Procedures for Providing Information regarding the Effects on Biological Diversity of Organisms Obtained through Genome Editing Technology in the Field of Agriculture, Forestry, and Fisheries

Date: October 9th, 2019
Notification No. 2743 issued by the Director-General of Food Safety and Consumer Affairs Bureau, Ministry of Agriculture, Forestry and Fisheries of Japan

I Purpose

Under "the Act on the Conservation and Sustainable Use of Biological Diversity through Regulations on the Use of Living Modified Organisms" (Act No. 97 of 2003) (hereinafter referred to as "the Act"), the Central Environment Council of Japan reviewed the handling of organisms obtained through genome editing technology. Based on the result, the Director-General of Nature Conservation Bureau, Ministry of the Environment of Japan (MoE) issued "Notification: Handling of organisms which are obtained through genome editing technology but which are not regarded as "living modified organisms (LMOs)" stipulated in the Act (Notification No. 1902081)" (hereinafter referred to as "the MoE Notification") on February 8th, 2019.

This notification is, based on the MoE Notification, to specify procedures for providing information regarding effects on biological diversity of organisms obtained through genome editing technology, whose production or distribution is under the jurisdiction of the Minister of Agriculture, Forestry and Fisheries of Japan (MAFF). [The organisms include those used for businesses under the jurisdiction of MAFF if they are used taking containment measures. They exclude those stipulated as LMOs in Article 2, paragraph 2 of the Act, and those in the research and development stage (those related to research and development if they are used taking containment measures); hereinafter referred to as "subject organisms."]

Matters specified in this notification will be reviewed as necessary, taking account for the latest scientific knowledge and international trends of management regarding effects on biological diversity resulting from the use (including use for provision as food, animal feed or other purposes, cultivation and other growing, processing, storage, transportation and disposal, and other acts attendant with

these; hereinafter the same shall apply) of organisms obtained through genome editing technology.

II Summary of the MoE Notification

1. In the MoE Notification, "the scope of regulations under the Act for organisms obtained through genome editing technology" shall be handled as follows.

(1) If an extracellularly processed nucleic acid is not inserted into the host, the organisms are not regarded as "LMOs" in the Act.

(2) If an extracellularly processed nucleic acid is inserted into the host and the finally obtained organisms contain the nucleic acid or a replicated product thereof or are not confirmed as free of it, the organisms are regarded as "LMOs" in the Act. It is necessary to take appropriate measures in the Act.

(3) If an extracellularly processed nucleic acid is inserted into the host and the finally obtained organisms are confirmed as free of the nucleic acid or a replicated product thereof, the organisms are not regarded as "LMOs" in the Act.

2. In the MoE Notification, organisms obtained by the genome editing technology but not regarded as " LMOs" in the Act shall be handled as follows.

(1) Prior to the use of such organisms, those who intend to use them are requested to provide information regarding the characteristics of the organisms and the results of a review of the possible effects on biological diversity to the competent government agencies. However, this shall not apply to cases where the organisms are used by taking the containment measures stipulated in the Ordinance based on Article 12 of the Act or the measures approved by the competent government agencies are being taken.

(2) After the use of the organisms, if it is determined that effects on biological diversity could arise from them, the user shall immediately take necessary measures to prevent the effects and shall report it promptly to the competent government agencies.

III Procedures for the Use of Subject Organisms

Based on the MoE Notification, the procedures for the use of subject organisms are as follows.

1. General use (used in open system)

Those who use subject organisms without taking any containment measures described in III 2 are requested to have a prior consultation based on (1), be confirmed that the organisms are not regarded as LMOs, and submit the information form based on (2) before making the use.

If the subject organisms are used in accordance with the information published on the MAFF website based on the provisions of (ii) in (2) [except for addresses in 3 (1)], there is no need to provide the information.

(1) Prior consultation

(i) Prior to the use of subject organisms, a draft information form filled out information from (a) to (j) is prepared with Form 1, and the form is submitted to the Director of the Plant Products Safety Division, Food Safety and Consumer Affairs Bureau, MAFF (hereinafter referred to as "the Director") with Form 2.

(a) Name and summary of organisms obtained by genome editing technology

(b) Usage of the organisms

(c) Summary of the facility used

(d) The fact (and its evidence) that the organisms do not contain extracellularly processed nucleic acid or its replicated product as stipulated in Article 2, paragraph 2, item 1 of the Act

(e) Taxonomic species of the modified organism

(f) Method of genome editing used for the modification

(g) Modified gene and its functions

(h) Changes of traits added by the modification

(i) Whether there are any changes of traits other than (h) (describe the changes, if any)

(j) Discussion on the possibility of the effects on biological diversity (the effects caused by the use of the organisms that could pose unacceptable risk that impair the biological diversity; the same shall apply hereinafter) when the organisms are used (discussion is included for every item listed in Appendix 1 as well as the comprehensive discussion based on the items)

The draft information form is submitted with its copy. Also, an electromagnetic record containing the form is submitted, if available.

If it is difficult to judge whether organisms could be regarded as LMOs stipulated in the Act or if there are any matters need to be confirmed when providing information, consultation is undertaken with the Plant Products Safety Division, Food Safety and Consumer Affairs Bureau, MAFF (hereinafter referred to as "the Division").

(ii) The Division, when (i) is submitted, sends a copy of the draft information form to the Wildlife Division, Nature Conservation Bureau, MoE (hereinafter referred to as "the MoE Wildlife Division") without delay. Also, the Division confirms that the organisms are not regarded as LMOs, that the draft information form has been prepared appropriately from the perspective of effects on biological diversity and others.

In the process of the confirmation, the Division seeks opinions, as needed, from those specialized with academic experience regarding effects on biological diversity. The Division requests to provide additional information if any questions arise.

(iii) The Division, as a result of the confirmation based on (ii), reports to the person who submitted (i) that the organisms are not regarded as LMOs and that the draft information form has been prepared appropriately from the perspective of effects on biological diversity.

(2) Submission of information form

(i) Those who held the prior consultation based on (1) submit an information form, as well as its copy, regarding the completion of the prior consultation to the Director with Form 3. An electromagnetic record containing the form is submitted, if available. Also, when the start date of the use of the organisms has been determined, the date is reported to the Director with Form 4.

(ii) The Division, without delay, sends a copy of the information form to the MoE Wildlife Division when (i) is submitted. In addition, if (i) is submitted or reported, the information (excluding the information that may cause any unfair advantages or disadvantages to specific persons, if disclosed) is published on the MAFF website.

(3) Handling of crossbred progeny

(i) Those who plan to use organisms that have been bred and raised by breeding organisms published on the MAFF website based on (2)(ii), for the time being, contact the Division on a case-by-case basis.

(ii) The Division requests to provide the information if there is a possibility that changes could arise in either the characteristics of the organisms used for breeding or its effects on biological diversity.

2. Use by taking containment measures (used in closed system)

(1) Confirmation of containment measures

Those who plan to use subject organisms by taking containment measures (except for the use specified in (2)) submit a confirmation request based on (i) and receive the confirmation notice from the Director based on (iii) before their use.

(i) Prior to the use of subject organisms, those who intend to use the organisms provide a confirmation request filled out information with 1(1)(ｉ) (a), (b) and (d) to (i) as well as the information on containment measures to the Director with Form 5.

Also, an electromagnetic record containing the form is submitted, if available.

(ii) The Division, when (i) is submitted, confirms the effectiveness and others. of the containment measures.

In the process of the confirmation, the Division seeks opinions, as needed, from those specialized with academic experience regarding the containment measures. The Division requests to provide additional information if any questions arise.

(iii) When the Director, as a result of confirmation based on (ii), has confirmed that the containment measures can prevent dispersal of the subject organisms into the atmosphere, water or soil outside the facility, equipment or other structures in which the organisms are used, the Director issuets the confirmation notice to the person who submitted (i). The Division discloses names of the person and the subject organisms on the MAFF website.

(2) Use without the need for confirmation of containment measures

The use specified in the following (i) or (ii) does not need for confirmation based on (1).

(i) When only store or transport (excluding storage and transport during the production process) subject organisms by taking the containment measures listed in the right column in Attached Table 2, according to the corresponding category of the use listed in the left column.

(ii) When use the subject organisms during their production process, falling under all the following conditions (a) to (c), by taking the containment measures listed in the right column, according to the corresponding category of the use listed in the left column in Attached Table 3.

(a) The variety or strain of host organisms have already been confirmed to be subject to containment measures based on (1) or confirmed by the Minister of MAFF to be subject to containment measures stipulated in the provisions of Article 13, Paragraph 1 of the Act

(b) If the subject organisms are microorganisms, they have no or low pathogenicity to animals belonging to Mammalia (including humans) or Aves and have low transmissibility

(c) If the subject organisms are animals, their physical ability is comparable to or lower than that of the host

(3) Provision of information to transferee and others

Those who use subject organisms by taking containment measures, when transferring, supplying or entrusting the subject organisms to others, provide information specified in the following (i) to (iv) to those who receive them (hereinafter referred to as “recipients”).

(i) The fact that subject organisms are obtained through genome editing technology and are not regarded as LMOs stipulated in Article 2, Paragraph 2 of the Act

(ii) The fact that organisms are used by taking containment measures (their use has received the confirmation of containment measures based on (1) or the use is specified in (2))

(iii) Name of the host or parent of subject organisms as well as name of the target gene

(iv) Name and address of the person (for corporates, their name of the corporation as well as the name and contact information of the person in charge) who are transferred, supplied or entrusted the subject organism

3. Others

(1) Reporting of change of name and others

(i) Those who submitted the information form based on 1(2) or who submitted the confirmation form based on 2(1) report it to the Director with Form 6 immediately when there

are any changes of the name, address, or phone number (hereinafter referred to as "name") in information form or confirmation form.

(ii) The Division sends a copy of the submitted report to the MoE Wildlife Division without delay when the changes of name are reported with the information form based on (i).

(2) Responses in cases where there is potential risk of adverse effects on biological diversity

(i) Those who use or have used subject organisms, when they determine that there is potential risk of adverse effects on biological diversity, immediately take necessary measures to prevent the effects and promptly report it to the Director.

(ii) The Division reports to the MoE Wildlife Division of the contents of the report without delay when it is reported based on (i).

(iii) The Director takes necessary measures when it is reported based on (i) or when it is necessary from the perspective of adverse effects on biological diversity.

(3) Measures when procedures based on this notification are not implemented

If the Director confirms that the following procedures (i) and (ii) have not been implemented, the Director requests for those who have not implemented the procedures to implement them.

(i) Submission of an information form based on 1(2)

(ii) Confirmation of taking containment measures based on 2 (including cases where the containment measures have received confirmation but not actually implemented)

(4) Handling of self-cloning and natural occurrence

(i) Those who intend to use subject organisms are not required to implement the procedures based on 1 or 2, if the organism fall under the provisions of each item of Article 2 (i.e. self-cloning and natural occurrence) under the "Regulations related to the Enforcement of the Act" (Ministerial Ordinance No. 1 of 2003 from the Ministry of Finance; the Ministry of Education, Culture, Sports, Science and Technology; the Ministry of Health, Labour and Welfare; MAFF; the Ministry of Economy, Trade and Industry; and MoE; hereinafter referred to as "Enforcement Regulations"). However, they inquire the Division on a case-by-case basis since it requires scientific evidence to determine whether the organisms fall under the provisions.

(ii) The Division, if inquired based on (i), determines whether the organisms fall under the provisions of each item of Article 2 of the Enforcement Regulations, after seeking opinions, as needed, from those specialized with academic experience.

(5) Handling of new technologies to be developed in the future

The provisions of this notification apply, as needed, to organisms obtained through new breeding technologies other than genome editing technology, including new technologies that will be developed in the future. Those who intends to use the organisms contact the Division in advance whether information provision is required.

Attached table 1 (related to III-1-(1)-(i)-j)

Category of organisms	Items to be considered (property of organisms possibly causing effects on biological diversity)
Plants (organisms belonging to Plantae and mushrooms belonging to Fungi. Same shall apply hereinafter)	Competitiveness (property of competing against wild plants for resources such as nutrients, sunshine, habitat, and others. and interfering with their growth)
	Productivity of harmful substances (property of producing substances interfering with living or growth of wild plants or animals or microorganisms (hereinafter "wildlife"))
	Crossability (property of crossing with related wild plants and transmitting nucleic acid modified using genome editing technology to them)
	Other properties (properties other than those mentioned above, such as one which indirectly affects wildlife by changing the base of the ecosystem, for which discussion on possibility causing effects on biological diversity is considered necessary)
Animals (organisms belonging to Animalia. Same shall apply hereinafter)	Competitiveness (property of competing against wild animals for resources such as food, nesting sites, habitats, and others. and interfering with their living)
	Predacity or parasitism (property of interfering with living or growth of wild plants or animals by preying upon them or by being parasitic on them)
	Productivity of harmful substances (property of producing substances interfering with living or growth of wildlife)
	Crossability (property of crossing with related wild animals and transmitting nucleic acid modified using genome editing technology to them)
	Other properties (properties other than those mentioned above, such as one which indirectly affects wildlife by changing the base of the ecosystem, for which discussion on possibility causing effects on biological diversity is considered necessary)
Microorganisms (organisms belonging to Fungi (excluding mushrooms), organisms belonging to Protista, viruses	Property of reducing other microorganisms (property of reducing other microorganisms by competition, productivity of harmful substances, and others.)
	Pathogenicity (property of interfering with living or growth of wild plants or animals by infecting them)
	Productivity of harmful substances (property of producing substances interfering with living or growth of wild plants or animals)
	Property of transmitting nucleic acid horizontally (property of transmitting

and viroids. Same shall apply hereinafter)	nucleic acid modified using genome editing technology to wild plants or animals or other microorganisms)
	Other properties (properties other than those mentioned above, such as one which indirectly affects wildlife by changing the base of the ecosystem, for which discussion on possibility causing effects on biological diversity is considered necessary)

Attached table 2 (related to III-2-(2)-(i))

Category of use	Description of containment measures
Storage (excluding storage during production process)	1 A subject organism is put in a container of the structure that prevents the subject organism from leaking, escaping or other dispersion and it is indicated in an easily visible spot of the container that it contains an organism obtained through genome editing technology. 2 The container holding the subject organism in 1 is stored clearly in distinction from other organisms than subject organisms, and it is indicated in a easily visible spot of the equipment for storage that the subject organism is stored.
Transport (excluding transport during production process)	1 A subject organism is put in a container of a structure that prevents the subject organism from leaking, escaping or other dispersion. 2 It is indicated in an easily visible spot of the container (in case the container is packed, the packing) holding the subject organism in 1 is contained that care should be taken in handling.

Attached table 3 (related to III-2-(2)-(ii))

Category of organism	Contents of containment measures
Microorganisms	1 Facilities, and others. shall meet the following requirements (1) The facility, and others. has a working area (an area in which subject organisms are used and which is clearly distinguishable from other areas. The same shall apply hereinafter). (2) The working area in (1) has a structure and equipment adapted to serve as a work room for making ordinary use of microorganisms. (3) Management and operation of the facility, and others. is appropriately conducted, and their records are stored. The records of use are prepared for each piece of equipment in the room in which the microorganisms are produced, the room in which the microorganisms are stored, and others. If the microorganisms are transferred, records for the recipients, and others. are also prepared. 2 The following rules shall be complied with upon use (1) Waste (including waste liquid. The same shall apply hereinafter) containing microorganisms subject to containment measures (hereinafter referred to as "subject microorganisms") are appropriately treated to inactivate the subject microorganisms before disposal. (2) Equipment, instruments and apparatuses contaminated with subject microorganisms are appropriately treated to inactivate the subject microorganisms before disposal or reuse. (3) The workbench is appropriately treated to inactivate the subject microorganisms, either after work is finished for the day or immediately when the workbench is contaminated by subject microorganisms. (4) Doors of the work room are closed (except when persons engaged in the work enter or leave the room). (5) Necessary measures are taken to prevent entry of insects, and others. into the work room, such as closing windows and other openings. (6) Aerosol generation is kept to a minimum in all operations. (7) When subject microorganisms are carried out from the work room in the course of use, they are placed in a container with a structure that prevents leakage or dispersal of the microorganisms. (8) Necessary measures are taken to prevent contamination or infection by the

	subject microorganisms, such as washing hands after handling the subject microorganisms. (9) Measures are taken to prevent entry of persons other than educated and trained workers (for example, displaying “authorized personnel only” signs, installing door locks, and others.).
Animals	1 Facilities, and others. shall meet the following requirements (1) The facility, and others. has a working area. (2) The working area in (1) has a structure and equipment adapted to serve as an animal room for making ordinary use of the host animals (for example, a facility for raising, keeping, and others. ordinary mice for laboratory use if the host animals are mice for laboratory use). (3) Entrances, windows and other potential routes of escape of animals subject to containment measures (hereinafter referred to “subject animals”) shall have escape prevention equipment, instruments or apparatuses installed in accordance with the habits of the subject animals (for example, rat guards or double doors for mice or rats, double screen doors or adhesive tapes for insects). (4) Management and operation of the facility, and others. are appropriately conducted, and their records are stored. The records of use are prepared for each piece of equipment in the room in which the animals are raised, the room in which the animals are treated, and others. If the animals are transferred, records for the recipients, and others. are also prepared. 2 The following rules shall be complied with upon use (1) Doors of the animal room are closed (except when persons engaged in the work enter or leave the room). (2) Windows, drains and other openings of the animal room are closed, and necessary measures are taken such as installing screen doors or drainboards to prevent entry of insects or wild rats, and others. (3) Measures are taken to prevent entry of persons other than educated and trained workers (for example, displaying “authorized personnel only” signs, installing door locks, and others.). (4) When subject animals are carried out from the animal room in the course of use, they are placed in a container with a structure that prevents escape or dispersal of the animals. (5) Measures are taken to enable identification of the subject animals according

	to the modified nucleic acid (for example, attaching identification tags to individual animals, attaching labels to individual cages, and others.) (6) A notice indicating the keeping of animals obtained through genome editing technology is displayed at the entrance of the animal room. (7) When discontinuing the use of subject animals, measures are taken for inactivating the animals (euthanasia). When performing euthanasia, efforts are made to comply with the Standards relating to the Methods of Destruction of Animals (Notice No. 40 of the Prime Minister's Office No. 40, July 4, 1995).
Plants	1 Facilities, and others. shall meet the following requirements (1) The facility, and others. has a working area. (2) The working area in (1) has a structure and equipment adapted to serve as a cultivation room for ordinary plants. (3) When performing operations potentially causing scattering of pollen, and others. of plants subject to containment measures (hereinafter referred to as "subject plants"), exhaust and drainage systems are designed to minimize the amount of pollen, and others. of the subject plants contained in the air or water discharged from the cultivation room, and others. (for example, installation of filters, boiling treatment, and others.) (4) Management and operation of the facility are appropriately conducted, and their records are stored. The records of use are prepared for each piece of equipment in the room in which the plants are cultivated, the room in which their seeds are stored, and others. If the plants are transferred, records for the recipients, and others. are also prepared. 2 The following rules shall be complied with upon use (1) Waste containing subject plants are appropriately treated to inactivate the subject plants before disposal. (2) Equipment, instruments and apparatuses to which subject plants are attached are appropriately treated to inactivate the subject plants before disposal or reuse. (3) Doors of the cultivation room are closed (except when persons engaged in the work enter or leave the room). (4) Necessary measures are taken to prevent entry of insects, and others. into the cultivation room, such as closing windows and other openings. (5) Measures are taken to prevent entry of persons other than educated and

	trained workers (for example, displaying “authorized personnel only” signs, installing door locks, and others.). (6) When subject plants are carried out from the cultivation room in the course of use, they are placed in a container with a structure that prevents scattering or dispersal of the plants. (7) Measures are taken to enable identification of subject plants according to the modified nucleic acid. (8) A notice indicating the cultivating of plants obtained through genome editing technology is displayed at the entrance of the cultivation room.

(Form 1)

Information form for use of organisms obtained by genome editing technology

In order to use organisms obtained through genome editing technology, information of the subject organisms is provided as follows.

Items		Entry field
1 Name and summary of the organism obtained by genome editing technology		
2 Usage of the organisms		
3 Summary of the facility used		
4 The fact (and its evidence) that the organisms do not contain extracellularly processed nucleic acid or any replicated product thereof specified in Article 2, paragraph 2, item 1 of the Act	(1) Whether extracellularly processed nucleic acids were inserted or not (including information about the inserted nucleic acids, if inserted, are.)	
	(2) Whether residues of inserted nucleic acids exist or not (including information about the process of selection/breeding and the method of confirming the presence or absence of the corresponding inserted nucleic acids.)	
5 Taxonomic species of the modified organism	(1) Name of the species based on the taxonomic classification and the variety or strain of the host	
	(2) State of distribution in the natural environment and	

	history and current status of use and physiological / ecological characteristics	
6 Method of genome editing used for the modification	(1) Information about artificial nuclease and others.	
	(2) Method of introducing the corresponding artificial nuclease and others.	
7 Modified gene and its functions	(1) Target cleavage site on the host genome and variation that has occurred at the cleavage corresponding site	
	(2) Information about the gene with target cleavage site and the theoretically likely trait changes caused by the modification	
8 Changes of traits added by modification		
9 Whether there are any changes of traits other than 8 above (description of the changes, if any)	(1) Information about the possibility of other modifications than that at the target site	
	(2) Other trait changes than that mentioned in 8 above that were caused in the created organism compared with the host	
10 Discussion on possible adverse effects on biological diversity through the	(1) Competitiveness	
	(2) Predacity or Parasitism	
	(3) Productivity of harmful substances	
	(4) Crossability	

usage of the organisms	(5) Other properties	
	(6) Comprehensive discussion	

[Remarks]

In case of prior consultation based on Ⅲ-1- (1), “draft” is added to the title.

In cases where an applicant is a corporation, regarding the name, describe the name of the corporation and the name of the representative and append the enterprise identification number. Regarding the address, in case of a corporation, describe the location of the main office. Regarding the phone number, describe the phone number of the relevant department that can be contacted when the content of information form is needed to be confirmed.

Regarding the content of the information in each item of the table, describe it according to Annex 1 in case where the corresponding specie is agricultural crop, according to Annex 2 in case where the corresponding specie is fish. In case where the corresponding specie is other than agricultural crop or fish, describe in reference to Annex 1 or Annex 2 depending on the physiological and ecological characteristics of the corresponding specie. In addition, in case where the corresponding specie is microorganism, replace "Competitiveness" in 10 (1) to "Property of reducing other organisms," "Predacity or Parasitism" in (2) to "Pathogenicity," "Crossability" in (4) to "Property of transmitting nucleic acids horizontally " when describing.

In Annex 1 and Annex 2, regarding the references to be stored by the information provider, attach a list of the references to this information form. The information provider stores the references as such so that they can be submitted promptly to the Ministry of Agriculture, Forestry and Fisheries or the Ministry of the Environment, if required. The said materials are retained for a minimum of five years after the submission of an information form and the publication of the said information on the website of the Ministry of Agriculture, Forestry and Fisheries.

Annex 1 Specific contents of information to describe in case where the specie is agricultural crop

1 Clearly distinguish the name from that of other organisms by including information about the species name based on the taxonomic classification to which the host or original organism of the subject organism belongs, and the characteristics of the subject organism, and so on.
Regarding the summary, describe a summary of the characteristics obtained by using genome-editing technology, and others.

2 Regarding the usage of the subject organism, list any of the following usage that are applicable; "Food," "Feed," "Ornamental purposes," "Cultivation" and "Others." In case where the usage falls under "Others," briefly describe the content in brackets.
In case where the scope of the use of the subject organism is limited within a facility managed so as to prevent release of the subject organism outside such as an isolated field, describe "Cultivation in an isolated field" and describe specifications of the equipment and production methods in the corresponding facility in 3.

3 In case where the scope of the use of the subject organism is limited within a facility managed so as to prevent release of the subject organism outside such as an isolated field, describe the outlines of specifications of the equipment and production methods of a facility where the subject organism is cultivated.
The information provider stores references describing the name and location of the corresponding facility, the method of maintenance and inspection of the corresponding facility and equipment, the method of education and training of the worker, and the method of handling in the event that these production methods and maintenance and inspection methods can no longer be adopted, as well as references describing details of specifications of the equipment and production methods. And The information provider adds them to the list of the references.
In addition, in case where the scope of use, and others., of the subject organism is not limited within a facility, describe "-" in the entry field.

4 (1) In case extracellularly processed nucleic acids were inserted, describe a summary of the genetic elements and insert method of the nucleic acids (for example, direct insert of artificial nuclease of which the site involved in binding to the target DNA is RNA, insert of the mRNA of artificial nuclease, insert of the vector carrying the gene of the artificial nuclease, or plasmid insert, and others.). The information provider stores substantiating references and add them to the list of the references.

4(2) Regarding the process of selection/breeding, describe a summary of the process from the creation of individual in which extracellularly processed nucleic acids were inserted to the selection of the finally obtained individual (objective of this provided information).

Regarding the method of confirmation of the presence or absence of residues of inserted nucleic acid, describe a summary of the analytical method used for confirmation and the results of analysis. The information provider stores substantiating references and add them to the list of the references.

5(1) Regarding the name of the species based on the taxonomic classification, describe the Japanese name, English name and scientific name.

5(2) Regarding the state of distribution in the natural environment, describe the presence or absence of a natural growing area in the natural environment of Japan and outside of Japan, and if any, also describe the regional name.

For histories and current status of the use, and others., describe the regional name, country name, and others., where the subject organism is mainly cultivated.

For physiological and ecological characteristics, describe the characteristics of each of the following items.

a Basic characteristics (distinction of annual, biennial or perennial)

b Environmental conditions that allow growth (the temperature range, moisture conditions and soil conditions allowing growth)

c Mode of propagation or reproduction (presence or absence of shedding of the seeds, mode of dispersal of the seed, presence or absence of seed dormancy, seed longevity under natural conditions, presence or absence of vegetative propagation [if vegetative propagation occurs, the property of budding from the tissue or organs which could regenerate the plant body under natural conditions], the degree of autogamy/allogamy, presence or absence of self-incompatibility, presence or absence of wild relative [if any, kinds of wild relative, crossing rate, and others.], methods of pollination)

d Productivity of harmful substances (whether or not the species is known to produce substances that affect the living or growth of wild animals and plants or microorganisms in the surroundings [hereinafter referred to as "wildlife"] under natural conditions. If it is known, the type of the corresponding substance, toxicity, produced amount, exposure route and other related information)

6(1) Describe a summary of the type (ZFN, TALEN, CRISPR/Cas9, and others.) and composed elements of the artificial nuclease. The information provider stores the references including designs of the artificial nuclease and add to the list of the references.

6(2) Describe a summary of the introducing method, for example, insert of the artificial nuclease itself into the host cell, insert of the vector carrying the gene of the artificial nuclease into the host cell, integration of the gene of the artificial nuclease into the host genome. In addition, in case the gene of the artificial nuclease is integrated into the host genome, describe the method used (using Agrobacterium, particle bombardment, and others.).

7(1) Describe a summary of the target cleavage site and the change in the DNA sequence (insertion, substitution and/or deletion of bases) caused at the target cleavage site by the artificial nuclease. The information provider stores the references including figures about these and add to the list of the references.

7(2) Regarding the gene with target cleavage site, describe the name, function of the corresponding gene, function of the protein produced with the expression of the corresponding gene, as well as providing a summary of theoretically likely functional changes caused by modification of the corresponding gene. The information provider stores references to confirm the detailed contents and add to the list of the references.

8 Describe characteristically points regarding the physiological and ecological characteristics actually caused by modification of the target gene, compared with the host. The information provider stores references intended to confirm the detailed contents and add to the list of the references.

9(1) The presence or absence of a sequence that is similar to the target sequence is investigated in the genomic base sequence that has been determined for the host or the taxonomic species, breed, or strain to which the host belongs, and the results are recorded. If any sequence is found that is similar to the target sequence, an analysis is conducted to determine whether there is a sequence difference at the said site, and the results are described.

In either case, the information provider stores the references to confirm the adequacy of the corresponding method and add to the list of the references.

9(2) Describe other traits than those described in 8 above, such as morphological and growth characteristics, overwintering ability/summer survival, produced amount of seed, shedding of the seed, dormancy and germinability of the seed, possibility of having differences between the host and the organism obtained by genome-editing technology(If necessary, this discussion is undertaken based on the following matters: the progress of selection/growth, as specified separately; the functions of the target gene and the characteristics actually caused by modification of said gene; and, the presence or absence of sequence differences in the sequence that is similar to the target sequence.)

The information provider stores substantiating references and add them to the list of the references.

10 In case where the organism is used as described in 2 above, describe the possible effects on biological diversity.

This is discussed one by one for each item a to d listed below, and then further discussed comprehensively based on the content of each discussion. In addition, describe "-" in the entry field of 10 (2), "Predacity or Parasitism."

a Competitiveness (property of competing against wild plants for resources such as

nutrients, sunshine, habitat, and others. and interfering with their growth)

b Productivity of harmful substances property of producing substances interfering with living or growth of wildlife)

c Crossability (property of crossing with related wild plants and to transmitting nucleic acids modified by genome-editing technology to them)

d Other properties (properties other than those mentioned above, such as one which indirectly affects wildlife by changing the base of the ecosystem, for which discussion on possibility causing effects on biological diversity is considered necessary)

The information provider stores substantiating references of the corresponding discussion and add them to the list of the references.

Annex 2　Specific contents of information to describe in case where the specie is fish

1　Clearly distinguish the name from that of other organisms by including information about the species name based on the taxonomic classification to which the host or original organism of the subject organism belongs, and the characteristics of the subject organism, and so on.

Regarding the summary, describe a summary of the characteristics obtained by using genome-editing technology, and others.

2　If the use of the subject organism is limited to within a facility such as an onshore aquaculture facility that is managed so as to prevent outflow of the organism to outside of the facility, describe “rearing, and others. in onshore aquaculture facility”, and describe the specification of equipment in the facility and the method of production under item 3.

Otherwise, list any of following that are applicable; “food”, “feed”, “ornamental purpose”, “rearing” and “others”. In the case where the usage falls under “others”, briefly describe the content in brackets. Also describe the rearing method and, if the subject organism is reaed in a facility, and others., describe the specification of equipment in the facility and the method of production under item 3.

3　Describe a summary of the specification of equipment (including equipment installed in the drainage system to prevent outflow of eggs, sperm, larvae, juveniles, and others. to outside of the facility) in the facility used for rearing the subject organism and the method of production (number of seeds and adults planned to be produced and summary of the method of production).

If different facilities are used for seed production and reaeing, provide information for each facility.

The information provider stores references describing the name and location of the corresponding facility, the method of maintenance and inspection of the corresponding facility and equipment, the method of education and training of the operator, and the method of handling in the event that these production methods and maintenance and inspection methods can no longer be adopted, as well as references describing details of specifications of the equipment and production methods., And The information provider and adds them to the list of stored the references.

4(1) In case extracellularly processed nucleic acids were inserted, describe a summary of the genetic elements and insert method of the nucleic acids (for example, direct insert of artificial nuclease of which the site involved in binding to the target DNA is RNA, insert of the mRNA of artificial nuclease, insert of the vector carrying the gene of the artificial nuclease, or plasmid insert, and others.). The information provider stores substantiating references and add them to the list of the references.

4(2) Regarding the process of selection/breeding, describe a summary of the process from the creation of individual in which extracellularly processed nucleic acids were inserted to the

selection of the finally obtained individual (objective of this provided information).

Regarding the method of confirmation of the presence or absence of residues of inserted nucleic acid, describe a summary of the analytical method used for confirmation and the results of analysis. The information provider stores substantiating references and add them to the list of the references.

5 (1) Regarding the name of species based on the taxonomic classification, describe the Japanese name, the English name and the scientific name.

For “breed, strain, and others. of the host”, when using a host that has not undergone any genetic modification, describe information specifying the collection site, and others. of the host. When using a host (or parent strain) that has undergone a breeding process, specify the genetic characteristics modified through the breeding process. In cases where the species is known to have different genetic characteristics depending on the water area, and others., also describe the differences in genetic characteristics identified between the parent strain used and other strains, if any.

5 (2) Regarding the state of distribution in the natural environment, describe the presence or absence of a natural growing area in the natural environment of Japan or abroad and, if any, describe the regional name.

For “history and current status of use”, describe the history of the use in Japan and abroad. If the organism has a history of industrial use, the details and duration of such use are provided.

For “physiological and ecological characteristics”, describe the characteristics of each of the following items:

a Basic characteristics (main habitats (e.g. water depth), migration range, summary of growth stages, longevity, and others.)

b Environmental conditions that allow growth (viable water temperature range, classification as freshwater fish or marine fish (viable salinity concentration range))

c Predacity or parasitism (feeding habit, prey organisms consumed in individual growth stages, presence or absence of parasitic nature on other wild plants or animals)

d Mode of propagation or reproduction (age at maturity, spawning (breeding) season, number of spawning, number of eggs per spawn, spawning (breeding) sites (if identified), sperm motility (duration of motility), egg size and properties (isolated pelagic eggs (isolated floating eggs), adhesive demersal eggs, and others.), duration of fertility of eggs and sperm after they are released to the outside environment, mode of development, presence or absence of wild relatives (if present, the names of the wild relatives, crossing rate, possibility of natural crossing), and others.)

e Productivity of harmful substances (whether or not the organism species is known to produce substances that affect the living or growth of wild plants or animals or microorganisms (Hereinafter referred to as “wildlife”) in the surroundings under natural conditions. If it is known,

the type of corresponding substance, toxicity, produced amount, exposure route and other related information)

6(1) Describe a summary of the type (ZFN, TALEN, CRISPR/Cas9, and others.) and composed elements of the artificial nuclease. The information provider stores the references including designs of the artificial nuclease and add to the list of the references.

6(2) Describe a summary of the introducing method, for example, insert of the artificial nuclease itself into the host cell, insert of the vector carrying the gene of the artificial nuclease into the host cell, integration of the gene of the artificial nuclease into the host genome. In addition, in case the gene of the artificial nuclease is integrated into the host genome, describe the method used (using Agrobacterium, particle bombardment, and others.).

7(1) Describe a summary of the target cleavage site and the change in the DNA sequence (insertion, substitution and/or deletion of bases) caused at the target cleavage site targeted by the artificial nuclease. The information provider stores the references including figures about these and add to the list of the references.

7(2) Regarding the gene with target cleavage site, describe the name, function of the corresponding gene, function of the protein produced with the expression of the corresponding gene, as well as providing a summary of theoretically likely functional changes caused by modification of the corresponding gene. The information provider stores references to confirm the detailed contents and add to the list of the references.

8 Describe characteristically points regarding the physiological and ecological characteristics actually caused by modification of the target gene, compared with the host. The information provider stores references to confirm the detailed contents and add to the list of the references.

9(1) The presence or absence of a sequence that is similar to the target sequence is investigated in the genomic base sequence that has been determined for the host or the taxonomic species, breed, or strain to which the host belongs, and the results are recorded. If any sequence is found that is similar to the target sequence, an analysis is conducted to determine whether there is a sequence difference at the said site, and the results are recorded.

In either case, the information provider shall store the references to confirm the adequacy of the corresponding method and add to the list of stored references.

9 (2) Describe other traits than those described in 8 above, such as morphological and growth characteristics, viable water temperature range and salinity concentration range, feeding habit, mode of reproduction, and others., possibility of having differences between the host and the organism obtained through genome editing technology(If necessary, this discussion is undertaken based on the following matters: the progress of selection/growth, as specified separately; the functions of the target gene and the characteristics actually caused by modification of said gene; and, the presence or absence of sequence differences in the sequence that is similar to the target

sequence.)

The information provider stores substantiating references and add them to the list of the references.

10 In case where the organism is used as described in 2 above, describe the possible effects on biological diversity. This is discussed one by one for each item a to e listed below, and then further discussed comprehensively based on the content of each discussion.

a Competitiveness (property of competing against wild animals for resources such as food, nesting sites, habitats, and others. and interfering with their living)

b Predacity or Parasitism (property of interfering with living or growth of wild plants or animals by preying upon them or being parasitic on them)

c Productivity of harmful substances (property of producing substances interfering with living or growth of wildlife)

d Crossability (property of crossing with the same species or related wild species and transmitting nucleic acid modified by genome editing technology to them)

e Other properties (properties other than those mentioned above, such as one which indirectly affects wildlife by changing the base of ecosystem, for which discussion on possibility causing effects on biological diversity is considered necessary)

The information provider stores substantiating references of the corresponding discussion and add them to the list of the references.

(Form 2)

Providing Information for use of organisms obtained by genome editing technology

(Prior consultation)

yyyy/mm/dd

To the Director of the Plant Products Safety Division,
Food Safety and Consumer Affairs Bureau,
MAFF

Applicant
Name
Address
Telephone number

I intend to use an organism obtained by the genome editing technology. And I consult based on III-1-(1)-(i) in "Procedures for Providing Information regarding the Effects on Biological Diversity of Organisms Obtained through Genome Editing Technology in the Field of Agriculture, Forestry, and Fisheries" (Notification No.2743 dated October 9, 2019 by Director-General of Food Safety and Consumer Affairs Bureau, Ministry of Agriculture, Forestry and Fisheries) with the draft of Form 1 fill out with information.

[Remarks]
Attach a draft of "Information form for use of organisms obtained by genome editing technology" prepared with Form 1.

(Form 3)

Providing Information for use of organisms obtained by genome editing technology

(Submission of information form)

yyyy/mm/dd

To the Director of the Plant Products Safety Division,
Food Safety and Consumer Affairs Bureau,
MAFF

Applicant
Name
Address
Telephone number

For using the organism obtained by the genome editing technologies, I submit information form based on III-1-(2)-(i) in "Procedures for Providing Information regarding the Effects on Biological Diversity of Organisms Obtained through Genome Editing Technology in the Field of Agriculture, Forestry, and Fisheries" (Notification No.2743 dated October 9, 2019 by Director-General of Food Safety and Consumer Affairs Bureau, Ministry of Agriculture, Forestry and Fisheries).

[Remarks]
Attach "Information form for use of organisms obtained by genome editing technology" completed the prior consultation.

(Form 4)

Providing Information for use of organisms obtained by genome editing technology

(Report for starting of commercial use)

yyyy/mm/dd

To the Director of the Plant Products Safety Division,
Food Safety and Consumer Affairs Bureau,
MAFF

Applicant
Name
Address
Telephone number

I hereby report based on III-1-(2)-(i) in "Procedures for Providing Information regarding the Effects on Biological Diversity of Organisms Obtained through Genome Editing Technology in the Field of Agriculture, Forestry, and Fisheries" (Notification No.2743 dated October 9, 2019 by Director-General of Food Safety and Consumer Affairs Bureau, Ministry of Agriculture, Forestry and Fisheries) that start to use the organism obtained by the genome editing technology and submitted the information at yyyyy/mm/dd.

Name of the organism starting to use	
Starting date of use	
Scheduled starting date of sale	

[Remarks]
Scheduled starting date of sale is the date when the organism is planned to be sold or transferred to unspecified persons.

(Form 5)

Confirmation form of containment measures pertaining to use of organisms obtained by genome editing technology

yyyy/mm/dd

To the Director of the Plant Products Safety Division,
Food Safety and Consumer Affairs Bureau,
MAFF

submitter
Name
Address
Telephone number

For using by taking containment measures the organism obtained by the genome editing technology, I submit confirmation form based on III-2-(1)-(i) in "Procedures for Providing Information regarding the Effects on Biological Diversity of Organisms Obtained through Genome Editing Technology in the Field of Agriculture, Forestry, and Fisheries" (Notification No.2743 dated October 9, 2019 by Director-General of Food Safety and Consumer Affairs Bureau, Ministry of Agriculture, Forestry and Fisheries).

Items		Entry field
1 Name and summary of the organism obtained by genome editing technology		
2 Usage of the organisms		
3 The fact (and its evidence) that the organisms do not contain extracellularly processed nucleic acid or any replicated product thereof specified in	(1) Whether extracellularly processed nucleic acids were inserted or not (including information about the inserted nucleic acids, if inserted.)	
	(2) Whether residues of inserted nucleic acids exist or not (including information about	

Article 2, paragraph 2, item 1 of the Act	the process of selection/breeding and the method of confirming the presence or absence of the corresponding inserted nucleic acids.)	
4 Taxonomic species of the modified organism	(1) Name of the species based on the taxonomic classification and the variety or strain of the host	
	(2) State of distribution in the natural environment and history and current status of use and physiological / ecological characteristics	
5 Method of genome editing used for the modification	(1) Information about artificial nuclease and others.	
	(2) Method of introducing the corresponding artificial nuclease and others.	
6 Modified gene and its functions	(1) Target cleavage site on the host genome and variation that has occurred at the cleavage corresponding site	
	(2) Information about the gene with target cleavage site and the theoretically likely trait changes caused by the modification	
7 Changes of traits added by modification		
8 Whether there are any changes of traits other	(1) Information about the possibility of other modifications than that at	

than 7 above (description of the changes, if any)	the target site	
	(2) Other trait changes than that mentioned in 7 above that were caused in the created organism compared with the host	
9 Containment measures	(1) Category of the use	
	(2) Summary of working area	
	(3) Operational control by company	

[Remarks]

In cases where an applicant is a corporation, regarding the name, describe the name of the corporation and the name of the representative and append the enterprise identification number. Regarding the address, in case of a corporation, describe the location of the main office. Regarding the phone number, describe the phone number of the relevant department that can be contacted when the content of confirmation form is needed to be confirmed.

Regarding the content of the information in each item of the table, describe it according to Annex 1 in case where the corresponding specie is microorganism, according to Annex 2 in case where the corresponding specie is animal, according to Annex 3 in case where the corresponding specie is plant.

In Annex 1 to Annex 3, regarding the references to be stored by the information provider, attach a list of the references to this confirmation form. The submitter stores the references as such so that they can be submitted promptly to the Ministry of Agriculture, Forestry and Fisheries, if required. The said materials are retained for a minimum of five years after the submission of an information provision form and the publication of the said information on the website of the Ministry of Agriculture, Forestry and Fisheries.

Annex 1 Specific contents of information to describe in case where the specie is microorganism

1 Clearly distinguish the name from that of other organisms by including information about the species name based on the taxonomic classification to which the host or original organism of the subject organism belongs, and the characteristics of the subject organism, and so on.
Regarding the summary, describe a summary of the characteristics obtained by using genome-editing technology, and others.

2 Describe purpose and a summary (contents of the use and planned production scale) of the subject organism.

3 (1)In case extracellularly processed nucleic acids were inserted, describe a summary of the genetic elements and insert method of the nucleic acids (for example, direct insert of artificial nuclease of which the site involved in binding to the target DNA is RNA, insert of the mRNA of artificial nuclease, insert of the vector carrying the gene of the artificial nuclease, or plasmid insert, and others.). The submitter stores substantiating references and add them to the list of the references.

3(2) Regarding the process of selection/breeding, describe a summary of the process from the creation of individual in which extracellularly processed nucleic acids were inserted to the selection of the finally obtained individual (objective of this provided information).
Regarding the method of confirmation of the presence or absence of residues of inserted nucleic acid, describe a summary of the analytical method used for confirmation and the results of analysis. The submitter stores substantiating references and add them to the list of the references.

4(1) Describe the following items.

a Scientific name (genus and species) and the name of strain

b Describe the name of organization and strain No., if the microorganism is provided by a public organization for conservation of microorganisms. Otherwise, describe the matters that serve as the grounds for identification (for example, points of identity to and difference from a species of which the scientific name has been officially recognized and the ground thereof, the separation source of the strain and the place to which a standard strain produced from it is deposited and storage No.)

c Describe the contents of the genetic modification, if the host is obtained by carrying out genetic modification (however, if the host is a strain already described in major scientific literature, describe the name of the strain)
The submitter stores substantiating references and add them to the list of the references as well as references describing details of the genetic modification (Mention the progress of genetic modification from the wild strain to the strain of the host as well as the

operation of genetic modification used for inducement (for example, induction of mutation by means of irradiation of ultraviolet rays, or zygosis)

4(2) Describe the state of distribution in the natural environment, if wild type strain was used as a host.

For histories and current status of the use, and others., describe the contents and the period if the host strain was ever used as industrial use.

For physiological and ecological characteristics, describe the characteristics of each of the following items.

a Mode of propagation or reproduction (the characteristics of a cycle of sexual or asexual reproduction, a temperature range for propagation, the speed of propagation, auxotrophy and drug sensitivity)

b Pathogenicity

(a) Whether the host or the taxonomic species to which the host belongs is pathogenic or not (including its evidence), the presence or absence of pathogenicity-related virus and plasmid.

(b) If there are any pathogenicity, the details and preventive and therapeutic methods.

c Other information

(a) The presence or absence of the production of a biogenic substance that has harmful effect on the host or the species to which the host belongs.

(b) If there are any substances known as (a), the name and the intensity activities and toxicity.

(c) Main physiological properties such as the production of antibiotics.

The submitter stores substantiating references and add them to the list of the references.

5(1) Describe a summary of the type (ZFN, TALEN, CRISPR/Cas9, and others.) and composed elements of the artificial nuclease. The submitter stores the references including designs of the artificial nuclease and add to the list of the references.

5(2) Describe a summary of the introducing method, for example, insert of the artificial nuclease itself into the host cell, insert of the vector carrying the gene of the artificial nuclease into the host cell, integration of the gene of the artificial nuclease into the host genome. In addition, in case the gene of the artificial nuclease is integrated into the host genome, describe the method used.

6(1) Describe a summary of the target cleavage site and the change in the DNA sequence (insertion, substitution and/or deletion of bases) caused at the target cleavage site by the artificial nuclease. The submitter stores the references including figures about these changes and add to the list of the references.

6(2) Regarding the gene with target cleavage site, describe the name, function of the

corresponding gene, function of the protein produced with the expression of the corresponding gene, as well as providing a summary of theoretically likely functional changes caused by modification of the corresponding gene. The submitter stores references to confirm the detailed contents and add to the list of the references.

7 Describe characteristically points regarding the physiological and ecological changes actually caused by modification of the target gene, compared with the host. The submitter stores references intended to confirm the detailed contents and add to the list of the references (include the references regarding the characteristics of the subject organisms that can distinguish from the host or the taxonomic species.).

8(1) The presence or absence of a sequence that is similar to the target sequence is investigated in the genomic base sequence that has been determined for the host or the taxonomic species, breed, or strain to which the host belongs, and the results are recorded. If any sequence is found that is similar to the target sequence, an analysis is conducted to determine whether there is a sequence difference at the said site, and the results are described.

In either case, the submitter stores the references to confirm the adequacy of the corresponding method and add to the list of the references.

8(2) Describe other traits than those described in 7 above, such as mode of propagation or reproduction and pathogenicity, possibility of having differences between the host and the organism obtained by genome-editing technology. The submitter stores substantiating references and add them to the list of the references. (If necessary, this discussion is undertaken based on the following matters: the progress of selection/growth, as specified separately; the functions of the target gene and the characteristics actually caused by modification of said gene; and, the presence or absence of sequence differences in the sequence that is similar to the target sequence.)

9(1) Classify into the following categories and described that containment measures stipulated in the right-hand column of the annexed table of “the Ministerial Ordinance Providing Containment Measures to Be Taken in the Industrial Use of Type 2 Use of Living Modified Organisms” will be implemented according to the classification of subject organisms listed in the left-hand column (“modified organisms” are read as the “subject microorganisms”).

Those which do not fall in any of the following categories is classified as “Others”, and detail of the containment measures planned to be taken is described on annex.

a GILSP (host, donor nucleic acid, vector and modified microorganism meet the following standards).

(a) Host

(A) Not being pathogenic.

(B) Not containing pathogenic virus and plasmid.

(C) Either having a record of being used safely for a long period of time or propagation under special conditions of culture with limitation in propagation under other conditions.

(b) Donor nucleic acid and vector

(A) Properties are sufficiently known and do not contain sequences recognized to be harmful.

(B) Hardly transmissible and not transmitting a resistant marker gene to living cells that are not known to acquire resistance originally.

(c) Modified microorganisms

(A) Not being pathogenic.

(B) Not having higher prolificity compared to host.

b Category 1 equivalent (Modified microorganisms which are low in the possibility of having pathogenicity and not included in a above.)

9(2) Describe the summary of position of working area (the area where subject organisms are used and others, that can be clearly distinguished from other areas. Hereinafter refer to same.), arrangement of equipment, structure and production process. The submitter stores the references including detail about these and add to the list of the references (including the references of the following).

a Position of working area; a diagram the arrangement of buildings in and outside the place of work and their names and the working area.

b Arrangement of equipment; indicate a plane view which includes the working area, and the position and name of the major equipment for handling the corresponding microorganism are described.

c Structure of equipment; Regarding the facilities and equipment for handling, describe the specification of the equipment, drainage system and ventilation equipment, and illustrated if necessary.

d Production process; An outline of the production process of the corresponding microorganism or a substance to be carried out by using the corresponding microorganism is shown by a diagram. (In the diagram, names of various machines and apparatuses and positions of valves are indicated, and the name and detailed description of each process are mentioned if necessary.)

9(3) Describe the summary of maintenance and inspection system of facilities and equipment, assignment of experienced personnel, and education and training system and measures to be taken in an emergency such as accidents. The submitter stores the references including detail about these and add to the list of the references.

Annex 2 Specific contents of information to describe in case where the specie is animal

1 Clearly distinguish the name from that of other organisms by including information about the species name based on the taxonomic classification to which the host or original organism of the subject organism belongs, and the characteristics of the subject organism, and so on.
Regarding the summary, describe a summary of the characteristics obtained by using genome-editing technology, and others.

2 Describe purpose and a summary (contents of the use and planned production scale) of the subject organism.

3 (1)In case extracellularly processed nucleic acids were inserted, describe a summary of the genetic elements and insert method of the nucleic acids (for example, direct insert of artificial nuclease of which the site involved in binding to the target DNA is RNA, insert of the mRNA of artificial nuclease, insert of the vector carrying the gene of the artificial nuclease, or plasmid insert, and others.). The submitter stores substantiating references and add them to the list of the references.

3(2) Regarding the process of selection/breeding, describe a summary of the process from the creation of individual in which extracellularly processed nucleic acids were inserted to the selection of the finally obtained individual (objective of this provided information).
Regarding the method of confirmation of the presence or absence of residues of inserted nucleic acid, describe a summary of the analytical method used for confirmation and the results of analysis. The submitter stores substantiating references and add them to the list of the references.

4(1) Describe the following items.

a Name of the species based on the taxonomic classification (Japanese name, English name and scientific name)

b Name of breed and strain of the host.

c Contents of the genetic modification used to obtain the corresponding breed and others.
The submitter stores substantiating references and add them to the list of the references as well as references describing details of the genetic modification (a genealogical chart from the variety of origin through the variety of the recipient organism intended for use and the operation of genetic modification used for creation (subculturing in inbreed line).

4(2) Regarding the state of distribution in the natural environment, describe the presence or absence of a natural growing area in the natural environment of Japan and abroad, and if any, also describe the regional name.
For histories and current status of the use and others., describe the histories and main mode of use and main usage.

For physiological and ecological characteristics, describe the characteristics of each of the following items.

a Mode of reproduction (describe the period of sexual maturation, breeding season, estrous cycle, pregnant period and litter size in the case of viviparity of Mammalia; and equivalent information for other modes of reproduction or propagation)

b Viability and fecundity in natural environment (the assumed points about the viability and fecundity of the variety of the host by comparing the state in general, free environment with the environment of the main form of the use.)

c Other information (main physiological properties such as the production of substances, including harmful ones, which affect individuals of other living organisms)

5(1) Describe a summary of the type (ZFN, TALEN, CRISPR/Cas9, and others.) and composed elements of the artificial nuclease. The submitter stores the references including designs of the artificial nuclease and add to the list of the references.

5(2) Describe a summary of the introducing method, for example, insert of the artificial nuclease itself into the host cell, insert of the vector carrying the gene of the artificial nuclease into the host cell, integration of the gene of the artificial nuclease into the host genome. In addition, in case the gene of the artificial nuclease is integrated into the host genome, describe the method used.

6(1) Describe a summary of the target cleavage site and the change in the DNA sequence (insertion, substitution and/or deletion of bases) caused at the target cleavage site by the artificial nuclease. The submitter stores the references including figures about these changes and add to the list of the references.

6(2) Regarding the gene with target cleavage site, describe the name, function of the corresponding gene, function of the protein produced with the expression of the corresponding gene, as well as providing a summary of theoretically likely functional changes caused by modification of the corresponding gene. The submitter stores references to confirm the detailed contents and add to the list of the references.

7 Describe characteristically points regarding the physiological and ecological changes actually caused by modification of the target gene, compared with the host. The submitter stores references intended to confirm the detailed contents and add to the list of the references.

8(1) The presence or absence of a sequence that is similar to the target sequence is investigated in the genomic base sequence that has been determined for the host or the taxonomic species, breed, or strain to which the host belongs, and the results are recorded. If any sequence is found that is similar to the target sequence, an analysis is conducted to determine whether there is a sequence difference at the said site, and the results are described.

In either case, the submitter stores the references to confirm the adequacy of the

corresponding method and add to the list of the references.

8(2) Describe other traits than those described in 7 above, such as morphological and growth characteristics, mode of reproduction, survival and fertility in nature and feeding habitat, possibility of having differences between the host and the organism obtained by genome-editing technology. The submitter stores substantiating references and add them to the list of the references. (If necessary, this discussion is undertaken based on the following matters: the progress of selection/growth, as specified separately; the functions of the target gene and the characteristics actually caused by modification of said gene; and, the presence or absence of sequence differences in the sequence that is similar to the target sequence.)

9(1) Enter "-". (Not applicable to animals)

9(2) Describe the summary of position of working area (the area where subject organisms are used and others., that can be clearly distinguished from other areas. Hereinafter refer to same.), arrangement of equipment and structure. The submitter stores the references including detail about these and add to the list of the references (including the references of the following).

a Position of working area; a diagram the arrangement of buildings in and outside the place of work and their names and the working area.

b Arrangement of equipment; indicate a plane view which includes the working area and the position and name of the major equipment for handling the corresponding animal and the location of notices to outsiders as necessary are described.

c Structure of equipment; describes the specifications of equipment used to handle the corresponding animal, and illustrates special equipment for drainage systems and others. used to handle the animal.

9(3) Describe the summary of maintenance and inspection system of facilities and equipment, assignment of experienced personnel, keeping management, and education and training system and measures to be taken in an emergency such as accidents. The submitter stores the references including detail about these and add to the list of the references.

Annex 3 Specific contents of information to describe in case where the specie is plant

1 Clearly distinguish the name from that of other organisms by including information about the species name based on the taxonomic classification to which the host or original organism of the subject organism belongs, and the characteristics of the subject organism, and so on.
Regarding the summary, describe a summary of the characteristics obtained by using genome-editing technology, and others.

2 Describe purpose and a summary (contents of the use and planned production scale) of the subject organism.

3 (1)In case extracellularly processed nucleic acids were inserted, describe a summary of the genetic elements and insert method of the nucleic acids (for example, direct insert of artificial nuclease of which the site involved in binding to the target DNA is RNA, insert of the mRNA of artificial nuclease, insert of the vector carrying the gene of the artificial nuclease, or plasmid insert, and others.). The submitter stores substantiating references and add them to the list of the references.

3(2) Regarding the process of selection/breeding, describe a summary of the process from the creation of individual in which extracellularly processed nucleic acids were inserted to the selection of the finally obtained individual (objective of this provided information).
Regarding the method of confirmation of the presence or absence of residues of inserted nucleic acid, describe a summary of the analytical method used for confirmation and the results of analysis. The submitter stores substantiating references and add them to the list of the references.

4(1) Describe the following items.

a The name of species based on the taxonomic classification (Japanese name, English name and scientific name)

b Name of the host of breed and strain.

c Contents of the genetic modification used to obtain the corresponding breed and others.
The submitter stores substantiating references and add them to the list of the references as well as references describing details of the genetic modification (a genealogical chart from the variety of origin through the variety of the recipient organism intended for use and the operation of genetic modification used for creation (subculturing in inbreed line)

4(2) Regarding the state of distribution in the natural environment, describe the presence or absence of a natural growing area in the natural environment of Japan and abroad, and if any, also describe the regional name.
For histories and current status of the use, and others., describe the histories and main mode of use and main usage.

For physiological and ecological characteristics, describe the characteristics of each of the following items.

a Mode of propagation or reproduction

(a) Shedding habit, mode of dispersion, dormancy and longevity of the seed

(b) Mode of vegetative propagation (sucker, tuber, tuberous root, runner, and others.) and the property of budding from any tissue or organ which could regenerate the plant body under natural conditions)

(c) The degree of autogamy and allogamy, presence or absence of self-incompatibility, crossability with wild relative, and the degree of apomixes causing characteristics, if present

(d) Production, fertility, shape, method of pollination, dispersal distance and longevity of pollen

b Viability and fecundity in natural environment (the assumed points about the viability and fecundity of the variety of the host by comparing the state in general, free environment with the environment of the main form of the use.)

c Other information (Main physiological characteristics such as the production of substances, including harmful ones, which affect individuals of other living organisms)

5(1) Describe a summary of the type (ZFN, TALEN, CRISPR/Cas9, and others.) and composed elements of the artificial nuclease. The submitter stores the references including designs of the artificial nuclease and add to the list of the references.

5(2) Describe a summary of the introducing method, for example, insert of the artificial nuclease itself into the host cell, insert of the vector carrying the gene of the artificial nuclease into the host cell, integration of the gene of the artificial nuclease into the host genome. In addition, in case the gene of the artificial nuclease is integrated into the host genome, describe the method used (using Agrobacterium, particle bombardment, and others.).

6(1) Describe a summary of the target cleavage site and the change in the DNA sequence (insertion, substitution and/or deletion of bases) caused at the target cleavage site by the artificial nuclease. The submitter stores the references including figures about these changes and add to the list of the references.

6(2) Regarding the gene with target cleavage site, describe the name, function of the corresponding gene, function of the protein produced with the expression of the corresponding gene, as well as providing a summary of theoretically likely functional changes caused by modification of the corresponding gene. The information provider shall store references intended to confirm the detailed contents and add to the list of stored references.

7 Describe characteristically points regarding the physiological and ecological changes

actually caused by modification of the target gene, compared with the host. The submitter stores references intended to confirm the detailed contents and add to the list of the references.

8(1) The presence or absence of a sequence that is similar to the target sequence is investigated in the genomic base sequence that has been determined for the host or the taxonomic species, breed, or strain to which the host belongs, and the results are recorded. If any sequence is found that is similar to the target sequence, an analysis is conducted to determine whether there is a sequence difference at the said site, and the results are described.

In either case, the submitter stores the references to confirm the adequacy of the corresponding method and add to the list of the references.

8(2) Describe other traits than those described in 7 above, such as morphological and growth characteristics, overwintering ability/summer survival, produced amount of seed, shedding of the seed, dormancy and germinability of seed, possibility of having differences between the host and the organism obtained by genome-editing technology. The submitter stores substantiating references and add them to the list of the references. (If necessary, this discussion is undertaken based on the following matters: the progress of selection/growth, as specified separately; the functions of the target gene and the characteristics actually caused by modification of said gene; and, the presence or absence of sequence differences in the sequence that is similar to the target sequence.)

9(1) Enter "-". (Not applicable to plants)

9(2) Describe the summary of position of working area (the area where subject organisms are used and others. that can be clearly distinguished from other areas. Hereinafter refer to same.), arrangement of equipment, structure and production process. The submitter stores the references including figures about these changes and add to the list of the references (including the references of the following).

a Position of working area; a diagram the arrangement of buildings in and outside the place of work and their names and the working area.

b Arrangement of equipment; indicate a plane view which includes the working area and the position and name of the major equipment for handling the corresponding plants and the location of notices to outsiders as necessary are described.

c Structure of equipment; describes the specifications of equipment used to handle the corresponding plants, and illustrates special equipment for drainage systems and others. used to handle the plants.

d Production process; An outline of the production process by culture using culture equipment of the corresponding plants or the production of a substance to be carried out by using the corresponding plants is shown by a diagram. (In the diagram, names of various machines and apparatuses and positions of valves are indicated, and the name and

detailed description of each process are mentioned if necessary.)

9(3) Describe the summary of maintenance and inspection system of facilities and equipment, assignment of experienced personnel, breeding management, and education and training system and measures to be taken in an emergency such as accidents. The submitter stores the references including figures about these changes and add to the list of the references.

(Form 6)

Report of changes

yyyyy/mm/dd

To the Director of the Plant Products Safety Division,
Food Safety and Consumer Affairs Bureau,
MAFF

Applicant Name
Address

I report the following in accordance with III-3-(1) in "Procedures for Providing Information regarding the Effects on Biological Diversity of Organisms Obtained through Genome Editing Technology in the Field of Agriculture, Forestry, and Fisheries" (Notification No.2743 dated October 9, 2019 by Director-General of Food Safety and Consumer Affairs Bureau, Ministry of Agriculture, Forestry and Fisheries) due to the change in the name / the address / the phone number of the information providing form for usage of organisms obtained by genome editing technology / the confirmation form of containment measures pertaining to use of organisms obtained by genome editing technology submitted on yyyyy/mm/dd.

The name, address and phone number before change	
The name, address and phone number after change	
The date of the changes	

[Remarks]
For the wavy part, enter the corresponding contents.
In cases where an applicant is a corporation, regarding the name, describe the name of the corporation and the name of the representative and append the enterprise identification number. Regarding the address, in case of a corporation, describe the location of the main office. Regarding the phone number, describe the phone number of the relevant department that can be contacted when the content of information form or confirmation forms is needed to be confirmed.