Official Journal
of the European Union

EN
L series

2026/1305

12.6.2026

COMMISSION IMPLEMENTING REGULATION (EU) 2026/1305

of 11 June 2026

amending Implementing Regulation (EU) 2020/1641 regarding imports of live, chilled, frozen or processed bivalve molluscs, echinoderms, tunicates and marine gastropods for human consumption from the United States of America

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products, amending Regulations (EC) No 999/2001, (EC) No 396/2005, (EC) No 1069/2009, (EC) No 1107/2009, (EU) No 1151/2012, (EU) No 652/2014, (EU) 2016/429 and (EU) 2016/2031 of the European Parliament and of the Council, Council Regulations (EC) No 1/2005 and (EC) No 1099/2009 and Council Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC and 2008/120/EC, and repealing Regulations (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council, Council Directives 89/608/EEC, 89/662/EEC, 90/425/EEC, 91/496/EEC, 96/23/EC, 96/93/EC and 97/78/EC and Council Decision 92/438/EEC (Official Controls Regulation) ([1]), and in particular Article 126(3) and Article 129(1) thereof,

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') ([2]), and in particular Article 238(3) thereof,

Whereas:

(1) Commission Implementing Regulation (EU) 2020/1641 ([3]) establishes rules and a model certificate for imports into the Union of live, chilled, frozen or processed bivalve molluscs, echinoderms, tunicates and marine gastropods intended for human consumption from the United States.

(2) Article 118(1) read in combination with Article 107(2) of Regulation (EU) 2019/6 of the European Parliament and of the Council ([4]) establishes that operators in third countries are not to use antimicrobial medicinal products in animals to promote growth or increase yield. From Article 118(1) of Regulation (EU) 2019/6 it follows that also medicinal products containing antimicrobials that are included in the list of antimicrobials reserved for the treatment of certain infections in humans laid down in Commission Implementing Regulation (EU) 2022/1255 ([5]) are not to be used in respect of animals or products of animal origin, exported from third countries to the Union.

([1]) OJ L 95, 7.4.2017, p. 1, ELI: http://data.europa.eu/eli/reg/2017/625/oj.
([2]) OJ L 84, 31.3.2016, p. 1, ELI: http://data.europa.eu/eli/reg/2016/429/oj.
([3]) Commission Implementing Regulation (EU) 2020/1641 of 5 November 2020 regarding imports of live, chilled, frozen or processed bivalve molluscs, echinoderms, tunicates and marine gastropods for human consumption from the United States of America (OJ L 370, 6.11.2020, p. 4, ELI: http://data.europa.eu/eli/reg_impl/2020/1641/oj).
([4]) Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products and repealing Directive 2001/82/EC (OJ L 4, 7.1.2019, p. 43, ELI: http://data.europa.eu/eli/reg/2019/6/oj).
([5]) Commission Implementing Regulation (EU) 2022/1255 of 19 July 2022 designating antimicrobials or groups of antimicrobials reserved for treatment of certain infections in humans, in accordance with Regulation (EU) 2019/6 of the European Parliament and of the Council (OJ L 191, 20.7.2022, p. 58, ELI: http://data.europa.eu/eli/reg_impl/2022/1255/oj).

(3) Commission Delegated Regulation (EU) 2023/905 [6] supplements Regulation (EU) 2019/6 by establishing conditions for the entry into the Union of consignments of live food-producing animals and products of animal origin intended for human consumption that are exported from third countries to the Union.

(4) Article 4 of Delegated Regulation (EU) 2023/905 requires among others that consignments of live food-producing animals and products of animal origin intended for human consumption are to only enter the Union where they are accompanied by an official certificate attesting compliance with the Union rules on the use of antimicrobial medicinal products laid down in Article 3 of the same delegated Regulation.

(5) An attestation concerning compliance with these Union rules should therefore be inserted in the model certificate set out in the Annex to Implementing Regulation (EU) 2020/1641.

(6) In the interests of clarity and consistency of Union rules, the model certificate set out in the Annex to Implementing Regulation (EU) 2020/1641 should be updated, including updating references, notes and structural elements, and be replaced by the model certificate set out in the Annex to this Regulation.

(7) Implementing Regulation (EU) 2020/1641 should therefore be amended accordingly.

(8) In order to avoid any disruption to trade as regards the entry into the Union of consignments of live, chilled, frozen or processed bivalve molluscs, echinoderms, tunicates and marine gastropods intended for human consumption from the United States due to the amendments made to the Annex to Implementing Regulation (EU) 2020/1641 by this Regulation, the use of official certificates issued in accordance with Implementing Regulation (EU) 2020/1641 as applicable prior to the amendments made by this Regulation, should continue to be authorised during a transitional period, subject to certain conditions.

(9) 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

The Annex to Implementing Regulation (EU) 2020/1641 is replaced by the text set out in the Annex to this Regulation.

Article 2

For a transitional period until 3 December 2026, the use of official certificates issued in accordance with the model set out in the Annex to Implementing Regulation (EU) 2020/1641, as applicable before the amendments made to that Regulation by the this Regulation, shall continue to be authorised for the entry into the Union of consignments of live, chilled, frozen or processed bivalve molluscs, echinoderms, tunicates and marine gastropods for human consumption from the USA provided that those certificates were issued no later than 3 September 2026.

[6] Commission Delegated Regulation (EU) 2023/905 of 27 February 2023 supplementing Regulation (EU) 2019/6 of the European Parliament and of the Council as regards the application of the prohibition of use of certain antimicrobial medicinal products in animals or products of animal origin exported from third countries into the Union (OJ L 116, 4.5.2023, p. 1, ELI: http://data.europa.eu/eli/reg_del/2023/905/oj).

Article 3

This Regulation shall enter into force on the twentieth 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, 11 June 2026.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

‘*ANNEX*

MODEL ANIMAL HEALTH/OFFICIAL CERTIFICATE FOR THE ENTRY INTO THE UNION OF LIVE BIVALVE MOLLUSCS, ECHINODERMS, TUNICATES AND MARINE GASTROPODS AND PRODUCTS OF ANIMAL ORIGIN FROM THOSE ANIMALS INTENDED FOR HUMAN CONSUMPTION FROM THE UNITED STATES OF AMERICA

<table>
<tr><td colspan="3">COUNTRY</td><td colspan="4">Animal health/official certificate to the EU</td></tr>
<tr><td rowspan="9">Part I: Description of consignment</td><td>I.1</td><td>Consignor/Exporter
Name
Address
Country ISO country code</td><td>I.2</td><td>Certificate reference</td><td>I.2a</td><td>IMSOC reference</td></tr>
<tr><td></td><td></td><td>I.3</td><td>Central Competent Authority</td><td colspan="2" rowspan="2">QR CODE</td></tr>
<tr><td></td><td></td><td>I.4</td><td>Local Competent Authority</td></tr>
<tr><td>I.5</td><td>Consignee/Importer
Name
Address
Country ISO country code</td><td>I.6</td><td colspan="3">Operator responsible for the consignment
Name
Address
Country ISO country code</td></tr>
<tr><td>I.7</td><td>Country of origin ISO country code</td><td>I.9</td><td>Country of destination</td><td colspan="2">ISO country code</td></tr>
<tr><td>I.8</td><td>Region of origin Code</td><td>I.10</td><td>Region of destination</td><td colspan="2">Code</td></tr>
<tr><td>I.11</td><td>Place of dispatch
Name Registration/Approval No
Address
Country ISO country code</td><td>I.12</td><td colspan="3">Place of destination
Name Registration/Approval No
Address
Country ISO country code</td></tr>
<tr><td>I.13</td><td>Place of loading</td><td>I.14</td><td colspan="3">Date and time of departure</td></tr>
<tr><td></td><td>I.15</td><td>Means of transport
☐ Aircraft ☐ Vessel
☐ Railway ☐ Road vehicle
Identification</td><td>I.16</td><td colspan="3">Entry Border Control Post</td></tr>
<tr><td></td><td></td><td></td><td>I.17</td><td colspan="3">Accompanying documents
Type Code
Country ISO country code
Commercial document reference</td></tr>
<tr><td></td><td>I.18</td><td>Transport conditions</td><td colspan="2">☐ Ambient</td><td>☐ Chilled</td><td>☐ Frozen</td></tr>
<tr><td></td><td>I.19</td><td colspan="5">Container number/Seal number
Container No Seal No</td></tr>
</table>

I.20	**Certified as or for**			
	☐ Products for human consumption	☐ Live aquatic animals for human consumption	☐ Dispatch centre	☐ Further processing

I.21	☐ **For transit**	I.22	☐ **For internal market**
	Third country ISO country code	I.23	

I.24	**Total number of packages**	I.25	**Total quantity**	I.26	**Total net weight/gross weight (kg)**

I.27	**Description of consignment**			
CN code	Species			
	Cold store		Type of packaging	Net weight
	Treatment type	Nature of commodity	Number of packages	Batch No
☐ Final consumer	Date of collection/production	Manufacturing plant		

COUNTRY **Certificate model US-LBM-HC**

Part II: Certification

II. **Health information**	II.a **Certificate reference**	II.b **IMSOC reference**

II.1. **Public health attestation**

I, the undersigned hereby certify that:

II.1.1. The herein described products comply with and were produced in accordance with relevant US standards and requirements of the US molluscan shellfish regulatory control program.

II.1.2. The herein described products are labelled as not destined to be immersed or in contact with any Union's water.

II.1.3. All foreign-sourced shellfish material used in these products originates from third countries or regions thereof listed in Annex VIII to Commission Implementing Regulation (EU) 2021/405 and from establishments/growing areas authorised for entry into the Union of consignments of live, chilled, frozen or processed bivalve molluscs, echinoderms, tunicates and marine gastropods.

([1]) ([7]) II.2. **Attestation as regards Commission Delegated Regulation (EU) 2023/905**

I, the undersigned, declare that I am aware of the relevant requirements of Regulation (EU) 2019/6 of the European Parliament and of the Council and Delegated Regulation (EU) 2023/905 and hereby certify that the [live bivalve molluscs] ([1]) [live echinoderms] ([1]) [live tunicates] ([1]) [live marine gastropods] ([1]) of on-land aquaculture origin and the products of animal origin derived therefrom described in Part I were produced in accordance with these requirements, and in particular, that the aquaculture animals from which the products have been derived have not been administered antimicrobial medicinal products for growth promotion or yield increase or antimicrobial medicinal products containing an antimicrobial that is included in the list of antimicrobials reserved for the treatment of certain infections in humans laid down in Commission Implementing Regulation (EU) 2022/1255 as set out in Article 3 of Delegated Regulation (EU) 2023/905 and originate from a third country or region thereof listed in the Annex to Commission Implementing Regulation (EU) 2024/2598 ([8]).

([2]) ([3]) [II.3. **Animal health attestation for live bivalve molluscs** ([4]) **of listed species intended for human consumption**

I, the undersigned official veterinarian, hereby certify that the aquatic animals referred to in box I.27 of Part I meet:

II.3.1. the general animal health requirements for entry into the Union, which are set out in Article 6(1), in points (a) ([5]), and (b), Article 6(2) and Article 7(1) and Article 8 of Commission Delegated Regulation (EU) 2020/692;

II.3.2. the specific animal health requirements for entry into the Union of the commodities to which this certificate applies, which are set out in Article 167, points (a), (c)(ii), (c)(iii) and (d), and Article 169(1) and (2) of Delegated Regulation (EU) 2020/692.]

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 Windsor Framework (see Joint Declaration No 1/2023 of the Union and the United Kingdom in the Joint Committee established by 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 of 24 March 2023 (OJ L 102, 17.4.2023, p. 87)) in conjunction with Annex 2 to that Framework, references to the Union in this animal health/official certificate include the United Kingdom in respect of Northern Ireland.

COUNTRY **Certificate model US-LBM-HC**

Part I:

Box reference I.8: Region of origin: Indicate a state of US harvest and a code of approved production area.

Part II:

([1]) Keep if appropriate/delete if not applicable.

([2]) Part II.3. of this animal health/official certificate applies only to the following commodities of live bivalve molluscs intended for human consumption:

(a) molluscs of listed species transported without water which are packaged and labelled for human consumption in accordance with the specific requirements for those animals as set out in Regulation (EC) No 853/2004 of the European Parliament and of the Council and which are no longer able to survive as living animals if returned to the aquatic environment;

(b) molluscs of listed species transported without water which are intended for human consumption without further processing, provided they are packaged for retail sale in compliance with the requirements for such packaging as set out in Regulation (EC) No 853/2004;

(c) molluscs of listed species transported without water which are packaged and labelled for human consumption in accordance with the specific requirements for those animals as set out in Regulation (EC) No 853/2004 and which are intended for further processing without temporary storage at the place of processing.

([3]) Part II.3 of this animal health/official certificate does not apply and shall be deleted when the consignment consists of wild aquatic animals which are landed from fishing vessels.

([4]) Species listed in columns 3 and 4 of the table in the Annex to Commission Implementing Regulation (EU) 2018/1882. Species listed in column 4 of that table shall only be regarded as vectors under the conditions set out in Article 171(1) of Delegated Regulation (EU) 2020/692.

([5]) Where disease is relevant and reportable.

([6]) To be signed by:

— an official veterinarian when the animal health attestation of Part II.3 is completed,

— a certifying officer or an official veterinarian when the animal health attestation in Part II.3 is deleted.

([7]) Applicable to consignments entering the Union as from 3 September 2026.

([8]) Or listed in other implementing acts adopted in accordance with Article 5 of Delegated Regulation (EU) 2023/905.

[Official veterinarian] ([1]) ([6])/**[Certifying officer]** ([1]) ([6])

Name (in capital letters)

Date Qualification and title

Stamp Signature’