Instructions for completing the "MODEL ANIMAL HEALTH CERTIFICATE FOR THE ENTRY INTO THE UNION OF AQUATIC ANIMALS INTENDED FOR CERTAIN AQUACULTURE ESTABLISHMENTS, FOR RELEASE INTO THE WILD OR FOR OTHER PURPOSES, EXCLUDING HUMAN CONSUMPTION (MODEL 'AQUA-ENTRYESTAB/RELEASE/OTHER')" to the European Union.

The requirements to export live aquatic animals to countries in the European Union (EU) will depend on the species to be exported, whether the EU considers this species "susceptible" to or a "vector" for the pathogens of concern, and whether the importing EU Member State has measures in place for the pathogens of concern.

Follow the 2 steps below to determine if pre-export testing/freedom<sup>1</sup> is required and how to make the appropriate lineouts before submitting a health certificate for APHIS review and endorsement.

<sup>1</sup>The pre-export testing, country, or premises freedom measures required for each EU Member State or associated EU Aquaculture Establishment<sup>2</sup> will hereafter be referred to as "pre-export testing/freedom" as determined in Step 1, and the details affiliated with meeting these measures as defined in Step 2.

<sup>2</sup>See "Additional Information & References" section below for establishment-level details, which may apply.

# STEP 1: Determine Species Susceptibility to EU Pathogens of Concern

The European Union (EU) lists the following pathogens of concern on the health certificate, so *pre-export testing/freedom may be required* if the species to be exported is considered "susceptible" or a "vector":

## Fish

- Bacterial kidney disease (BKD)
- Epizootic haematopoietic necrosis (EHN)
- Gyrodactylus salaris (GS)
- Infectious haematopoietic necrosis (IHN)
- Infectious pancreatic necrosis (IPN)
- o Infectious salmon anaemia virus (ISA HPR-deleted)
- Koi herpes virus disease (KHV)
- Salmonid alphavirus (SAV)
- Spring viraemia of carp (SVC)
- Viral haemorrhagic septicaemia (VHS)

#### Mollusks

- Bonamia exitiosa
- o Bonamia ostreae
- Martiella refringens
- Mikrocytos mackini
- o Perkinsus marinus

#### Crustaceans

- Taura syndrome virus (TSV)
- Yellowhead virus (YHV)
- White spot syndrome virus (WSSV)

Determining species susceptibility and whether pre-export testing/freedom is required will depend on susceptibility as determined by the European Union (EU), as well as the importing EU Member State's measures for a given pathogen of concern – see instructions and examples below.

i. "Listed" vs. "unlisted" species. Determine if the species to be exported is considered "susceptible" to or a "vector" for the pathogens of concern to the EU using the <u>European Union Aquatic Animal Diseases of Concern and Listed Species Classification</u> table posted on the <u>Export Live Animals to European Union</u> web page.

*NOTE:* In some cases, both the *Genus* and *species* are listed for a given pathogen of concern, but others are grouped at a higher taxonomic level (e.g., Order).

- If the species to be exported is considered either "susceptible" to or a "vector" for a pathogen of concern (hereafter referred to as a "listed species"), then further steps are needed to determine if pre-export testing/freedom is required.
- If the species to be exported is <u>not</u> considered "susceptible" to or a "vector" for a pathogen of concern (hereafter referred to as an "unlisted species"), then no pre-export testing/freedom is required. Skip to the "Additional Information & References" section of these instructions for more information.
- ii. **Listed "susceptible" species**. Determine whether the EU Member State has measures in place for a given pathogen of concern using the <u>Aquaculture Pathogens by EU Country</u> table posted on the <u>Export Live</u>

  <u>Animals to European Union</u> web page. If an EU Member State has measures in place for a given pathogen of concern, then the cell will state "Req", meaning pre-export testing/freedom is required.
  - If the listed species to be exported is considered "susceptible" for a pathogen of concern AND the EU Member State has measures in place, then pre-export testing/freedom is required.
  - If the listed species to be exported is considered "susceptible" for a pathogen of concern BUT the EU
    Member State does not have measures in place, then pre-export testing/freedom is not required.<sup>2</sup>
    - <sup>2</sup>See "Additional Information & References" section below for establishment-level details, which may apply.

*EXAMPLE.* If exporting rainbow trout (*Oncorhynchus mykiss*), this species is considered "susceptible" to viral hemorrhagic septicemia (VHS).

- If exporting this species to **Finland** (which has measures in place for VHS), then pre-export testing for VHS is required.
- If exporting this species to **Germany** (which does NOT have measures in place for VHS), then preexport testing for VHS is <u>NOT required</u>.

- iii. **Listed "vector" species.** Determine whether the EU Member State has measures in place for a given pathogen of concern using the <u>Aquaculture Pathogens by EU Country</u> table posted on the <u>Export Live Animals to European Union</u> web page. If an EU Member State has measures in place for a given pathogen of concern, then the cell will state "Req", meaning pre-export testing/freedom is required.
  - If the listed species to be exported is considered a "vector" for a pathogen of concern AND the EU Member State has measures in place, then <u>further steps</u> are needed to determine if pre-export testing/freedom is required (see below).
  - If the listed species to be exported is considered a "vector" for a pathogen of concern BUT the EU Member State does not have measures in place, then pre-export testing/freedom is not required.<sup>2</sup>

<sup>2</sup>See "Additional Information & References" section below for establishment-level details, which may apply.

If the *listed "vector" species* will be exported to an EU Member State that has *measures* in place for a given pathogen of concern, then determine whether there are additional pathogen-specific considerations using the <u>Aquaculture Pathogens by EU Country</u> table posted on the <u>Export Live Animals to European Union</u> web page.

• If the "†" symbol appears in the table for a given pathogen, then there are pathogen-specific "vector" conditions, and pre-export testing/freedom is only required if the "vector" species to be exported cohabitates/shares water with any "susceptible" species at the exporting facility.

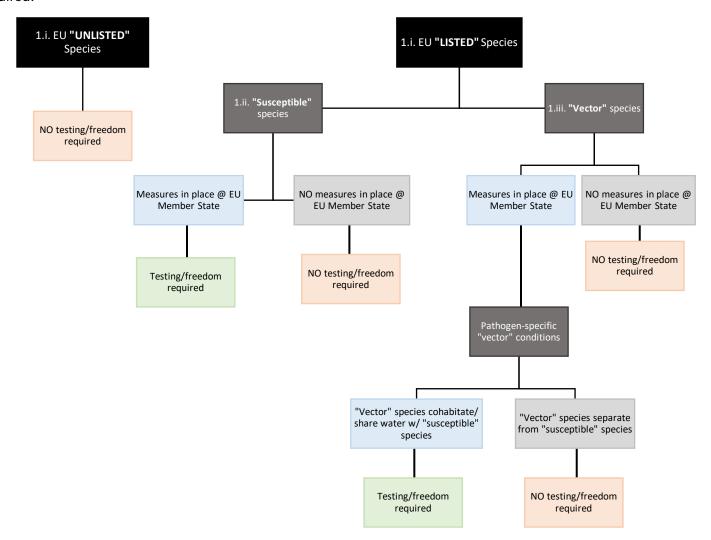
*EXAMPLE*. If exporting glass shrimp (*Machrobrachium lanchesteri*), this species is considered a "vector" for Taura syndrome virus (TSV).

- If the glass shrimp **cohabitate/share waters** with white leg shrimp (*Penaeus/Litopenaeus vannamei*) which are "susceptible" to TSV, then pre-export testing for TSV is required for the glass shrimp.
- If the glass shrimp do NOT cohabitate/share waters with white leg shrimp, then pre-export testing for TSV is NOT required for the glass shrimp.
- iv. Quick references related to Step 1.

Table 1. Summary table of when pre-export testing/freedom is required based on the species to be exported, the destination EU Member State, and if there are additional pathogen-specific conditions.

Is the listed species "susceptible"?	Is the listed species a "vector"?	Does the EU Member State have measures in place?	Are there pathogen- specific "vector" conditions?	Does the "vector" cohabitate/ share water with "susceptible" species?	Is pre-export testing/freedom required?
No					No
Yes		No			No
Yes		Yes			Yes
	No				No
	Yes	No			No
	Yes	Yes	Yes	No	No
	Yes	Yes	Yes	Yes	Yes

Figure 1. Decision tree to help visualize the steps necessary to determine if the species being exported to a specific European Union (EU) Member State is considered listed vs. unlisted, and whether pre-export testing/freedom is required.



# Step 2: Determine Pre-export Testing/Freedom & Facility Registration Requirements

If the species to be exported is considered "susceptible" to or a "vector" for a given pathogen of concern, AND pre-export testing/freedom is required per Step 1 above, then pre-export testing/freedom must be met via either country-level freedom or premises freedom.

Use the following guidance to determine how to certify pre-export testing/freedom requirements have been met for the species being exported and the pathogens of concern:

# Country-level Freedom

 No further testing is required for those EU pathogens of concern for which APHIS has declared freedom at the country-level. For more information about the specific pathogens and these freedom declarations, visit the <u>APHIS Aquatic Animal Health Status Reviews</u> web page.

#### • Premises-level Freedom

exporters must meet the <u>APHIS Criteria for Establishing Premises Freedom</u> for all other pathogens of concern, and submit their Premises Freedom Letter at the time of APHIS certificate endorsement to document this requirement has been met. For more information on how to obtain and maintain premises freedom recognition, visit the <u>APHIS Export Aquatic Animals: RAEF Production Facility Approval Plus Premises Freedom</u> web page.

If the species to be exported is considered "susceptible" to or a "vector" for a given pathogen of concern, AND pre-export testing/freedom is required per Step 1 above, then the exporting facility must be approved under the APHIS Registered Aquaculture Export Facility (RAEF) inspection program. For more information on how to obtain and maintain facility approval, visit the <u>APHIS Export Aquatic Animals: APHIS-Registered Aquaculture Export Facility Inspection Program</u> web page.

## **Additional Information & References:**

- Aquatic animal definition. The EU defines "aquatic animals" as animals of the following species, at all lifestages, including eggs, sperm, and gametes, per Article 4(3) of the Animal Health Law:
  - o fish belonging to the superclass *Agnatha* and to the classes *Chondrichthyes*, *Sarcopterygii* and *Actinopterygii*;
  - o aquatic mollusks belonging to the phylum *Mollusca*;
  - o aquatic crustaceans belonging to the subphylum Crustacea.
- "Unlisted" species. If the species to be exported is considered "unlisted" per Step 1 above, then the requirements are determined by the importing EU Member State, and the importer should request this information in writing from the EU Member State government officials directly.
  - If the government officials of the importing country advise the use of the AQUA-ENTRY-ESTAB/RELEASE/OTHER health certificate, then the pre-lined out <u>AQUA-ENTRY-</u> ESTAB/RELEASE/OTHER UNLISTED health certificate may be used.
- **Research aquatic animals.** If the species to be exported is intended for research AND considered "susceptible" or a "vector" species per Step 1 above, then there are 2 options:
  - Option 1: Exporting facility must be registered AND meet pre-export testing/freedom requirements (see Step 2 above). Use the <u>AQUA-ENTRY-ESTAB/RELEASE/OTHER</u> health certificate; or
  - o Option 2: Exporting facility does not need to be registered AND pre-export testing/freedom is not required BUT must be exported directly to an eligible confined establishment in the EU. Use the pre-lined out AQUA-ENTRY-ESTAB/RELEASE/OTHER RESEARCH health certificate and section II.2. should be lined out. In box I.20 select "Confined establishment" to indicate the animals will be sent to a confined establishment in the EU which meets the requirements in Article 6(d) of Delegated Regulation 2020/990.
- Wild-caught aquatic animals intended for confined establishments. If the species to be exported is wild-caught AND considered "susceptible" or a "vector" species per Step 1 above AND won't be released into the wild once in the EU Member State, then the exporting facility does not need to be registered (as they are not aquacultured animals) AND pre-export testing/freedom is not required. Use the pre-lined out AQUA-ENTRY-ESTAB/RELEASE/OTHER WILD CAUGHT health certificate. In box I.20 select "Confined establishment" to indicate the animals will be sent to a confined establishment in the EU which meets the requirements in Article 6(d) of Delegated Regulation 2020/990.
- Animals to be released into the wild. If the species to be exported will be released into the wild in the
  EU, then pre-export testing/freedom is required regardless of the species being exported and regardless
  of the destination EU Member State. Use the <u>AQUA-ENTRY-ESTAB/RELEASE/OTHER</u> health certificate.
  Do not line out certification statement II.2.
- **Establishment-specific information.** Pre-export testing/freedom may or may not be required when exporting to a specific EU aquaculture establishment. Visit the EU Member State-specific page for more information on the EU's <u>Aquaculture Establishments</u> web page.

- Full list of European Union legislation. It's important to keep in mind that these are fluid lists and can be updated as the status of different EU Member States changes. The lists will be updated/amended in new pieces of legislation which will be incorporated into the existing regulations (and decision) as the 'current consolidated version' on the EU's EUR-LEX website.
  - The main regulations where relevant lists are published in the EU legislation (and referenced in this document) are:
    - Commission Implementing Regulation (EU) 2018/1882 last amended 1 February 2024
    - Commission Implementing Regulation (EU) 2021/620 last amended 23 February 2025
    - Commission Implementing Decision (EU) 2021/260 last amended 23 March 2025
    - Commission Implementing Decision (EU) 2024/216 last amended 11 January 2024
    - Commission Implementing Regulation (EU) 2025/403 last amended 28 February 2025
  - The general entry/import legislation for the EU is:
    - Commission Delegated Regulation (EU) 2020/692 last amended 7 February 2023
  - The list referred to in Point II.3.1 of the <u>Certificate Model AQUA-ENTRY-ESTAB/RELEASE/OTHER</u> is:
    - Commission Implementing Regulation (EU) 2021/404 last amended 08 January 2025
       Note: In most cases, the code for the United States is "US-0"
  - Additional references:
    - Animal Health Law for the definition of aquatic animals, Article 4(3) last amended 21 April
       2021
    - Commission Delegated Regulation (EU) 2020/990 for confined establishment requirements, Article 6(d) last amended 10 July 2020
    - Aquaculture Establishments for the health status of specific establishments by EU
      Member State, as defined in Commission Delegated Regulation (EU) 2016/429, Article
      4(27)

\*\*NOTE: While the European Commission provides flexibility on how to meet their aquatic animal import requirements, the instructions described above are based on current USDA APHIS systems for oversight and certification.\*\*

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Exports to non-EU Member States in Europe. While the EU legislation may be relevant to
countries in Europe that are not part of the European Union (EU), such as Switzerland or Norway,
those countries may have their own or additional requirements. Additionally, the health status/
measures in place for the EU pathogens of concern are not listed in the EU legislation for non-EU
Member States. Please contact non-EU Member States directly to determine their requirements.