COMMISSION IMPLEMENTING REGULATION (EU) 2021/1709

of 23 September 2021

amending Implementing Regulation (EU) 2019/627 as regards uniform practical arrangements for the performance of official controls on products of animal origin

(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 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) 2019/627 ([2]) lays down rules on the practical arrangements for the performance of official controls on products of animal origin in accordance with Article 18(8) of Regulation (EU) 2017/625.

(3) Since the date of application of Implementing Regulation (EU) 2019/627 on 14 December 2019, experiences on the practical implementation of this Regulation highlighted the need for more clarity of certain legal provisions, in particular with regard to certain practical arrangements for post-mortem inspection and recognised methods for detection of marine biotoxins in bivalve molluscs.

(4) As regards practical arrangements for post-mortem inspection, Implementing Regulation (EU) 2019/627 should not specify who is to carry out the additional practical arrangements for post-mortem inspection in case of a possible risk to human health, animal health or animal welfare. Whether the official veterinarian or the official auxiliary should carry out post-mortem inspection is already laid down in Article 18.2(c) of Regulation (EU) 2017/625, supplemented by Articles 7 and 8 of Commission Delegated Regulation (EU) 2019/624 ([3]) and is therefore not required in Implementing Regulation (EU) 2019/627. In addition, a duplication of the requirement for an incision of the bronchial and mediastinal lymph nodes in Article 19(1)(b) and (2)(b) should be avoided.

([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 Delegated Regulation (EU) 2019/624 of 8 February 2019 concerning specific rules for the performances of official controls on the production of meat and relaying areas of live bivalve molluscs in accordance with Regulation (EU) 2017/625 of the European Parliament and of the Council (OJ L 131, 17.5.2019, p. 1).

(5) In addition, requirements for post-mortem inspection for farmed game contain duplications in particular with regard to requirements applicable to the family of *Suidae*. The requirements should be further clarified to facilitate implementation of the Regulation.

(6) Article 22 of Council Regulation (EC) No 1099/2009 ([4]) has been deleted from 14 December 2019 on by Regulation (EU) 2017/625. Measures in cases of noncompliance with the requirements for animal welfare, referred to in that Article were replaced by provisions in Article 138 of Regulation (EU) 2017/625. The reference to Article 22 of Regulation (EC) No 1099/2009 in Article 44(1) of Implementing Regulation (EU) 2019/627 should therefore be deleted accordingly.

(7) Article 48 of Implementing Regulation (EU) 2019/627 lays down conditions for health marking. These conditions are as already established in Commission Implementing Regulation (EU) 2015/1375 ([5]) in case of *Trichinella* testing, and in Regulation (EC) No 999/2001 of the European Parliament and of the Council ([6]) for the testing of transmissible spongiform encephalopathy (TSE). For reasons of clarity, it is appropriate to replace the wordings concerned in Article 48 of Implementing Regulation (EU) 2019/627 by references to the relevant Regulations.

(8) Article 4 of Directive 2010/63/EU of the European Parliament and of the Council ([7]) requires Member States to ensure that, wherever possible, a method not entailing the use of live animals is to be used. Taking into account that for the detection of Paralytic Shellfish Poisoning (PSP) toxins the Standard EN 14526 is available as an alternative method, complying with the conditions of Article 4 of Directive 2010/63/EU, the use of the mouse bioassay should therefore be discontinued.

(9) Live bivalve molluscs placed on the market are not to contain marine biotoxins that exceed the limits established in Annex III, Section VII, Chapter V (2) of Regulation (EC) No 853/2004 of the European Parliament and of the Council ([8]). Regarding Pectenotoxins (PTX), the European Food Safety Authority (EFSA) has concluded that there are no reports on adverse effects in humans associated with Pectenotoxins (PTX) group toxins ([9]). As PTX have been removed from the health standards for live bivalve molluscs in Commission Delegated Regulation (EU) 2021/1374 ([10]), it is therefore appropriate to remove them as well from the provisions of Implementing Regulation (EU) 2019/627.

(10) Fishery products derived from aquaculture are to be tested in accordance with Council Directive 96/23/EC ([11]) and Commission Decision 97/747/EC ([12]) as regards contaminants and pesticides. Wild caught fishery products should also be tested to establish compliance as regards contaminants in accordance with Commission Regulation (EC) No 1881/2006 ([13]). The current legislation should be modified accordingly.

(11) Implementing Regulation (EU) 2019/627 should be amended accordingly.

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

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([4]) Council Regulation (EC) No 1099/2009 of 24 September 2009 on the protection of animals at the time of killing (OJ L 303, 18.11.2009, p. 1).

([5]) Commission Implementing Regulation (EU) 2015/1375 of 10 August 2015 laying down specific rules on official controls for *Trichinella* in meat (OJ L 212, 11.8.2015, p. 7).

([6]) Regulation (EC) No 999/2001 of the European Parliament and of the Council of 22 May 2001 laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies (OJ L 147, 31.5.2001, p. 1).

([7]) Directive 2010/63/EU of the European Parliament and of the Council of 22 September 2010 on the protection of animals used for scientific purposes (OJ L 276, 20.10.2010, p. 33).

([8]) Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin (OJ L 139, 30.4.2004, p. 55)

([9]) https://doi.org/10.2903/j.efsa.2009.1109

([10]) Commission Delegated Regulation (EU) 2021/1374 of 12 April 2021 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 (OJ L 297, 20.8.2021, p. 1).

([11]) Council Directive 96/23/EC of 29 April 1996 on measures to monitor certain substances and residues thereof in live animals and animal products and repealing Directives 85/358/EEC and 86/469/EEC and Decisions 89/187/EEC and 91/664/EEC (OJ L 125, 23.5.1996, p. 10)

([12]) Commission Decision 97/747/EC of 27 October 1997 fixing the levels and frequencies of sampling provided for by Council Directive 96/23/EC for the monitoring of certain substances and residues thereof in certain animal products (OJ L 303, 6.11.1997, p. 12)

([13]) Commission Regulation (EC) No 1881/2006 of 19 December 2006 setting maximum levels for certain contaminants in foodstuffs (OJ L 364, 20.12.2006, p. 5)

HAS ADOPTED THIS REGULATION:

Article 1

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

(1) in Articles 18(3), 19(2), 20(2), 21(2), 22(2) and 23(2), the introductory sentence is replaced by the following:

'Post-mortem inspection procedures shall be carried out in accordance with Article 18(2)(c) of Regulation (EU) 2017/625 and Article 7 and 8 of Regulation (EU) 2019/624, using incision and palpation of the carcase and offal, when there are indications of a possible risk to human health, animal health or animal welfare indicated in accordance with Article 24:';

(2) in Article 19(2), point (b), the words 'an incision of the bronchial and mediastinal lymph nodes (*Lnn. bifurcationes, eparteriales and mediastinales*);' are deleted.

(3) in Article 24, the introductory sentence is replaced by the following:

'The additional post-mortem inspection procedures referred to in Articles 18(3), 19(2), 20(2), 21(2), 22(2) and 23(2) shall be carried out using incision and palpation of the carcase and offal, where, in the opinion of the official veterinarian, a possible risk to human health, animal health or animal welfare is indicated by one of the following:';

(4) In Article 27(1), point(c) is replaced by the following:

'(c) in the case of other game ungulates, not covered by points (a) and (b) the post-mortem procedures for bovine animals laid down in Article 19;';

(5) in Article 44, paragraph 1 is replaced by the following:

'1. In cases of non-compliance with the rules concerning the protection of animals at the time of slaughter or killing laid down in Articles 3 to 9 and Articles 14 to 17 and 19 of Regulation (EC) No 1099/2009, the official veterinarian shall verify that the food business operator immediately takes the necessary corrective measures and prevents recurrence.';

(6) in Article 48(2), point (a) is replaced by the following:

'(a) the health mark is applied only to domestic ungulates and farmed game mammals other than lagomorphs, having undergone ante-mortem and post-mortem inspection, and large wild game having undergone post mortem inspection, in accordance with Article 18(2)(a), (b) and (c) of Regulation (EU) 2017/625, where there are no grounds for declaring the meat unfit for human consumption. However, the mark may be applied before the results of any examination for *Trichinella* and/or TSE testing are available, in accordance with the provisions laid down respectively in Article 4(3) of Implementing Regulation (EU) 2015/1375 and in Chapter A of Annex III to Regulation (EC) No 999/2001, points 6.2 and 6.3 of point I and points 7.2 and 7.3 of point II.';

(7) Annex V is amended in accordance with the text set out in the Annex to this Regulation;

(8) Annex VI is amended in accordance with the text set out in the Annex to this Regulation.

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, 23 September 2021.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

Annex V and Annex VI to Implementing Regulation (EU) 2019/627 are amended as follows:

(1) in Annex V Chapter I is replaced by the following:

'CHAPTER I

PARALYTIC SHELLFISH POISON DETECTION METHOD

A. The paralytic shellfish poisoning (PSP) toxins content of the whole body or any part edible separately of bivalve molluscs shall be determined using the method described in the Standard EN 14526 (*) or any other internationally recognised validated method not entailing the use of a live animal.

B. The abovementioned methods shall determine at least the following compounds:

(a) Toxins Carbamate STX, NeoSTX, gonyautoxin 1 and 4 (GTX1 and GTX4 isomers determined together) and gonyautoxin 2 and 3 (GTX2 and GTX3 isomers determined together);

(b) Toxins N-sulfo-carbamoyl (B1), gonyautoxin-6 (B2), N-sulfocarbamoyl-gonyautoxin 1 and 2 (C1 and C2 isomers determined together), N-sulfocarbamoyl-gonyautoxin 3 and 4 (C3 and C4 isomers determined together);

(c) Toxins decarbamoyl dcSTX, dcNeoSTX, decarbamoylgonyautoxin-2 and -3 (isomers determined together).

B.1. If new analogues of the above toxins, for which a toxicity equivalent factor (TEF) has been established, appear, they shall be included in the analysis;

B.2. Total toxicity will be expressed in µg STX 2HCL equivalents/Kg and shall be calculated using TEFs as recommended in the most recent EFSA opinion or FAO OMS report, upon proposal of the European Reference Laboratory for marine biotoxins and its National Reference Laboratories network and acceptance by the European Commission. The TEFs used will be published in the European Reference Laboratory for marine biotoxins website (**);

C. If the results are challenged, the reference method shall be the method described in the Standard EN 14526 as referred in Part A.

(*) Determination of saxitoxin-group toxins in shellfish – HPLC method using pre-column derivatization with peroxide or periodate oxidation.

(**) http://www.aecosan.msssi.gob.es/en/CRLMB/web/home.html";

(2) in Annex V, Chapter III, point (b) of Part A is deleted;

(3) in Annex VI, Part D of Chapter I, a new paragraph is added at the end:

'For wild caught fishery products monitoring arrangements shall be established to control compliance with the EU legislation on contaminants, in accordance with Regulation (EC) No 1881/2006 setting maximum levels for certain contaminants in food'.