COMMISSION IMPLEMENTING REGULATION (EU) 2023/516
of 8 March 2023
amending Implementing Regulation (EU) 2020/2236 as regards the model animal health certificate for the entry into the Union of consignments of aquatic animals intended for certain aquaculture establishments, for release into the wild or for other purposes, excluding direct human consumption

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) 2016/429 of the European Parliament and of the Council of 9 March 2016 on transmissible animal diseases and amending and repealing certain acts in the area of animal health (‘Animal Health Law’) (1), and in particular Articles 238(3), points (a) and (c), thereof,


Whereas:

(1) Commission Implementing Regulation (EU) 2020/2236 (3) sets out the model animal health certificates for the entry into the Union and movements within the Union of consignments of aquatic animals and of certain products of animal origin from aquatic animals.

(2) In particular, Annex II to Implementing Regulation (EU) 2020/2236 sets out the model animal health certificate for the entry into the Union of consignments of aquatic animals intended for certain aquaculture establishments, for release into the wild or for other purposes, excluding direct human consumption (model ‘AQUA-ENTRY-ESTAB/RELEASE/OTHER’). Article 166 of Commission Delegated Regulation (EU) 2020/692 (4) was recently amended by Delegated Regulation (EU) 2023/119 (5) in order to permit aquatic animal health professionals to perform clinical

inspections on consignments of aquatic animals prior to export to the Union, provided they are authorised to do so under the law of the exporting third country or territory. Those new requirements for the entry into the Union of those consignments should be reflected in point II.3.2. of that model animal health certificate. Annex II to Implementing Regulation (EU) 2020/2236 should therefore be amended accordingly.

(3) In order to avoid any disruption to trade as regards the entry into the Union of consignments of aquatic animals intended for certain aquaculture establishments, for release into the wild or for other purposes, excluding direct human consumption, the use of animal health certificate issued in accordance with Implementing Regulation (EU) 2020/2236, as applicable prior to the amendments made by this Implementing Regulation, should continue to be authorised during a transitional period subject to certain conditions.

(4) As Implementing Regulation (EU) 2020/2236 applies from 21 April 2021, in the interest of legal certainty and to facilitate trade, the amendments to be made to Implementing Regulation (EU) 2020/2236 by this Regulation should take effect as a matter of urgency.

(5) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

Article 1
Annex II to Implementing Regulation (EU) 2020/2236 is amended in accordance with the Annex to this Regulation.

Article 2
For a transitional period until 15 December 2023, consignments of aquatic animals intended for certain aquaculture establishments, for release into the wild or for other purposes, excluding direct human consumption, accompanied by the animal health certificate issued in accordance with the model set out in Annex II to Implementing Regulation (EU) 2020/2236, as applicable before the amendments made to that Implementing Regulation by this Implementing Regulation, shall continue to be authorised for entry into the Union provided that the certificate was issued no later than 15 September 2023.

Article 3
This Regulation shall enter into force on the day following that of its publication in the Official Journal of the European Union.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 8 March 2023.

For the Commission
The President
Ursula VON DER LEYEN
ANNEX

Annex II to Implementing Regulation (EU) 2020/2236 is replaced by the following:

ANNEX II

Annex II contains the following model animal health certificate:

Model

| AQUA-ENTRY-ESTAB/RELEASE/OTHER | 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 direct human consumption |
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 DIRECT HUMAN CONSUMPTION (MODEL 'AQUA-ENTRY-ESTAB/RELEASE/OTHER')

<table>
<thead>
<tr>
<th>COUNTRY</th>
<th>Animal health certificate to the EU</th>
</tr>
</thead>
</table>
| 1.1 Consignor/Exporter | L.1 Certificate reference
Name  | L.2a IMSOC reference
Address | ISO country code |
Country | |
| 1.5 Consignee/Importer | L.6 Operator responsible for the consignment
Name  | Name
Address | Address
Country | Country ISO country code |
| 1.7 Country of origin | ISO country code |
| 1.9 Country of destination | ISO country code |
| 1.8 Region of origin | Code |
| 1.10 Region of destination | Code |
| 1.11 Place of dispatch | L.12 Place of destination
Name | Name Registration/Approval No
Address | Address
Country | Country ISO country code |
| 1.13 Place of loading | |
| 1.14 Date and time of departure | |
| 1.15 Means of transport | L.16 Entry Border Control Post
☐ Aircraft ☐ Vessel |
☐ Railway ☐ Road vehicle |
Identification |
| L.17 Accompanying documents |
Type Code |
Country ISO country code |
Commercial document reference |
| 1.18 Transport conditions | ☐ Ambient ☐ Chilled ☐ Frozen |
| 1.19 Container number/Seal number | |
Container No Seal No |
| 1.20 Certified as or for |
☐ Further keeping ☐ Confined establishment ☐ Release into the wild |
☐ Quarantine establishment ☐ Other ☐ Ornamental aquaculture establishment |
☐ Relaying area |
<p>| 1.21 ☐ For transit | L.22 ☐ For internal market |
| Third country | ISO country code |
| 1.23 | |</p>
<table>
<thead>
<tr>
<th>Column 1.24</th>
<th>Column 1.25</th>
<th>Column 1.26</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Total number of packages</strong></td>
<td><strong>Total quantity</strong></td>
<td><strong>Total net weight/gross weight (kg)</strong></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Column 1.27</th>
<th>Column 1.28</th>
<th>Column 1.29</th>
<th>Column 1.30</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Description of consignment</strong></td>
<td><strong>Species</strong></td>
<td><strong>Subspecies/Category</strong></td>
<td><strong>Nature of commodity</strong></td>
</tr>
<tr>
<td><strong>Type of packaging</strong></td>
<td><strong>Age</strong></td>
<td><strong>Quantity</strong></td>
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<thead>
<tr>
<th>Column 1.31</th>
<th>Column 1.32</th>
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<tbody>
<tr>
<td><strong>Number of packages</strong></td>
<td><strong>Net weight</strong></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Column 1.33</th>
<th>Column 1.34</th>
</tr>
</thead>
<tbody>
<tr>
<td>Approval or registration number of establishment</td>
<td></td>
</tr>
</tbody>
</table>
II. Health information

<table>
<thead>
<tr>
<th>Certificate model</th>
<th>AQUA-ENTRY-ESTAB/RELEASE/OTHER</th>
</tr>
</thead>
<tbody>
<tr>
<td>II.a Certificate reference</td>
<td>II.b IMSOC reference</td>
</tr>
</tbody>
</table>

I, the undersigned official veterinarian, hereby certify:

II.1. According to official information, the aquatic animals of the consignment described in Box I.27 meet the following animal health requirements:

II.1.1. The aquatic animals originate from [an establishment] [(1)] [a habitat] [(1)] which is not subject to national restriction measures for animal health reasons or because of the occurrence of abnormal mortalities with an undetermined cause, including the listed diseases referred to in Annex I to Commission Delegated Regulation (EU) 2020/692 [(1) relevant for the species and emerging diseases.

II.1.2. The aquatic animals are not intended to be killed under a national programme for the eradication of diseases, including the listed diseases referred to in Annex I to Delegated Regulation (EU) 2020/692 relevant for the species and emerging diseases.

(1) II.2. The aquaculture animals of the consignment described in Box I.27 meet the following requirements:

II.2.1. They come from an aquaculture establishment which is [registered] [(1)] [approved] [(1)] by, and under the control of, the competent authority of the third country or territory of origin and has a system in place to maintain and to keep for a period of at least three years, up-to-date records containing information regarding:

(i) the species, categories and number of aquaculture animals on the aquaculture farm;

(ii) movements of aquatic animals into, and aquaculture animals out of, the aquaculture farm;

(iii) mortality in the aquaculture farm.

II.2.2. They come from an aquaculture establishment which receives regular animal health visits from a veterinarian for the purpose of the detection of, and information on, signs indicative of the listed diseases referred to in Annex I to Delegated Regulation (EU) 2020/692 relevant for the species and of emerging diseases, at a frequency that is proportionate to the risk posed by the aquaculture establishment.

II.3. General health requirements

The aquatic animals of the consignment described in Box I.27 meet the following animal health requirements:

II.3.1. The aquatic animals originate from a [country] [(1)] [territory] [(1)], [zone] [(1)] [compartment] [(1)] with code: ___ ___ ___ [(2)] which, at the date of issuing this animal health certificate is listed in Part 1 of Annex XXI to Commission Implementing Regulation (EU) 2021/404 [(1) for the entry into the Union of certain species of aquatic animals.

II.3.2. They have undergone clinical inspection in accordance with Article 166 of Delegated Regulation (EU) 2020/692 within a period of 72 hours prior to the time of loading. During the inspection, the aquatic animals showed no clinical symptoms of transmissible disease and, according to the relevant records of the aquaculture establishment, there was no indication of disease problems.

II.3.3. They will be dispatched to the Union directly from the establishment of origin.

II.3.4. They have not been in contact with aquatic animals of a lower health status.

(1) either

II.4. Specific health requirements

[End of text]
### [II.4.1](#) Requirements for listed (3) species for Epizootic haemato poetic necrosis, Infection with *Mikrocysts mackini*, Infection with *Perkinsus marinus*, Infection with Taura syndrome virus and Infection with yellow head virus

The aquatic animals of the consignment described in Box I.27 originate from a [country] (1) [territory] (1) [zone] (1) [compartment] (1) declared free from [Epizootic haematopoietic necrosis] (1) [Infection with *Mikrocysts mackini*] (1) [Infection with *Perkinsus marinus*] (1) [Infection with Taura syndrome virus] (1) [Infection with yellow head virus] (1) in accordance with conditions which are at least as stringent as those set out in Article 66 or in Article 73(1) and Article 73(2), point (a), of Commission Delegated Regulation (EU) 2020/689 and where all listed (3) species for the relevant disease(s):

(i) are introduced from another country or territory, or zone or compartment thereof which has been declared free from the same disease(s);

(ii) are not vaccinated against [that] (1) [those] (1) disease(s).

### [II.4.2](#) Requirements for listed (3) species for Viral haemorrhagic septicemia (VHS), Infectious haematopoietic necrosis (IHN), infection with HPR-deleted infectious salmon anaemia virus (ISAV), infection with *Martelia refringens*, infection with *Bonamia exitiosa*, infection with *Bonamia ostreae*, and infection with White spot syndrome virus

The aquatic animals of the consignment described in Box I.27 originate from a [country] (1) [territory] (1) [zone] (1) [compartment] (1) declared free from [Viral haemorrhagic septicemia (VHS)] (1) [Infectious haematopoietic necrosis (IHN)] (1) [infection with HPR-deleted infectious salmon anaemia virus (ISAV)] (1) [infection with *Martelia refringens*] (1) [infection with *Bonamia exitiosa*] (1) [infection with *Bonamia ostreae*] (1) [infection with White spot syndrome virus] (1) in accordance with Part II, Chapter 4, of Delegated Regulation (EU) 2020/689 and where all listed (3) species for the relevant disease(s):

(i) are introduced from another country or territory, or zone or compartment thereof which has been declared free from the same disease(s);

(ii) are not vaccinated against [that] (1) [those] (1) disease(s).

### [II.4.3](#) Requirements for species (3) susceptible to infection with Spring viraemia of carp virus (SVC), Bacterial Kidney disease (BKD), infection with Infectious pancreatic necrosis virus (IPN), infection with *Gyrodactylus salaris* (GS), infection with Salmonid alphavirus (SAV) infection with Ostreid herpes virus 1 μναρ (OshV-1 μναρ) and species (3) susceptible to Koi herpes virus disease

The aquatic animals of the consignment described in Box I.27 originate from a [country] (1) [territory] (1) [zone] (1) [compartment] (1) which fulfils the health guarantees as regards [SVC,] (1) [BKD,] (1) [IPN,] (1) [GS,] (1) [SAV,] (1) [OshV-1 μναρ,] (1) [KHV,] (1) which are necessary to comply with the national measures which apply in the Member State of destination in accordance with Article 175 of Delegated Regulation (EU) 2020/692, and for which the Member State or part thereof, is listed in [Annex I] (1) [Annex II] (1) to Commission Implementing Decision (EU) 2021/260.

### [II.4. Specific health requirements](#)

The aquatic animals of the consignment described in Box I.27 are aquatic animals destined for a confined establishment fulfilling the requirements of Article 9 of Commission Delegated Regulation (EU) 2020/691 where they are to be used for research purposes.
### II.4. Specific health requirements

The aquatic animals of the consignment described in Box I.27 are wild aquatic animals which, [have been subject to quarantine in an establishment approved for that purpose by the competent authority in the [country] [territory] of origin in accordance with Article 15 of Delegated Regulation (EU) 2020/691.] [will be subject to quarantine in an establishment which is approved for that purpose in accordance with Article 15 of Delegated Regulation (EU) 2020/691.]

II.5. To the best of my knowledge, and as declared by the operator, the aquatic animals of the consignment described in Box I.27 show no symptoms of disease and come from [an establishment] [a habitat] where:

(i) there were no abnormal mortalities with an undetermined cause; and

(ii) the aquatic animals have not been in contact with kept animals of listed species which did not comply with the requirements referred to in point II.1.

### II.6. Transport requirements

Arrangements have been made to transport the aquatic animals of the consignment described in Box I.27 in accordance with the requirements laid down in Articles 167 and 168 of Delegated Regulation (EU) 2020/692 and specifically that:

II.6.1. the aquatic animals are dispatched to the Union directly from the establishment of origin and are not unloaded from their container when transported by air, sea, railway or by road;

II.6.2. the water in which they are transported is not changed in a third country or territory, or zone, or compartment thereof which is not listed for entry into the Union of the particular species and category of aquatic animals;

II.6.3. the animals are not transported under conditions that jeopardise their health status, in particular:

(i) when the aquatic animals are transported in water, it does not alter their health status;

(ii) the means of transport and the containers are constructed in such a way that the health status of the aquatic animals is not jeopardised during transportation;

(iii) the [container] [well-boat] is previously unused or cleaned and disinfected, in accordance with a protocol and with products approved by the competent authority of the third country or territory of origin, prior to loading for dispatch to the Union;

II.6.4. from the time of loading at the establishment of origin until the time of arrival in the Union, the aquatic animals of the consignment described in Box I.27 are not transported in the same water or [container] [well-boat] together with aquatic animals which are of a lower health status or which are not intended for entry into the Union;

II.6.5. where a water exchange is necessary in a [country] [territory] [zone] [compartment] which is listed for entry into the Union of the particular species and category of aquatic animals, it only occurs [in the case of transport on land, at water exchange points approved by the competent authority of the third country or territory where the water exchange takes place] [in the case of transport by well-boat, at a distance which is at least 10 km from any aquaculture establishments which are located en-route from the place of origin to the place of destination in the Union].
## II.7. Labelling requirements

Arrangements have been made to identify and label the [means of transport] \(^{(1)}\) [containers] \(^{(1)}\) in accordance with Article 169(1) and (2) of Delegated Regulation (EU) 2020/692 and specifically that:

- **II.7.1.** the consignment is identified by [a legible and visible label on the exterior of the container] \(^{(1)}\) [an entry in the ships manifest when transported by well-boat.] \(^{(1)}\) which clearly links the consignment to this animal health certificate;

- **II.7.2.** the legible and visible label will contain at least the following information:
  
  (a) the number of containers in the consignment;

  (b) the name of the species present in each container;

  (c) the number of aquatic animals in each container for each of the species present;

  (d) the purpose for which the aquatic animals are intended.

## II.8. Validity of the animal health certificate

This animal health certificate is valid for a period of 10 days from the date of issuing. In the case of transport by waterway/sea of aquatic animals, this period of 10 days may be extended by the duration of the journey by waterway/sea.

### Notes

In accordance with the Agreement on the withdrawal of the United Kingdom of Great Britain and Northern Ireland from the European Union and the European Atomic Energy Community, and in particular Article 5(4) of the Protocol on Ireland/Northern Ireland in conjunction with Annex 2 to that Protocol, references to the Union in this animal health certificate include the United Kingdom in respect of Northern Ireland.

‘Aquatic animals’ are animals as defined in Article 4, point (3), of Regulation (EU) 2016/429.

‘Aquaculture animals’ are aquatic animals which are subject to aquaculture as defined in Article 4, point (7), of Regulation (EU) 2016/429.

This animal health certificate is intended for entry into the Union of aquatic animals for the purposes indicated in the title of the certificate, including when the Union is not the final destination of those animals.

This animal health certificate shall not be used for the entry into the Union of aquatic animals intended for human consumption in accordance with Regulation (EC) No 853/2004 of the European Parliament and of the Council \(^{1}\) and Commission Regulation (EC) No 2073/2005 \(^{1}\), including those animals which are intended for the following aquaculture establishments:

(i) a disease control aquatic food establishment as defined in Article 4, point (52), of Regulation (EU) 2016/429, or

(ii) a dispatch centre as defined in Article 2, point (3), of Delegated Regulation (EU) 2020/691.

For those aquatic animals, the model certificate FISH-CRUST-HC as set out in Chapter 28 of Annex III to Commission Implementing Regulation (EU) 2020/2235 \(^{5}\), or MOL-HC as set out in Chapter 31 of Annex III to that Regulation, must be used, as relevant.

This animal health certificate shall be completed in accordance with the notes for the completion of certificates provided for in Chapter 4 of Annex I to Implementing Regulation (EU) 2020/2235.
### Part II:

1. Keep if appropriate/delete if not applicable. In the case of Part II.4.1., deletion is not permitted if the consignment contains listed species for Epizootic haematopoietic necrosis, Infection with *Mikrocytos mackini*, Infection with *Perkinsus marinus*, Infection with Taura syndrome virus or Infection with yellow head virus.

2. Code of the third country or territory, or zone or compartment thereof as it appears in column 2 of the table in Part I of Annex XXI to Implementing Regulation (EU) 2021/404.

3. Listed species as referred to in columns 3 and 4 of the table in the Annex to Commission Implementing Regulation (EU) 2018/1882. Vector species listed in column 4 of that table shall only be regarded as vectors if they fulfil the conditions set out in Annex XXX to Delegated Regulation (EU) 2020/692.

4. Applicable in all cases when aquatic animals are to be released into the wild in the Union or when the Member State of destination either has disease-free status for a category C disease as defined in Article 1, point (3), of Implementing Regulation (EU) 2018/1882 or is subject to an optional eradication programme established in accordance with Article 31(2) of Regulation (EU) 2016/429.

5. Only applicable when the Member State of destination of part thereof, has approved national measures for a specific disease as listed in Annex I or Annex II to Implementing Decision (EU) 2021/260, otherwise delete.


### Official veterinarian

Name (in capital letters)

<table>
<thead>
<tr>
<th>Date</th>
<th>Qualification and title</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stamp</td>
<td>Signature</td>
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