



Australian Government
**Department of Agriculture
and Water Resources**

Appendices

Model health certificates (for use from 1 March 2016)

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Appendix 6: Health certification for freshwater ornamental finfish exported to Australia

Health certification for marine ornamental finfish exported to Australia

Exporter details:

Invoice number:..... Exporter name:.....

Address:.....

Phone No:..... Fax No:.....

E-mail:..... Import Permit number:.....

Number (tails) of fish:.....

I, the undersigned, certify that:

1. Only finfish listed in the *List of Permitted Live Marine Fish Suitable for Import* are included in this consignment and are documented on the attached invoice.
2. The fish in the consignment have been inspected within seven (7) days prior to export and show no clinical signs of infectious disease or pests.
3. The Export Premises are approved for export to Australia, meeting standards of the Department of Agriculture and Water Resources.
4. The fish were collected from an area at least five (5) kilometres from any finfish aquaculture operations and the fish in the consignment have not come into contact with water, equipment, or fish associated with farmed food fish (fish farmed for human consumption including recreational fishing).
5. The fish are not sourced from a population associated with any significant infectious disease or pests and there have not been any outbreaks of infectious fish disease or pests in the areas from which the fish have been collected during the six (6) months prior to collection.
6. The fish are wild caught and have not been bred or hatched on a farm or other premises.

Official details:

Signature:..... Issued at:.....

Name:..... Date:.....

Position:..... Stamp:

Address:.....

.....

.....

Phone No:.....

Fax No:.....

E-mail:.....

Health certification for goldfish exported to Australia

Exporter details:

Invoice number:..... Exporter name:.....

Address:.....

Phone No:..... Fax No:.....

E-mail:..... Import Permit number:.....

Number (tails) of fish:.....

I, the undersigned, certify that:

1. Only finfish listed in the *List of Permitted Live Freshwater Fish Suitable for Import* are included in this consignment and are documented on the attached invoice.
2. The goldfish (*Carassius auratus*) originate from a country, zone or export premises (the population) determined to be free from spring viraemia of carp virus (SVCV) and *Aeromonas salmonicida* (other than goldfish ulcer disease strains) based on:
 - a. the absence of clinical, laboratory or epidemiological evidence of these disease agents in the source fish population in the previous two (2) years; and
 - b. a system of monitoring and surveillance for the previous two (2) years acceptable to the Competent Authority and consistent with the Department of Agriculture and Water Resources Import Conditions '*Additional health certification criteria and procedures for goldfish exported to Australia*'.
3. The fish in the consignment have been inspected within seven (7) days prior to export and show no clinical signs of infectious disease or pests.
4. The Export Premises are approved for export to Australia, meeting standards of the Department of Agriculture and Water Resources.
5. All fish being held at the Export Premises exhibit no clinical signs of significant infectious disease or pests and are sourced from populations not associated with any significant disease or pests within the 6 months prior to certification.
6. All fish in the consignment have been in approved Export Premises for fourteen (14) days prior to export.
7. The fish have not been kept in water in common with farmed foodfish (fish farmed for human consumption including recreational fishing) or koi carp.
8. All fish in the consignment have been effectively treated for gill flukes *Dactylogyrus vastator* and *D. extensus* within seven (7) days prior to export by bathing in the parasiticide.....
9. Adequate quarantine safeguards are in place to maintain the health status of the certified fish until export. The fish are effectively isolated in holding systems that prevent infection by direct contact with other fish or indirect contact via water, equipment or any other means.

Official details:

Signature:..... Issued at:.....

Name:..... Date:.....

Position:..... Stamp:

Address:.....

Phone No:.....

Fax No:.....

E-mail:.....

Additional health certification criteria and procedures for goldfish exported to Australia

1. Source freedom of Spring viraemia of carp virus (SVCV) and *Aeromonas salmonicida* for goldfish (other than goldfish ulcer disease strains)

1. The certification of (2) 'The goldfish originate from a country, zone or export premises determined to be free from spring viraemia of carp virus (SVCV) and *Aeromonas salmonicida* (other than goldfish ulcer disease strains) based on a) the absence of clinical, laboratory or epidemiological evidence of these disease agents in the source fish population in the previous two years; and b) a system of monitoring and surveillance for the previous two years acceptable to the Competent Authority and consistent with the Department of Agriculture and Water Resources Import Conditions *Additional health certification criteria and procedures for goldfish*' must be based on active targeted surveillance in the country, zone or compartment described under Sections 1.1 to 1.8 below.
 - 1.1. Surveillance must demonstrate the absence of SVCV and *A. salmonicida* and suspected clinical signs in the source population during a two (2) year period of surveillance. To certify source freedom, the active targeted surveillance program must include a minimum of two rounds of sampling and testing for SVCV and *A. salmonicida* in the source population of fish to be exported to Australia. Chapter 1.4 *Aquatic Animal Health Surveillance* of the [OIE Aquatic Animal Health Code](#) (OIE Code) should be referred to when designing a surveillance program for health certification purposes.
 - 1.2. The Competent Authority may recognise the country, a zone or compartment as free of SVCV and *A. salmonicida* based on negative test results using internationally recognised diagnostic protocols referred to under Section 1.4 and 1.5 below. The testing regimens apply in addition to the requirement for an absence of suspected clinical signs associated with SVCV and *A. salmonicida*, and that *basic biosecurity conditions*, as defined in the OIE Code and stated under Section 1.7 below, must have been continuously met during the two year surveillance period.

Sample size for source freedom

- 1.3. The sample size within a source population should be calculated using the guidelines in Chapter 1.4 *Aquatic Animal Health Surveillance* of the OIE Code. The sampling design of active targeted surveillance for demonstrating SVCV-free and *A. salmonicida*-free status for a country, zone or compartment must require a minimum level of sampling appropriate for a 5 % assumed prevalence with a 95 % confidence level of SVCV and *A. salmonicida* detection in a source population. The population size is defined as the number of fish of the same species that share a common water supply and originate from the same broodstock. Examples of sample sizes for various combinations of design prevalence, test sensitivity and specificity values are provided in Table 1 below.

Diagnostic tests

- 1.4. **SVCV:** The appropriate test methods for the purpose of demonstrating freedom of SVCV are those capable of detecting subclinical carriers of the virus, as described in the [OIE Manual of Diagnostic Tests for Aquatic Animals](#) (OIE Manual) or equivalent published peer reviewed reference material.
- 1.5. ***A. salmonicida*:** The appropriate diagnostic test methods for the purpose of demonstrating freedom of *A. salmonicida* are those capable of detecting subclinical carriers of the bacteria, such as those described in the AQUAVETPLAN Disease Strategy Manual: Furunculosis Version 2 (2009) or from equivalent published peer reviewed reference material.
<http://www.agriculture.gov.au/animal/aquatic/aquavetplan/furunculosis>

Ongoing surveillance

- 1.6. Ongoing surveillance to demonstrate SVCV and *A. salmonicida* freedom should involve twice yearly sampling and testing at a level appropriate for a 10 % assumed prevalence with a 95 % confidence level of detecting SVCV and *A. salmonicida* in a source population. The conditions for ongoing surveillance to demonstrate pathogen freedom will only be recognised following two (2) years of continuous active targeted surveillance with no positive detections of SVCV or *A. salmonicida*, an absence of suspected

clinical signs and demonstration that *basic biosecurity conditions* (see OIE Code and section 1.7 below) were continuously met for the period.

- 1.7. *Basic biosecurity conditions* are defined in the OIE Code as a set of conditions applying to a particular disease, and a particular compartment, zone or country, required to ensure adequate disease security, such as:
- the disease, including suspicion of the disease, is compulsorily notifiable to the Competent Authority; and
 - an early detection system is in place within the compartment, zone or country; and
 - import requirements to prevent the introduction of disease into the compartment, zone or country, as outlined in the OIE Code, are in place.

Health certification

- 1.8. Exporting countries are required to provide health certification attesting to freedom from SVCV and *A. salmonicida* for all fish destined for export to Australia. This includes attestations of disease freedom for fish that may have been sourced from a different country to the final export country. Attestations of disease freedom in these circumstances must be based on satisfactory certification arrangements between the original source country and the final exporting country's Competent Authority.

Health certification for gouramis, bettas, paradise fish¹,cichlids and poeciliids exported to Australia

Exporter details:

Invoice number:..... Exporter name:.....
Address:.....
.....
Phone No:..... Fax No:.....
E-mail:..... Import Permit number:.....
Number (tails) of fish:.....

I, the undersigned, certify that:

1. Only finfish listed in the *List of Permitted Live Freshwater Fish Suitable for Import* are included in this consignment, and are documented on the attached invoice.
2. (tick a or b):
 - a. SOURCE POPULATION FREEDOM
The fish originate from a country, zone or export premises determined by the Competent Authority to be free from megalocytiviruses consistent with the procedures described in the Department of Agriculture and Water Resources Import Conditions '*Additional health certification criteria and procedures forgouramis, bettas, paradise fish, cichlids and poeciliids exported to Australia*', OR;
 - b. BATCH TEST NEGATIVE
The batch of consigned fish have been tested by the Competent Authority and found negative for megalocytiviruses consistent with definitions and testing methodology described in the Department of Agriculture and Water Resources Import Conditions '*Additional health certification criteria and procedures forgouramis, bettas, paradise fish, cichlids and poeciliids exported to Australia*'.
3. The fish in the consignment have been inspected within seven (7) days prior to export and show no clinical signs of infectious disease or pests.
4. The Export Premises are approved for export to Australia, meeting standards of the Department of Agriculture and Water Resources.
5. All fish being held at the Export Premises exhibit no clinical signs of significant infectious disease or pests and are sourced from populations not associated with any significant disease or pests within the six (6) months prior to certification.
6. All fish in the consignment have been in approved Export Premises for fourteen (14) days prior to export.
7. The fish have not been kept in water in common with farmed foodfish (fish farmed for human consumption including recreational fishing) or koi carp.
8. Adequate quarantine safeguards are in place to maintain the health status of the certified fish until export. The fish are effectively isolated in holding systems that prevent infection by direct contact with other fish or indirect contact via water, equipment or any other means.

Official details:

Signature:..... Issued at:.....
Name:..... Date:.....
Position:..... Stamp:
Address:.....
.....
Phone No:.....
Fax No:.....
E-mail:.....

¹ Gouramis, bettas and paradise fish include all species belonging to subfamilies Luciocephalinae and Macropodusinae of the family Osphronemidae listed in the *List of Permitted Live Freshwater Fish Suitable for Import*.

Additional health certification criteria and procedures for gouramis, bettas, paradise fish, cichlids and poeciliids exported to Australia

1. SOURCE FREEDOM of megalocytiviruses for gouramis, bettas, paradise fish, cichlids and poeciliids

The certification of (2A) 'The fish originate from a country, zone or compartment determined by the Competent Authority to be free from *Megalocytivirus* based on the procedures described in the Department of Agriculture Import Condition' must be based on active targeted surveillance in the country, zone or compartment described under Sections 1.1 to 1.9.

1.1. Surveillance must demonstrate the absence of megalocytiviruses and suspected clinical signs in the source population during a surveillance period specified by the Competent Authority. The active targeted surveillance program must include a minimum of two rounds of sampling and testing for megalocytiviruses in the source population of fish to be exported to Australia. Chapter 1.4 Aquatic Animal Health Surveillance of the OIE *Aquatic Animal Health Code* (OIE Code) should be referred to when designing a surveillance program for health certification purposes.

1.2. The Competent Authority may recognise a zone or compartment as free of megalocytiviruses based on negative test results using internationally recognised molecular diagnostic protocols referred to under Section 1.6 below. The testing regimens apply in addition to the requirement for an absence of suspected clinical signs associated with megalocytiviruses, and that *basic biosecurity conditions*, as defined in Section 1.8, must have been continuously met during the surveillance period.

Sample size for source freedom

1.3. The sample size within a source population should be calculated using the guidelines in Chapter 1.4 Aquatic Animal Health Surveillance of the OIE Code. Source populations of fish to be included in a sampling regime may be of a single susceptible species if epidemiologically isolated, or if mixed populations of susceptible species, then these may be sampled using a stratified approach as described in the aforementioned chapter. Suggested sampling methodology is provided below for situations where disease prevalence in the source population is unknown (Section 1.4) or known (Section 1.5).

1.4. Should the health status of source fish be unknown then the sampling design of targeted active surveillance for demonstrating megalocytivirus-free status of a country, zone or compartment must require a minimum level of sampling appropriate for a 5 % assumed prevalence with a 95 % confidence level of detecting megalocytiviruses in a source population. Examples of sample sizes for various combinations of design prevalence, diagnostic sensitivity and specificity values are provided in Table 1.

1.5. Should the Competent Authority be aware of the likely megalocytivirus prevalence in the source population (based on the previous baseline surveillance and/or published scientific literature), the sampling size can be designed with an expected prevalence that differs to 5 %. The sampling design should take into account epidemiological factors, including but not limited to, the virus characteristics (e.g. transmissibility, incubation period, the virus infecting homogeneously or clustering within the population), population dynamics and biosecurity practices (e.g. the number of ponds/aquaria, physical structures of the farm, frequency and duration of population mixing, water intake and water sharing).

Diagnostic tests

1.6. The appropriate test methods for the purpose of demonstrating freedom of megalocytiviruses are those based on the polymerase chain reaction (PCR). These molecular tests must be capable of detecting subclinical carriers of the virus, such as two-step (nested) PCR and quantitative PCR methods published in peer-reviewed journals or equivalent. The standard PCR test for red seabream iridovirus (RSIV) described in the current OIE *Manual of Diagnostic Tests for Aquatic Animals* (OIE Manual) is not considered suitable at present as there is insufficient evidence that the test is capable of detecting the presence of megalocytiviruses in subclinically infected fish.

Ongoing surveillance

1.7. Ongoing surveillance to demonstrate disease freedom should involve twice yearly sampling and testing at a level appropriate for a 10 % assumed prevalence with a 95 % confidence level of detecting megalocytiviruses in a source population. The conditions for ongoing surveillance to demonstrate disease freedom will only be recognised following two years of continuous active targeted surveillance with no positive detections of megalocytiviruses, an absence of suspected clinical signs and demonstration that *basic biosecurity conditions* (as defined Section 1.8) were continuously met for the period.

1.8. *Basic biosecurity conditions* are defined in the OIE Code as a set of conditions applying to a particular disease, and a particular compartment, zone or country, required to ensure adequate disease security, such as:

- the disease, including suspicion of the disease, is compulsorily notifiable to the Competent Authority; and
- an early detection system is in place within the compartment, zone or country; and
- import requirements to prevent the introduction of disease into the compartment, zone or country, as outlined in the OIE Code, are in place.

Health certification

1.9. Exporting countries are required to provide health certification attesting to freedom from megalocytiviruses for all fish destined for export to Australia. This includes attestations of disease freedom for fish that may have been sourced from a different country to the final export country. Attestations of disease freedom in these circumstances must be based on satisfactory certification arrangements between the original source country and the final exporting country.

2. BATCH TEST NEGATIVE for megalocytiviruses for gouramis, bettas, paradise fish, cichlids and poeciliids

The certification of (2B) 'The fish originate from a batch that has been tested by the Competent Authority and found negative for *Megalocytivirus* using a testing method that is consistent with the Department of Agriculture Import Condition' must be based on batch testing described under Sections 2.1 to 2.6.

2.1. Pre-export batch testing for megalocytiviruses is not required if fish are sourced from a country, zone or compartment recognised by the Competent Authority of the exporting country to be free of the virus on the basis of a surveillance program consistent with Section 1 above.

Batch definition

2.2. For the purposes of batch testing for freedom from megalocytiviruses, a batch can be defined as fish of susceptible species sharing water in a single holding system at the time of sample collection that have remained epidemiologically isolated for at least 14 days from fish not of equivalent health status prior to export.

Diagnostic tests

2.3. Refer to the information in Section 1.6.

Sample size for batch testing

2.4. The sample size within a batch should be calculated using the guidelines in Chapter 1.4 Aquatic Animal Health Surveillance of the OIE Code. The design of a pre-export batch testing surveillance program for demonstrating freedom from megalocytiviruses must require a minimum level of sampling appropriate for a 5 % assumed prevalence. Examples of sample sizes for various combinations of design prevalence, diagnostic sensitivity and specificity values are provided in Table 1.

2.5. For some species, the number of animals constituting a batch is not large enough to meet the required sample size for pre-export batch testing. The Competent Authority of the exporting country may make an alternative arrangement for the suitable sample size for batch testing, either generally or case-by-case. Such arrangements should be supported by scientific data that would clearly demonstrate equivalence of the alternative arrangement.

2.6. All consignments of gouramis, bettas, paradise fish, cichlids and poeciliids must be held in quarantine at the export premises while being sampled for testing and remain under quarantine control at the export premises until the results of the tests are available. Only fish from batches that return negative results are permitted to be exported to Australia.

3. Health certification for imported fish

Exporting countries are required to provide health certification attesting to freedom from megalocytiviruses for all fish destined for export to Australia. This includes attestations of disease freedom for fish that may have been sourced from a different country to the final export country. Attestations of disease freedom in these circumstances must be based on satisfactory certification arrangements between the original source country and the final exporting country.

4. Non-lethal sampling

Non-lethal or non-tissue derived diagnostic approaches may be considered for demonstrating disease freedom via source freedom surveillance or batch testing, if suitable methods become available. Such methods may include sampling of water, faeces or non-lethally obtained tissue samples (e.g. gill or fin clips) derived from fish of a single susceptible species or multiple susceptible species destined for export. Exporting countries wishing to apply non-lethal diagnostic methods to demonstrate disease freedom must be able to provide peer reviewed scientific evidence that such methods provide an equivalent level of confidence for the detection of megalocytiviruses in sub-clinically infected susceptible populations of fish. Scientific evidence supporting non-lethal sampling must be acceptable to the exporting country's Competent Authority.

Table 1: Examples of sample sizes generated by FreeCalc (Sergeant 2015) for various combinations of design prevalence, test sensitivity and specificity values (<http://epitools.ausvet.com.au/content.php?page=FreeCalc2>)

Design prevalence	Sensitivity (%)	Specificity (%)	Sample size	Maximum number of false positives if the population is free
5	100	100	59	0
5	100	99	128	3
5	100	95	330	23
5	99	100	59	0
5	99	99	129	3
5	99	95	331	23
5	95	100	62	0
5	95	99	134	3
5	95	95	351	24
5	90	100	66	0
5	90	99	166	4
5	90	95	398	27
5	80	100	74	0
5	80	99	183	4
5	80	95	486	32

**Health certification for freshwater ornamental finfish
exported to Australia**

(other than goldfish, gouramis, bettas, paradise fish, cichlids and poeciliids)

Exporter details:

Invoice number:..... Exporter name:.....
Address:.....
.....
Phone No:..... Fax No:.....
E-mail:..... Import Permit number:.....
Number (tails) of fish:.....

I, the undersigned, certify that:

1. Only finfish listed in the *List of Permitted Live Freshwater Fish Suitable for Import* are included in this consignment and are documented on the attached invoice.
2. The fish in the consignment have been inspected within seven (7) days prior to export and show no clinical signs of infectious disease or pests.
3. The Export Premises are approved for export to Australia, meeting standards of the Department of Agriculture and Water Resources.
4. All fish being held at the Export Premises exhibit no clinical signs of significant infectious disease or pests and are sourced from populations not associated with any significant disease or pests within the six (6) months prior to certification.
5. All fish in the consignment have been in approved Export Premises for fourteen (14) days prior to export.
6. The fish have not been kept in water in common with farmed foodfish (fish farmed for human consumption including recreational fishing) or koi carp.
7. Adequate quarantine safeguards are in place to maintain the health status of the certified fish until export. The fish are effectively isolated in holding systems that prevent infection by direct contact with other fish or indirect contact via water, equipment or any other means.

Official details:

Signature:..... Issued at:.....
Name:..... Date:.....
Position:..... Stamp:
Address:.....
.....
.....
Phone No:.....
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E-mail:.....