

A guideline for issuance of health certificate for the export of
NISHIKIGOI

1. Purpose

These guidelines, for Nishikigoi exported from Japan, stipulate the procedure for the registration of an aquaculture establishment to the list prepared by the Fish and Fishery Products Safety Office, Animal Products Safety Division, Food Safety and Consumer Affairs Bureau, Ministry of Agriculture, Forestry, and Fishery (hereinafter referred as "Fish and Fishery Products Safety Office") and for issuing the prefectural health certificate relating to spring viremia of carp (SVC) and koi herpes virus (KHV) disease. However, in the case that a guideline for issuance of health certificates for the export of Nishikigoi to each country is stipulated, the guideline is considered to have determined in accordance with these guidelines.

2. Definition of Terms

The definitions of the terms used in each of the items in this guideline shall be specified in the respective items:

(1) Aquaculture establishment

This means a rearing facility (a pond, water tank, rearing building and any equipment incidental to them) aiming for farming only Nishikigoi.

(2) Aquaculture farmer

This means the person who owns or manages an aquaculture establishment, and who engages in an aquaculture industry of Nishikigoi by exclusively using the establishment for the industry.

(3) List

This means the list on which are registered the aquaculture establishment that export Nishikigoi to foreign countries or that supply Nishikigoi to an export aquaculture establishment, and where prefecture and the Fish and Fishery Products Safety Office have confirmed that the strict prevention measures against SVC and KHV diseases have been conducted.

(4) List-registered aquaculture establishment

This means an aquaculture establishment registered on the list.

(5) List-registered aquaculture farmer

This means the aquaculture farmer who engages in aquaculture of Nishikigoi at a list-registered aquaculture establishment.

(6) Transport form

This means a form to be attached to the Nishikigoi which is transported after writing the necessary matters when Nishikigoi are transported between the list-registered aquaculture establishments.

3. List-registered aquaculture establishment

(1) Registration of aquaculture establishment to the list

(i) The aquaculture farmers, who intend to register their own aquaculture establishment to the list, need to submit the application for the list-registration of aquaculture establishment shown in the Appended Form 1, which shall be submitted for each intended aquaculture establishment, to the Fish and Fishery Products Safety Office via their prefectures together with the following documents:

a. A Location map indicating the location of aquaculture establishment

b. A breakdown list of the aquaculture establishment (Appended Form 1-2)

c. The inspection results on SVC and KHV disease in Nishikigoi that have reared in the aquaculture establishment in the past two years(Appended Form 1-3)

d. A written pledge regarding the compliance matters of 4 in this guideline (Appended Form 1-4)

e. A copy of the documents to prove the relationship between the parties(a lease agreement for the aquaculture establishment, etc.), if the aquaculture farmer who is applying is different from the owner of the aquaculture establishment

(ii) The prefecture, which has received the submission of (i) from the aquaculture farmer, shall confirm the submitted application documents and aquaculture establishment. When the prefecture confirms that it matches the criteria of (2), the prefecture shall transmit a set of applications of (i) to the Fish and Fishery Products Safety Office using the Appended Form 2. In the case that

the person who has been entrusted by the prefecture confirms the aquaculture establishment, the entrusted person shall report the result to the prefecture using the Appended Form 1-5.

(iii) In the case that the Fish and Fishery Products Safety Office determines that the forms for the aquaculture establishment transmitted by the prefecture are appropriate in comparison with this guideline, the Fish and Fishery Products Safety Office shall register the establishments to the list using the Appended Form 3 and shall notify the prefecture and the All Japan Nishikigoi Promotion Association about the modified list. The prefecture, that has received the notification, shall contact the aquaculture farmer thereof.

(2) Criteria for registering to the list

(i) The aquaculture establishment must satisfy all criteria from "a" to "d".

a. The aquaculture establishments are protected from any free invasion of people and animals outside by such measures as setting up fences.

b. Groundwater, tap water or water sterilized completely is used for the rearing water.

c. Neither SVC nor KHV disease has been occurred in the aquaculture establishments for the past two years.

d. The aquaculture establishment has never is not deleted from the list due to a deviation from the criteria during the past two years.

(ii) All Nishikigoi reared in the aquaculture establishment have satisfied the following criteria of 'a' and 'b' over the past two years:

a. It must be derived from the aquaculture establishment. (including the Nishikigoi introduced by the list-registered aquaculture establishment and the one introduced by the not-list-registered aquaculture establishment which has received the inspection certificate of the SVC and KHV disease (Appended Form 10) issued by the prefecture.)

b. As a result of inspection in (1) of 4, SVC and KHV disease are not recognized.

(iii) The aquaculture farmer complies with the matters of 4 and pledges to continue to comply with them.

- (3) Changing the contents of the listed-registered establishment registered on the list
- (i) The list-registered aquaculture farmers who intend to change the application contents of list-registered aquaculture establishments must submit the application for change of list-registered contents of the establishment using the Appended Form 4 to the Fish and Fishery Products Safety Office via their prefecture.
 - (ii) The prefecture, which has received the submission of (i) from the aquaculture farmer, shall confirm the submitted documents and aquaculture establishment which apply for change. After confirming that the aquaculture establishment is satisfied the criteria of (2), the prefecture shall transmit the application for change of (i) using the Appended Form 5 to the Fish and Fishery Products Safety Office. In the case that the person who has been entrusted by the prefecture confirms the aquaculture establishment, the entrusted person shall report the results to the prefecture using the Appended Form 1-5.
 - (iii) In the case that the Fish and Fishery Products Safety Office determines that the list-registered aquaculture establishment transmitted by the prefecture are appropriate according to these guidelines, the Fish and Fishery Products Safety Office shall change the list-registered matters on the Appended Form 3 and shall notify the prefecture and the All Japan Nishikigoi Promotion Association of the changes. The prefecture, which has received the notification, shall inform the aquaculture farmer thereof.
- (4) Deregistration from the list of list-registered aquaculture establishment
- (i) The aquaculture farmers, who intend to deregister the list-registered aquaculture establishment from the list, need to submit the application for the deregistration of the aquaculture establishment using the Appended Form 6 to the Fish and Fishery Products Safety Office via their prefecture.
 - (ii) The prefecture, which has received the submission of (i) from the aquaculture farmer, shall confirm the reason for the deregistration and transmit it to the Fish and Fishery Products Safety Office using the Appended Form 7.

- (iii) The prefecture shall immediately report to the Fish and Fishery Products Safety Office when the SVC or KHV disease has been occurred at the list-registered aquaculture establishment, or when it is found that the list-registered aquaculture establishment has not satisfied the criteria of (2) either by related documents or on-site check, or when any suspicionsects have arisen by the report of public. In addition, the prefecture shall investigate the list-registered aquaculture establishment to confirm whether or not the matters of 4 have been complied with and, at the same time, investigate the cause of the infection of SVC or KHV disease; and report its result to the Fish and Fishery Products Safety Office.
- (iv) When the list-registered aquaculture farmer requests or when the list-registered aquaculture establishment no longer satisfies the criteria of (2) (It shall not be applied when the list-registered aquaculture farmer complies with the compliance matters of 4, and the aquaculture establishment satisfies the criteria of (2) after immediate improvement of the list-registered aquaculture establishment), the Fish and Fishery Products Safety Office shall deregister the list-registered aquaculture establishment, and shall submit Appended Form 8 to notify the prefecture where the aquaculture establishment is located, as well as send the list after the deregistration to the prefecture and the All Japan Nishikigoi Promotion Association. The prefecture, which has received the list, shall inform the aquaculture farmer thereof.
- (5) The prefecture shall provide an on-site the technical instruction to the list-registered aquaculture establishment and strive to provide instruction such as the compliance matters of 4 to the list-registered aquaculture farmers.
- (6) The prefecture shall summarize both results of the introduction of Nishikigoi provided by the establishments other than the list-registered aquaculture establishments during the period of January to December of each year and the inspection of the introduced Nishikigoi (Appended Form 12-1 and 12-2),both of which were submitted by the list-registered aquaculture establishment. This summary shall be submitted using the Appended Form 12-3 to the Fish and Fishery Products Safety Office by the end of February of the following year.

4. Compliance matters of the list-registered aquaculture farmers

All list-registered aquaculture farmers must comply with all matters described in the following (1) to (6):

- (1) The aquaculture farmers shall conduct inspection for SVC and KHV disease for the Nishikigoi per list-registered aquaculture establishment twice a year over an interval of at least three months in accordance with (i) to (iv), and shall ensure that there is no infection. In addition, the results of inspection shall be stored for at least three years after the inspection day.
 - (i) The inspection method shall be based on the diagnosis guidelines of the measures guidelines for specified diseases (dated on October 21, 2005, No.17shouan7497, the notification of the director of Food Safety and Consumer Affairs Bureau).
 - (ii) The inspection shall be conducted by sampling Nishikigoi kept at the water temperature to be able to develop clinical signs of SVC and KHV disease in the list-registered aquaculture establishment. Furthermore, the prefecture or person entrusted by the prefecture, or the private laboratory approved by the prefecture shall clinically observe the sampled Nishikigoi to confirm that there is no abnormality in the fish.
 - (iii) More than 30 Nishikigoi shall be sampled , and 5 samples can be pooled to make them one specimen.
 - (iv) The inspection can be conducted by the prefectures or the private laboratories with the capacity to conduct accurate virus inspection with the notification in (1) described above which was confirmed by the prefecture. In the case that the prefecture approves a private laboratory as an inspection organization, the prefecture shall notify it to the Fish and Fishery Products Safety Office using the Appended Form 9 in advance.
- (2) No Nishikigoi shall be introduced by any establishments other than the establishments of (i) or (ii).
 - (i) List-registered aquaculture establishments
 - (ii) Not the list-registered aquaculture establishment, but for which the prefecture has issued the certificate (Appended Form 10) regarding the matters related to the matters of 'a' and 'b'.
 - a. The aquaculture establishment shall satisfy the criteria (i) of (2) in 3.

- b. The Nishikigoi in the aquaculture establishment shall satisfy the criteria of 'a' of (ii) in 3-(2) and shall be inspected using the methods specified from (i) to (iv) in (1) to confirm that they are not infected by SVC and KHV diseases before .
- (3) When the aquaculture farmer intend to introduce Nishikigoi by the list-registered aquaculture establishment, they shall receive the transport form of Appended Form 11 from the original aquaculture establishment. The transport form shall be stored at the list-registered aquaculture establishment which has received the form, and the copy of the form shall be stored at the aquaculture establishment which sent the form: both shall be respectively stored at least for three years after the introduction of Nishikigoi.
- (4) When the aquaculture farmer intent to introduce Nishikigoi from the establishment of (ii) in (2), they shall receive the certificate issued by the prefecture in accordance with (ii) in (2) for each introduction from the original aquaculture establishment, and shall store it for at least three years after the introduction of Nishikigoi.
- (5) The aquaculture farmer shall summarize the results of introduction of Nishikigoi by other aquaculture establishment from January to December of each year as well as inspection results of (1) in 4 using the Appended Form 12-1 and 12-2, and submit to their prefecture by the end of January of the following year. In addition, when the prefecture requests any documents related to the inspection results and transport form, etc. the aquaculture farmer shall submit them.
- (6) In order to prevent invasion by any disease, the aquaculture farmer shall pay adequate attention to the water used, the management of establishment access, and the conditions of Nishikigoi. Also when the aquaculture farmer finds any abnormalities to the Nishikigoi reared in the establishment, such as poor swimming, debility and unexplained mass mortality, etc., the aquaculture farmer shall immediately report to the representative department of the prefecture.

5. Issuing the health certificate

When list-registered aquaculture farmers or exporters handling Nishikigoi of the list-registered aquaculture establishment apply to the prefecture for the issuance of the health certificate for SVC and KHV

diseases in exporting Nishikigoi to foreign countries, they shall follow the following procedures. In the case that it is possible for the prefecture to issue the health certificate for the Nishikigoi reared in the establishment other than the list-registered aquaculture establishment regardless of these guidelines, these provisions do not preclude it:

- (1) The person who applies for the issuance of the health certificate shall submit the application for the issuance of the health certificate (Appended Form 13) with (i) and (ii) to the prefecture.
 - (i) Nishikigoi Production Certificate (Appended Form 14), Nishikigoi Transport form (Appended Form 11), or the Copy of the Certificates issued by the prefecture (Appended Form 10)
 - (ii) A Copy of the inspection result of (1) of 4 conducted most recently
- (2) The prefecture shall confirm that exported Nishikigoi is not any clinical signs (the person who is entrusted by the prefecture regarding this confirmation shall submit the report of clinical observation using the Appended Form 15 to the prefecture). When the prefecture has been determined that Nishikigoi is not any clinical sign, the prefecture shall be able to issue the health certificate to the form specified by the exporting destination country or the form made by the prefecture and approved by the exporting destination country. In the case that the health certificate needs to be translated, an applicant shall prepare the translated version.

Supplementary provisions

1. These guidelines are applied from June 12, 2014.
2. As of June 12, 2014, the aquaculture establishments that were registered before the revision as list-registered aquaculture establishments in accordance with the guidelines, shall continue to be registered to the list that will be created after the revision for the guidelines.