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 (Text with EEA relevance)

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

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

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 129(1) thereof,

Whereas:

(1) Regulation (EU) 2017/625 lays down general rules for the performance of official controls to verify compliance with rules aimed at preventing, eliminating or reducing to acceptable levels risks to humans and animals, either directly or through the environment.

(2) In particular, Regulation (EU) 2017/625 lays down general conditions for the entry into the Union of animals and goods from third countries or regions thereof, including food intended for human consumption. Article 129 of Regulation (EU) 2017/625 empowers the Commission to recognise that measures applied by third countries, or regions thereof, are equivalent to the requirements laid down in certain rules referred to in Article 1(2) of that Regulation, if the third countries offer objective proof in this respect. It also empowers the Commission to set out the conditions governing the entry into the Union of such animals and goods from such third countries or regions thereof, in particular with regard to the nature and content of the official certificates or attestations that are to accompany those commodities.

Changes to legislation: *There are outstanding changes not yet made to Commission Implementing Regulation (EU) 2020/1641. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes*

(3) Council Decision 98/258/EC[(2)] approves the Agreement between the European Community and the United States of America on sanitary measures to protect public and animal health in trade in live animals and animal products, with the objective to facilitate trade, inter alia, by establishing a mechanism for the recognition of equivalence of sanitary measures. Live, chilled, frozen or processed bivalve molluscs, echinoderms, tunicates and marine gastropods for human consumption fall within the scope of this Agreement (Annex I 'Product coverage').

(4) Union controls in the United States were carried out from 17 to 27 March 2015 to evaluate the control system in place governing the production of bivalve molluscs and fishery products derived therefrom intended for export to the Union (Union controls). In the context of those controls, the United States authorities provided information about sanitary rules applicable to bivalve molluscs, echinoderms, tunicates and marine gastropods within their territory, risk-assessment procedures and factors taken into consideration for the assessment of risks and for the determination of the appropriate level of sanitary protection as regards those goods and control, inspection procedures, and official certification mechanisms.

(5) Echinoderms, tunicates and marine gastropods are subject to the hygiene rules applicable to live, chilled and frozen bivalve molluscs set out in Regulation (EC) No 853/2004 of the European Parliament and of the Council[(3)] according to its Annex III, Section VII, point 1. Accordingly, the finding as regards live bivalve molluscs in the context of the Union controls apply to echinoderms, tunicates and marine gastropods.

(6) Commission Implementing Regulation (EU) 2019/626[(4)] establishes the lists of third countries or regions thereof from which consignments of certain animals and goods intended for human consumption shall be authorised for entry into the Union from food safety perspective, in accordance with Article 126(2)(a) of Regulation (EU) 2017/625, which requires the compliance with the relevant requirements established by the rules referred to in its Article 1(2) or with requirements recognised to be at least equivalent thereto. Implementing Regulation (EU) 2019/626 provides that consignments of live chilled, frozen or processed bivalve molluscs, echinoderms, tunicates and marine gastropods intended for human consumption shall only be authorised for the entry into the Union if they come from third countries or regions thereof that are listed in its Annex I. States of Massachusetts and Washington of the United States appear on that list.

(7) The Union controls, the subsequent assurances provided by the United States and Implementing Regulation (EU) 2019/626 give grounds to establish that the measures applied in the States of Massachusetts and Washington of the United States for the protection of public health in relation to the production and placing on the market of live, chilled, frozen or processed bivalve molluscs, echinoderms, tunicates and marine gastropods for human consumption are equivalent to the requirements laid down in rules as regards food safety referred to in Article 1(2) of Regulation (EU) 2017/625.

(8) To enable the entry into the Union of live, chilled, frozen or processed bivalve molluscs, echinoderms, tunicates and marine gastropods intended for human consumption it is necessary to establish an official model certificate for imports of live, chilled, frozen or processed bivalve molluscs, echinoderms, tunicates and marine gastropods intended

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for human consumption from the United States of America, which requires to certify that the measures applied to the production and placing on the market of those goods are equivalent to the requirements laid down in rules as regards food safety referred to in Article 1(2) of Regulation (EU) 2017/625.

(9) When laying down requirements for the entry into the Union of consignments of certain animals and goods intended for human consumption, reference should be made to the Combined Nomenclature codes in accordance with Council Regulation (EEC) No 2658/87[(5)], which lays down codes for live, chilled, frozen or processed bivalve molluscs, echinoderms, tunicates and marine gastropods for human consumption.

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

HAS ADOPTED THIS REGULATION:

Article 1

Subject matter and scope

This Regulation lays down rules concerning 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 States of Massachusetts and Washington of the United States.

Article 2

Definition

For the purpose of this Regulation, the following definition shall apply:

‘Bivalve molluscs’ means bivalve molluscs as defined in point 2.1 of Annex I to Regulation (EC) No 853/2004.

Article 3

Equivalence

The measures applied in the States of Massachusetts and Washington of the United States for the protection of public health in relation to the production and placing on the market of live, chilled, frozen or processed bivalve molluscs, echinoderms, tunicates and marine gastropods for human consumption for which the Combined Nomenclature codes have been laid down in Part Two of Annex I to Regulation (EEC) No 2658/87 are equivalent to the requirements laid down in the rules referred to in Article 1(2)(a) of Regulation (EU) 2017/625.

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Article 4

Official certificate

Each consignment of live, chilled, frozen or processed bivalve molluscs, echinoderms, tunicates and marine gastropods intended for human consumption, as referred to Article 1, shall enter the Union only if they are accompanied by an official certificate duly completed in accordance with the model set out in the Annex.

Article 5

Entry into force

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, 5 November 2020.

For the Commission

The President

Ursula VON DER LEYEN