

MAFF JAPAN

Health Requirements for Live Crustaceans

Exported from the United States of America to Japan

The health requirements to be applied to live Crustaceans that are exported from the United States of America to Japan are as follows:

I. Definition

In this document, the definitions of terms are as follows:

1. Crustaceans: All life stages of live Crustaceans listed in the attachment, provided for in the item 2 of Article 1 in the Ordinance for the Act on the Protection of Fishery Resources (As for animals intended for human consumption, only those kept in public waters or facilities draining into public waters are subject to quarantine.)
2. Target diseases: Diseases listed in the attachment.
Those are targeted for import quarantine provided for in the item 2 of Article 1 in the Ordinance for the Act on the Protection of Fishery Resources.
3. Japanese authority in charge of aquatic animal disease control: Fish and Fishery Products Safety Office, Animal Products Safety Division, Food Safety and Consumer Affairs Bureau, Ministry of Agriculture, Forestry and Fisheries of Japan
4. Competent authority in the exporting country: the authority in charge of aquatic animal disease control in the exporting country

II. Health requirements for aquatic animals

1. The Japanese authority consults with the competent authority in the exporting country in light of occurrences of the target diseases and regulatory framework for disease control in the exporting country, and notifies beforehand the competent authority in the exporting country of which status will be assigned to the country for each target disease, status 1.A, status 1.B or status 1.B'. Status 1.B' is applicable only to Non OIE listed diseases.

1.A The country, zone, compartment or establishment is free of the target disease:

- a) The exported aquatic animal is confirmed to be from the country, zone, compartment or establishment that is confirmed to be free of the target disease

under the surveillance by the competent authority in the exporting country based on the OIE code or, if relevant OIE code does not exist, by reference to the OIE code.

AND

- b) In the event of an outbreak of the target disease, it shall be notified to the competent authority in the exporting country.

AND

- c) The target disease is designated as the target of the official surveillance program of the exporting country in accordance with the OIE code.

1.B The country, zone, compartment or establishment is not free of the target disease:

- a) No occurrence of the target disease has been reported in aquaculture facilities or fishing areas of the exported aquatic animal at least for one year before the export. Mass mortality of unknown cause has not occurred and the competent authority in the exporting country has not imposed any restriction with the intent of disease control.

AND

- b) Before exports, the exported aquatic animals (if the exported aquatic animal is eggs or juvenile shrimp, including their broodstock) should be isolated from aquatic animals under different health situation at least for detention periods in the attachment at the isolation facility designated by the competent authority in the exporting country. No clinical signs of diseases should be observed during the isolation period. During the isolation period, a sample of the exported aquatic animals should be taken based on the sampling criteria in accordance with the OIE code (prevalence: 2%, confidence: 95%) under the supervision of the competent authority in the exporting country. All tests must be thoroughly conducted in the following methods and all test results should be negative.

1.B' The country, zone, compartment or establishment is not free of the target disease:

- a) Mass mortality of unknown cause has not occurred at least for one year before the export and the competent authority in the exporting country has not imposed any restriction with the intent of disease control.

AND

- b) Before exports, the exported aquatic animals (or, if the exported animal is eggs or juvenile shrimp, including their broodstock) should be isolated from aquatic

animals under different health situation at least for detention periods indicated in the attachment at the isolation facility designated by the competent authority in the exporting country. No clinical signs of the target disease should be observed during the isolation period.

During the isolation period, a sample of the exported aquatic animals should be taken based on the sampling criteria in accordance with the OIE code (prevalence: 5%, confidence: 95%) under the supervision of the competent authority in the exporting country. All tests must be thoroughly conducted in the following methods and all test results should be negative.

	Diseases	Samples	Diagnostic methods
i	Yellow head disease	The gills, lymphoid organ or pleopod	RT-PCR
ii	Necrotising hepatopancreatitis	DNA extracted from hepatopancreas	Real-time PCR or PCR
iii	Taura syndrome	RNA extracted from hemolymph or pleopod	RT-PCR
iv	Infectious hypodermal and haematopoietic necrosis	DNA extracted from gills, cuticular epithelium, hemolymph or pleopod	PCR
v	Acute hepatopancreatic necrosis disease	DNA extracted from hepatopancreas	Nested-PCR or Duplex PCR
vi	Infectious myonecrosis	RNA extracted from muscle or lymphoid organ or pleopod	Nested-PCR or Real-time RT-PCR
vii	Tetrahedral baculovirus	DNA extracted from hepatopancreas	PCR
viii	Covert mortality disease of shrimp	RNA extracted from hepatopancreas and midgut or pleopod	Nested-PCR or RT-PCR
ix	Spherical Baculovirus	DNA extracted from hepatopancreas and midgut	PCR
x	Gill-associated virus disease	RNA extracted from the gills or lymphoid organ	RT-nested PCR

2. The thorough inspections must be conducted by the competent authority or at the facility designated by the competent authority in the exporting country.
3. Aquaculture facilities of the exported aquaculture animals must be equipped with basic biosecurity control in accordance with the OIE code under the supervision of the competent authority in the exporting country.
4. The exported aquatic animal should be inspected within 10 days prior to the

export and should not demonstrate any clinical signs of infectious diseases.

5. The exported aquatic animal should not be given any live vaccine for the target disease.

III. Requirements for transportation

1. Materials such as containers and equipment used for transporting the exported aquatic animal should be new, or washed and disinfected properly.
2. Water used for transporting the exported aquatic animal should be free of the pathogen of the target disease or disinfected properly.

IV. Items on the inspection certificate

The competent authority in the exporting country must issue an inspection certificate which describes in detail the aforementioned items II and III as well as the following items:

1. Name of the competent authority in the exporting country
2. Name and address of consignor and consignee
3. Name and address of the origin and destination
4. Port of embarkation, Date of departure, Means of transport, Flight number/Ship name, Source (Cultured/ Wild), and Use of commodities
5. Species (Common name/Scientific name), Life stage, Quantity/Weight
6. Target disease status (Disease by disease)
 - II.1.A: a), b) and c)
 - II.1.B: a) and b) (including information on latest examination)
 - II.1.B': a) and b) (including information on latest examination)
7. Issue date of Health certificate, Name and address of the issuing authority, Position, Name and signature of certifying official, Official stamp of the competent authority in the exporting country

Diseases and animal species subject to import quarantine and detention periods		
[CRUSTACEANS]		
Aquatic animals	Diseases subject to import quarantine	Detention periods
<i>Marsupenaeus japonicus</i>	Yellow head disease: YHD Necrotising hepatopancreatitis: NHP Taura syndrome Infectious hypodermal and haematopoietic necrosis: IHHN Acute hepatopancreatic necrosis disease: AHPND Tetraedral baculovirus Covert mortality disease of shrimp: CMD Gill-associated virus disease	10 days (18 days in case that MAFF considers that imported live shrimp may be infected with Necrotising hepatopancreatitis(NHP), 20 days in case that MAFF considers that imported live shrimp may be infected with Taura syndrome, 30 days in case that MAFF considers that imported live shrimp may be infected with Covert mortality disease of shrimp(CMD), and 50 days in case that MAFF considers that imported live shrimp may be infected with Infectious myonecrosis(IMN))
<i>Litopenaeus vannamei</i>	Yellow head disease: YHD Necrotising hepatopancreatitis: NHP Taura syndrome Infectious hypodermal and haematopoietic necrosis: IHHN Acute hepatopancreatic necrosis disease: AHPND Infectious myonecrosis: IMN Tetraedral baculovirus Covert mortality disease of shrimp: CMD	
<i>Penaeus monodon</i>	Yellow head disease: YHD Necrotising hepatopancreatitis: NHP Taura syndrome Infectious hypodermal and haematopoietic necrosis: IHHN Acute hepatopancreatic necrosis disease: AHPND Infectious myonecrosis: IMN Tetraedral baculovirus Gill-associated virus disease Spherical Baculovirus	
<i>Fenneropenaeus chinensis</i>	Yellow head disease: YHD Necrotising hepatopancreatitis: NHP Taura syndrome Infectious hypodermal and haematopoietic necrosis: IHHN Acute hepatopancreatic necrosis disease: AHPND Tetraedral baculovirus Covert mortality disease of shrimp: CMD Gill-associated virus disease Spherical Baculovirus	
Species of genus <i>Litopenaeus</i> (excluding <i>Litopenaeus vannamei</i>)	Yellow head disease: YHD Necrotising hepatopancreatitis: NHP Taura syndrome Infectious hypodermal and haematopoietic necrosis: IHHN Infectious myonecrosis: IMN Tetraedral baculovirus	
Species of genus <i>Penaeus</i> (excluding <i>Penaeus monodon</i>)	Yellow head disease: YHD Necrotising hepatopancreatitis: NHP Taura syndrome Infectious hypodermal and haematopoietic necrosis: IHHN Infectious myonecrosis: IMN Tetraedral baculovirus Gill-associated virus disease Spherical Baculovirus	
Species of genus <i>Fenneropenaeus</i> (excluding <i>Fenneropenaeus chinensis</i>)	Yellow head disease: YHD Necrotising hepatopancreatitis: NHP Taura syndrome Infectious hypodermal and haematopoietic necrosis: IHHN Tetraedral baculovirus Gill-associated virus disease Spherical Baculovirus	
Species of genus <i>Melicertus</i> species of genus <i>Metapenaeus</i>	Yellow head disease: YHD Necrotising hepatopancreatitis: NHP Taura syndrome Infectious hypodermal and haematopoietic necrosis: IHHN Tetraedral baculovirus Spherical Baculovirus	
Penaeidae (excluding <i>Marsupenaeus japonicus</i> , species of genera <i>Litopenaeus</i> , <i>Penaeus</i> , <i>Fenneropenaeus</i> , <i>Melicertus</i> and <i>Metapenaeus</i>)	Yellow head disease: YHD Necrotising hepatopancreatitis: NHP Taura syndrome Infectious hypodermal and haematopoietic necrosis: IHHN Tetraedral baculovirus	
Species of genus <i>Acetes</i>	Yellow head disease: YHD	
Palaemonidae		

仮訳 米国から日本向けに輸出される生きている甲殻類の衛生条件

米国から日本向けに輸出される生きている甲殻類に適用される衛生条件は、以下によることとする。

1. 定義

本条件の適用において、以下の通り定義する。

- (1) 甲殻類：水産資源保護法施行規則第1条の2に掲げられた別添リストの甲殻類であり、生きている全ての成長段階のもの。ただし、食用に供するものにあつては、輸入後、公共の用に供する水面又はこれに直接排水する施設において飼育されるものに限る。
- (2) 対象疾病：水産資源保護法施行規則第1条の2に掲げられた輸入防疫対象疾病である別添リストの疾病
- (3) 日本国水産動物衛生当局：日本国農林水産省消費・安全局畜水産安全管理課水産安全室
- (4) 輸出国所管当局：輸出国において水生動物衛生を所管する当局

2. 水生動物衛生に関する条件

- (1) 日本国水生動物衛生当局は、輸出国所管当局と輸出国における対象疾病の発生状況や水産防疫体制を踏まえて協議し、輸出国所管当局に対して対象疾病ごとに、(1. A)、(1. B) もしくは (1. B') のいずれかの条件に該当するかについて、あらかじめ通知するものとする。(1. B') は OIE リスト疾病以外のみ適用される。

(1. A) 対象疾病について清浄な国、地域、区画または施設由来の場合：

- a) 輸出水産動物は、輸出国所管当局の監視の下、OIE 基準に基づき又は準じて、対象疾病が清浄な国、地域、区画または施設由来であることが確認されていること。

かつ

- b) 輸出国において対象疾病の発生が確認された場合は、輸出国所管当局に届出ることとされていること。

かつ

- c) 対象疾病は、OIE 基準に準じた輸出国の公式なサーベイランス計画の対象であること。

又は

(1. B) 対象疾病が清浄ではない国、地域、区画または施設由来の場合：

- a) 輸出水産動物の養殖施設又は漁獲エリアでは、輸出前少なくとも1年間、対象疾病の発生がないこと。また、原因不明の大量死等が発生しておらず、輸出国所

管当局による疾病管理目的のいかなる制限もかけられていないこと。

かつ

b) 輸出水産動物（稚エビ又は卵の場合は、親エビも含めて）は、輸出前少なくとも別添リストの期間は、当該輸出水産動物と同等の衛生状態の動物以外の動物と隔離し、隔離期間中は臨床的に疾病の徴候が認められないこと。隔離期間中にその同一集団の中から、輸出国所管当局の監視の下、対象疾病ごとに OIE 基準に基づいた抽出率（感染率 2%、信頼度 95%）でサンプリングした上で、下記の方法で精密検査を行い、すべて陰性であることを確認すること。なお、隔離期間中、輸出水産動物は、輸出国所管当局が認定した隔離施設において保管されること。

(1. B') 対象疾病が清浄ではない国、地域、区画または施設由来の場合：

a) 輸出前少なくとも 1 年間、原因不明の大量死等が発生しておらず、輸出国所管当局による疾病管理目的のいかなる制限もかけられていないこと。

かつ

b) 輸出水産動物（稚エビ又は卵の場合は、親エビも含めて）は、輸出前少なくとも別添リストの期間は、当該輸出水産動物と同等の衛生状態の動物以外の動物と隔離し、隔離期間中は臨床的に疾病の徴候が認められないこと。隔離期間中にその同一集団の中から、輸出国所管当局の監視の下、対象疾病ごとに OIE 基準に基づいた抽出率（感染率 5%、信頼度 95%）でサンプリングした上で、下記の方法で精密検査を行い、すべて陰性であることを確認すること。なお、隔離期間中、輸出水産動物は、輸出国所管当局が認定した隔離施設において保管されること。

	対象疾病	検査材料	検査方法
i	イエローヘッド病	鰓あるいはリンパ様器官又は遊泳脚	RT-PCR 検査
ii	壊死性肝臓炎	肝臓組織の抽出 DNA	リアルタイム PCR 検査又は PCR
iii	タウラ症候群	血リンパ又は遊泳脚の抽出 RNA	RT-PCR 検査
iv	伝染性皮下造血器壊死症	鰓、遊泳脚等のクチクラ上皮を含む組織又は血リンパの抽出 DNA	PCR 検査
v	急性肝臓壊死症	肝臓の抽出 DNA	Nested-PCR 検査又は Duplex PCR
vi	伝染性筋壊死症	筋肉組織、リンパ様器官又は遊泳脚の抽出 RNA	Nested-PCR 検査又はリアルタイム PCR
vii	バキュロウイルス・ペナエイ感染症	肝臓の抽出 DNA	PCR 検査
viii	エビの潜伏死病	肝臓、横紋筋又はリンパ様器官の抽出 RNA	Nested-PCR 検査または RT-PCR
ix	モノドン型バキュロウイルス感染症	肝臓及び中腸の抽出 DNA	PCR 検査

x	鰓随伴ウイルス感染症	鰓又はリンパ様器官の抽出 RNA	RT-nested-PCR 検査
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- (2) 精密検査は、輸出国所管当局又は輸出国所管当局が認めた検査機関で実施すること。
- (3) 輸出水産動物の養殖施設は、輸出国所管当局の監視の下、OIE 基準に準じた基本的なバイオセキュリティが確保されていること。
- (4) 輸出水産動物は、輸出国所管当局又は輸出国所管当局が認めた検査機関による輸出前 10 日以内の目視検査により、いかなる伝染性疾病を疑う症状を示していないこと。
- (5) 輸出水産動物は、対象疾病の生ワクチンを打っていないこと。

3. 輸送の条件

- (1) 輸出水産動物の輸送に使用される輸送箱、機材等は、新しい、又は適切に洗浄及び消毒されていること。
- (2) 輸出水産動物の輸送に使用される水は、対象疾病が清浄である、又は対象疾病の病原体を殺滅する方法で取扱われていること。

4. 検査証明書への記載事項

輸出国所管当局は、前記 2、3 及び次の各事項を具体的に英語で記載した検査証明書を発行する。

- (1) 輸出国所管当局の名称
- (2) 荷送人及び荷受人の氏名及び住所
- (3) 仕出地及び仕向地の名称及び住所
- (4) 生産国、仕向国、搭載予定地、搭載年月日、輸送方法、搭載機名（船名）、由来（養殖／天然）及び用途
- (5) 動物の種類（一般名及び学名）、成長段階、数量
- (6) 対象疾病ごとに、
 - 2. (1. A) の場合：a)～c)の各事項
 - 2. (1. B) の場合：a)及びb)の各事項（最新の検査情報を含む）
 - 2. (1. B') の場合：a)及びb)の各事項（最新の検査情報を含む）
- (7) 検査証明書の発行年月日、発行機関の名称及び住所、署名者の役職、氏名及びサイン、輸出国所管当局の公印