above, that contain foreign genes or fragments of foreign genes, shall follow the Procedures of Application for Safety Assessment of Feeds and Feed Additives Produced by Recombinant DNA Techniques (Ministry of Agriculture, Forestry and Fisheries Notification No. 1780, 2002, hereinafter referred to as "Safety assessment notification") and undergo the safety assessment. Necessity of notification or safety assessment for those of which are not described above shall be judged individually and specifically by the Ministry of Agriculture, Forestry and Fisheries.

3. Genome-edited Feed Additives Subject to Notification

(1) In case genome-edited feed additives are derived from microorganisms

As for additives, it is basically assumed that they conform to the component standards defined in the standards for feed, additives, etc. (notice No. 35 of the Ministry of Agriculture, Forestry and Fisheries, 1976, hereinafter referred to as "standards notification").

Regarding microorganisms used to produce genome-edited feed additives;

- those of which no foreign genes or fragments of such genes introduced by using genome-editing technology remain,
- those of which results in deletion of base(s), substitution and insertion of a few bases caused by cleavage by an enzyme recognizing specific base sequences, and the consequent insertion of mutations of one to several bases due to failure of -repair at the cleavage site of an artificial restriction enzyme,

shall be subject to notification.

However, those meeting [1] or [2] described below do not require notification.

[1] The said additive is produced using the microorganism obtained by genome-editing technology and it is clear that the gene composition is equivalent to that of the microorganisms that belong to the same taxonomy species or exist in nature.

[2] The said additive is produced using the microorganism obtained by genome-editing technology and is a highly purified additive.

In addition, those excluded from the above, that contain foreign genes or fragments of the genes, shall follow Safety assessment notification and undergo the safety assessment.

Necessity of notification or safety assessment for those that are not described above shall be judged individually and specifically by the Ministry of Agriculture, Forestry and Fisheries.

(2) In case genome-edited feed additives are derived from others than microorganisms equivalent to handling described in Section 2.

4. Procedure for notification, etc. (See Annex)

(1) For feeds and feed additives derived from genome-editing technology that are subject to notification described in the above Section 2 and 3, the developer, agent or those who can submit appropriate documents (hereinafter referred to as "developers, etc.") have to file certain information in principle before launching, and Ministry of Health, Labour and Welfare shall announce some of the filed contents.

(2) As for genome-edited feeds, etc., to confirm whether the concerned feeds, etc., fall under the subject of notification or safety assessment, developers, etc., have to apply for prior consultation to the Office of Animal Products Safety Division, Food Safety and Consumer Affairs Bureau, Ministry of Agriculture, Forestry and Fisheries.

In addition, feeds, etc. that become the subject of prior consultation shall basically be limited to those that have already been developed for commercialization.

At the consultation, information in (1) and (2) of Section 5 shall be attached as far as possible.

(3) The Ministry of Agriculture, Forestry and Fisheries shall confirm with the Agricultural Materials Council/ Feed Committee/ Genetically Modified Feed Subcommittee (hereinafter referred to as "Subcommittee".) if needed, and answer developers, etc., whether feeds, etc., subjected to prior consultation fall under the subject of notification or safety assessment.

In addition, in case it is judged that it is required to ask for the opinions of the Food Safety Commission of Japan (hereinafter referred to as "Food Safety Commission".) during the confirmation process in the Subcommittee, the Minister of Agriculture, Forestry and Fisheries shall consult with the Food Safety Commission, and determine its handling based on the answer from Food Safety Commission and provide the result to the developers, etc.

(4) As for genome-edited feeds, etc., confirmed to fall under notification in the prior consultation, developers, etc. shall notify the Agriculture, Forestry and Fisheries of information described in (1) or (2) of Section 5 with the required attached documents before launching.

However, the month/year of launching shall be announced later when the concerned feed, etc., is launched.

(5) The Ministry of Agriculture, Forestry and Fisheries shall post and announce the information described in (3) or (4) of Section 5 on the website of the Ministry of Agriculture, Forestry and Fisheries without delay. However, the month/year of launching shall be announced after receiving a report from the developers, etc.

(6) The same procedure shall be taken for imported products. If it is possible, an importer is allowed to perform the procedure on behalf of the developers, etc.

(7) For genome-edited feed additives that developers, etc. judge to fall under the following [1] or [2] among the genome-edited feed additives that are subject to notification, they shall apply for prior consultation with the reason and references if required.

The procedures described in the above (4) and (5) are not required for those judged to fall under [1] or [2] as a result of the prior consultation since the notification is considered to be done through the said prior consultation.

[1] The said additive is produced using the microorganism obtained by genome-editing technology and it is clear that the gene composition is equivalent to that of microorganisms that belong to the same species or exist in nature.

[2] The said additive is produced using the microorganism obtained by genome-editing technology and is a highly purified additive.

5. Notification and Information to Be Announced

(1) Regarding genome-edited feed that becomes subject to notification, the developers, etc., are required to provide the following information as a notification to the Ministry of Agriculture, Forestry and Fisheries

- [1] Crop and variety name, usage and purpose of use of the developed feed
- [2] Method of the genome-editing technology applied and the details of the modification
- [3] Information regarding confirmation of absence of introduced foreign genes or residual fragments thereof
- [4] Information regarding confirmation that the identified changes in the DNA do not enhance known inherent toxic substances
- [5] In case modifications have been made to change a metabolic pathway to enhance or reduce specific components, information regarding changes in the main components (nutrient components only) involved in the targeted metabolic pathway
- [6] The month/year of launch (*Submit to Ministry of Agriculture, Forestry and Fisheries after launching)

(2) Regarding genome-edited feed additives, the developers, etc., are required to provide the following information as a notification to the Ministry of Agriculture, Forestry and Fisheries.

- [1] Name, strain name, usage and purpose of use of the developed feed additive
- [2] Method of the genome-editing technology applied and the details of the modification
- [3] Information regarding confirmation of absence of introduced genes or residual fragments thereof
- [4] Indication of meeting compositional standards defined in the standards notification
- [5] The month/year of launch (*Submit to the Ministry of Agriculture, Forestry and Fisheries)

(3) Regarding genome-edited feed, the Ministry of Agriculture, Forestry and Fisheries shall announce the following information.

- [1] Name of notifier and developer, date of notification
- [2] Crop and variety name, summary (usage, and purpose of use)
- [3] Method of the genome-editing technology applied and the summary of the modification of the gene
- [4] Summary regarding confirmation that the identified changes in the DNA do not result in adverse effects on animal health
- [5] Summary regarding changes in the main components (nutrient components only) involved in the targeted metabolic pathway
- [6] The month/year of launch (*Announced after receiving notification of Section 5, (1), [6])

(4) Regarding genome-edited feed additives, the Ministry of Agriculture, Forestry and Fisheries shall announce the following information.

- [1] Name of notifier and developer, date of notification
- [2] Item name
- [3] Methods of genome-editing technology applied and the summary of the modification of the gene
- [4] Indication of meeting the compositional standards defined in the standards notification
- [5] The month/year of launch (*Announced after receiving the notification of Section 5, (2), [5])

6. Handling of Crossbred Progeny

(1) Regarding genome-edited feed, notification is not required for the following.

[1] Progenies crossbred between varieties of which notification to the Ministry of Agriculture, Forestry and Fisheries was announced or crossbred with a conventional breed variety.

[2] Crossbred progenies between a variety of which notifications to the Ministry of Agriculture, Forestry and Fisheries were announced, and a living organism obtained using recombinant DNA technology of which safety assessment was completed.

(2) Among genome-edited feeds, prior consultation with the Ministry of Agriculture, Forestry and Fisheries is required for progenies crossbred between those of which are judged that safety assessment is required or crossbred with a living organism of which the metabolic pathway is modified by recombinant DNA technology

7. Others

Items in this guidelines shall be revised based on records of use of genome-edited feeds, etc., future advances in scientific knowledge and international movements as necessary.

It should be noted that in case the fact that this guideline is not followed is identified, such violation may be announced with the information of the said developers, etc. after confirming the background.

Attachments:

No Attachments