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SANTE/11414/2021 feedback
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[...] (2022) **XXX** draft

COMMISSION IMPLEMENTING REGULATION (EU) .../...

of **XXX**

amending and correcting Implementing Regulation (EU) 2019/627 as regards practical arrangements for the performance of official controls in live bivalve molluscs, fishery products, or related to UV-radiation

This draft has not been adopted or endorsed by the European Commission. Any views expressed are the preliminary views of the Commission services and may not in any circumstances be regarded as stating an official position of the Commission.

COMMISSION IMPLEMENTING REGULATION (EU) .../...

of **XXX**

amending and correcting Implementing Regulation (EU) 2019/627 as regards practical arrangements for the performance of official controls in live bivalve molluscs, fishery products, or related to UV-radiation

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 18(8) thereof,

Whereas:

- (1) Regulation (EU) 2017/625 lays down rules for the official controls and other official activities performed by the competent authorities of the Member States to verify compliance with Union legislation, inter alia, in the area of food safety at all stages of production, processing and distribution. In particular, it provides for official controls in relation to products of animal origin intended for human consumption.
- (2) Commission Implementing Regulation (EU) 2019/627² lays down uniform practical arrangements for the performance of official controls on products of animal origin intended for human consumption in accordance with Regulation (EU) 2017/625.
- (3) Article 10 of Implementing Regulation (EU) 2019/627 lays down obligations for the official veterinarian as regards checks of documents, in particular to take into account official certificates provided for in Commission Implementing Regulation (EU) 2019/628³. However, reference is made to the wrong certificate, and that reference should therefore be corrected. Since Implementing Regulation (EU) 2019/628 has been repealed and the certificates replaced by those in Commission Implementing

¹ OJ L 95, 7.4.2017, p. 1.

² Commission Implementing Regulation (EU) 2019/627 of 15 March 2019 laying down uniform practical arrangements for the performance of official controls on products of animal origin intended for human consumption in accordance with Regulation (EU) 2017/625 of the European Parliament and of the Council and amending Commission Regulation (EC) No 2074/2005 as regards official controls (OJ L 131, 17.5.2019, p. 51).

³ Commission Implementing Regulation (EU) 2019/628 of 8 April 2019 concerning model official certificates for certain animals and goods and amending Regulation (EC) No 2074/2005 and Implementing Regulation (EU) 2016/759 as regards these model certificates (OJ L 131, 17.5.2019, p. 101).

Regulation (EU) 2020/2235⁴, it is also appropriate to replace to replace all references to Implementing Regulation (EU) 2019/628 by the correct references in Implementing Regulation (EU) 2020/2235.

- (4) Article 45, point (1), of Implementing Regulation (EU) 2019/627 lays down that fresh meat is to be declared unfit for human consumption if it has been treated illegally with ionising radiation, including UV-radiation. Most UV-radiation is not to be considered as ionising radiation as defined in Article 4, point (46), of Council Directive 2013/59/Euratom⁵, Article 45, point (1), of Implementing Regulation (EU) 2019/627 should therefore be amended.
- (5) The specific requirements for official controls concerning live bivalve molluscs from classified production areas and relaying areas do not apply to live *Holothuroidea* that are not filter feeders, in accordance with Article 51 of Implementing Regulation (EU) 2019/627.
- (6) Regulation (EU) 2021/1756 of the European Parliament and of the Council⁶ amended Article 18 of Regulation (EU) 2017/625, extending to all echinoderms which are not filter feeders, and not only to Holothuroidea, the possibility to derogate from the requirement to classify the production and relaying areas, laid down in Article 18(7), point (g), of Regulation (EU) 2017/625. In addition, based on Article 18(7)(g) of Regulation (EU) 2017/625, Commission Delegated Regulation [SANTE/11310/2021]⁷ amended Article 11 of Commission Delegated Regulation (EU) 2019/624, whereby the classification of production and relaying areas is not required in relation to the harvesting of echinoderms which are not filter feeders. Consequently, Article 51 of Implementing Regulation (EU) 2019/627 should be amended accordingly.
- (7) Article 71 of Implementing Regulation (EU) 2019/627 lays down rules concerning the decisions that the competent authorities can take after controls on fishery products. Point (a) of that Article mistakenly refers to Section VII instead of Section VIII on fishery products of Annex III to Regulation (EC) No 853/2004. For reasons of consistency, that reference in Article 71 of Implementing Regulation (EU) 2019/627 should be corrected.

⁴ Commission Implementing Regulation (EU) 2020/2235 of 16 December 2020 laying down rules for the application of Regulations (EU) 2016/429 and (EU) 2017/625 of the European Parliament and of the Council as regards model animal health certificates, model official certificates and model animal health/official certificates, for the entry into the Union and movements within the Union of consignments of certain categories of animals and goods, official certification regarding such certificates and repealing Regulation (EC) No 599/2004, Implementing Regulations (EU) No 636/2014 and (EU) 2019/628, Directive 98/68/EC and Decisions 2000/572/EC, 2003/779/EC and 2007/240/EC (OJ L 442, 30.12.2020, p. 1).

⁵ Council Directive 2013/59/Euratom of 5 December 2013 laying down basic safety standards for protection against the dangers arising from exposure to ionising radiation, and repealing Directives 89/618/Euratom, 90/641/Euratom, 96/29/Euratom, 97/43/Euratom and 2003/122/Euratom (OJ L 13, 17.1.2014, p. 1).

⁶ Regulation (EU) 2021/1756 of the European Parliament and of the Council of 6 October 2021 amending Regulation (EU) 2017/625 as regards official controls on animals and products of animal origin exported from third countries to the Union in order to ensure compliance with the prohibition of certain uses of antimicrobials and Regulation (EC) No 853/2004 as regards the direct supply of meat from poultry and lagomorphs (OJ L 357, 8.10.2021, p. 27).

⁷ Commission Delegated Regulation (EU) .../...of XXX amending Annex III to Regulation (EC) No 853/2004 of the European Parliament and of the Council on specific hygiene requirements for food of animal origin as regards fishery products and certain highly refined products and Commission Delegated Regulation (EU) 2019/624 as regards certain bivalve molluscs [SANTE/11310/2021].

- (8) Annex VI to Implementing Regulation (EU) 2019/627 establishes practical arrangements for official controls on fishery products in accordance with Article 70 of that Implementing Regulation. In particular, it defines the analytical methods to be applied when the organoleptic examination gives rise to any doubt as to the freshness of the fishery products. In its scientific opinion⁸, EFSA identified methods capable of distinguishing between ‘superchilled’ fish and previously frozen fish commercially presented as ‘superchilled’. As those analytical methods should be added to Annex VI to Implementing Regulation (EU) 2019/627, that Annex should be amended.
- (9) Implementing Regulation (EU) 2019/627 should therefore be amended and corrected accordingly.
- (10) 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

Implementing Regulation (EU) 2019/627 is amended as follows:

- (1) In Article 10:
- (a) In point 2, ‘in accordance with Article 29 of Commission Implementing Regulation (EU) 2019/628⁽⁹⁾’ is replaced by ‘in accordance with Article 31 of Commission Implementing Regulation (EU) 2020/2235(*)’
- _____
- (*) COMMISSION IMPLEMENTING REGULATION (EU) 2020/2235 of 16 December 2020 laying down rules for the application of Regulations (EU) 2016/429 and (EU) 2017/625 of the European Parliament and of the Council as regards model animal health certificates, model official certificates and model animal health/official certificates, for the entry into the Union and movements within the Union of consignments of certain categories of animals and goods, official certification regarding such certificates and repealing Regulation (EC) No 599/2004, Implementing Regulations (EU) No 636/2014 and (EU) 2019/628, Directive 98/68/EC and Decisions 2000/572/EC, 2003/779/EC and 2007/240/EC (OJ L 442, 30.12.2020, p. 1);
- (b) In point 3, ‘in accordance with Article 29 of Commission Implementing Regulation (EU) 2019/628’ is replaced by ‘in accordance with Article 32 of Commission Implementing Regulation (EU) 2020/2235’
- (2) in Article 45, point (l) is replaced by the following:
- ‘(l) has been treated illegally with ionising radiation or UV-radiation;’;
- (3) Article 51 is replaced by the following:

‘Article 51

Exclusion

⁸ EFSA Journal 2021;19(1):6378.

This Title applies to live bivalve molluscs, live echinoderms, live tunicates and live marine gastropods. This Title does not apply to non filter feeder live marine gastropods and to non filter feeder live echinoderms.’;

- (4) in Article 71, point (a) is replaced by the following:
- ‘(a) official controls carried out in accordance with Article 70 reveal they are not in compliance with organoleptic, chemical, physical or microbiological requirements or requirements for parasites as established in Section VIII of Annex III to Regulation (EC) No 853/2004 or Regulation (EC) No 2073/2005;
- (5) in Article 72, point 1, ‘the model health certificate set out in Chapter B of Part II to Annex III to Implementing Regulation (EU) 2019/628.’ is replaced by ‘the model health certificate set out in Chapter 29 to Annex III to Implementing Regulation (EU) 2020/2235.’
- (6) in Annex VI, in Chapter I, in point B, ‘Freshness indicators’, the following paragraph is inserted between the first and the second paragraphs:
- ‘When the organoleptic examination gives rise to any doubt that previously frozen fish is commercially presented as fresh, samples may be taken for verification purposes and subjected to laboratory tests such as the Hydroxyacyl-coenzyme A dehydrogenase (HADH) test, , histology, ultraviolet–visible–near–infrared (UV-VIS/NIR) spectroscopy and hyperspectral imaging.’.

Article 2

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,

For the Commission
The President
Ursula VON DER LEYEN