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SANTE/10426/2020  
[...] (2020) XXX draft

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

**of XXX**

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

(Text with EEA relevance)

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

**of XXX**

**amending Commission 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) 1107/2009, (EU) 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)<sup>1</sup>, and in particular Article 18(8) thereof,

After consulting the Standing Committee on Plants, Animals, Food and Feed,

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<sup>2</sup> 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 Regulation (EU) 2019/628 on 14 December 2019, experiences on the practical implementation of this Regulation highlighted to 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 fishery products.
- (4) As regards practical arrangements for post-mortem inspection, Implementing Regulation (EU) 2019/627 should not specify who should 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 laid down in Article 18.2(c) of Regulation (EU) 2017/625 and should be removed from Implementing Regulation (EU) 2019/627.
- (5) In addition, requirements for post-mortem inspection for farmed game of the family of *Suidae* create confusion due to a certain duplication of requirements and should therefore be clarified.
- (6) For clarity reasons, it is appropriate to use consistent wording as regards health marking before the results of any examination for *Trichinella* testing are available, between this Regulation and Regulation (EU) 2015/1375, both laying down provisions on this issue.

(7) Article 4 of Directive 2010/63/EU establishes that when a method alternative to the use of biological method is available, this method must be used. Taking into account that

<sup>1</sup> OJ L 95, 7.4.2017, p. 1.

<sup>2</sup> 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)

for the detection of Paralytic Shellfish Poison (PSP) toxins an alternative method is available the use of the mouse test shall be avoided;

- (8) Bivalve molluscs placed on the market must not contain marine biotoxins. Pectenotoxins (PTX) in shellfish are always accompanied by toxins from the Okadaic acid (OA) group. EFSA in its opinion concluded that because PTX-group toxins do not share the same mechanism of action as OA-group toxins they should not be included in the regulatory limit for OA-group toxins. EFSA moreover concluded that there are no reports on adverse effects in humans associated with PTX-group toxins. It is opportune to remove PTX from the list of marine biotoxins that should be tested in bivalve molluscs.

- (9) Wild caught fishery products should also be tested for establish the compliance with the EU rules as regard contaminants and pesticide residues. The current legislation should be modified accordingly

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

- (11) 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 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 proceeded 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 24, the introductory sentence is replaced by the following:  
‘The following post-mortem inspection procedures referred to in Articles 18.3, 19.2, 20.2, 21.2, 22.2 and 23.2 shall be proceeded using incisions and palpations of the carcase and offal, where, in the opinion of the official veterinarian, one of the following indicates a possible risk to human health, animal health or animal welfare:’
- 3) In Article 27, paragraph 1(c) is replaced by the following:  
‘(c) in the case of large game of the family *Cervidae* and other large game not covered by paragraph (a) and in the case of large game of the family *Suidae* not covered by paragraph (b), the post-mortem procedures for bovine animals laid down in Article 19;’
- 4) In Article 48.2, paragraph (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, provided that the competent authorities formally approve the system introduced a system in place in the slaughterhouse or game handling establishment ensuring that all parts of the animal can be traced, and no parts of the examined animals bearing the mark leave the slaughterhouse or game handling establishment until a negative result has been

**Kommenterede [DSK(1):** ES suggestion since all game of the family *Suidae* are covered by (b).

**Kommenterede [DSK(2):** ES proposal for consistency with Regulation (EU) 2015/1375.

obtained except when provided for in accordance with Article 2(3) of Regulation (EU) 2015/1375;'

5) In Annex V, the following amendments are made:

#### 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 EN 14526 (Lawrence method), ~~the mouse bioassay~~ or any other internationally recognised validated method.

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[The above mentioned 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-sulfocarbamoylgonyautoxin-2 and -3 (C1 and C2 isomers determined together), N-sulfocarbamoylgonyautoxin-1 and -4 (C3 and C4 isomers determined together);

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

Total toxicity will be expressed in equivalence µg STX equivalents of HCl·Kg-1 and shall be calculated using TEFs as recommended by the European Food Safety Authority (EFSA) in Journal (2009) 1019, 1-76 or any updated EFSA advice. FAO OMS 2016.]

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

#### CHAPTER III

##### LIPOPHILIC TOXIN DETECTION METHODS

A. The reference method for the detection of marine toxins as referred to in points (c), (d) and (e) in Chapter V(2) of Section VII of Annex III to Regulation (EC) No 853/2004 shall be the EU reference laboratory liquid chromatography-mass spectrometry/mass spectrometry (EURL LC-MS/MS) method. This method shall determine at least the following compounds:

(a) okadaic acid group toxins: OA, DTX1 and DTX2, including their esters (DTX3);

(b) pectenotoxins group toxins: PTX1 and PTX2;

(c) yessotoxins group toxins: YTX, 45 OH YTX, homo YTX and 45 OH homo YTX;

(d) azaspiracids group toxins: AZA 1, AZA 2 and AZA 3.

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

Total toxicity equivalence shall be calculated using TEFs as recommended by the European Food Safety Authority (EFSA) in Journal (2008) 589, 1-62 or any updated EFSA advice.

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6) In Annex VI, the following amendments are made:

7)

#### CHAPTER I D

##### Residues and contaminants

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(1) Monitoring arrangements shall be established in accordance with Directive 96/23/EC and Decision 97/747/EC to control compliance with the EU legislation on:  
— maximum residue limits for pharmacologically active substances, in accordance with Regulations (EU) No 37/2010 and (EU) No 2018/470;  
— prohibited and non-authorised substances, in accordance with Regulation (EU) No 37/2010, Directive 96/22/EC and Decision 2005/34/EC;  
— contaminants, in accordance with Regulation (EC) No 1881/2006 setting maximum levels for certain contaminants in food; and  
— pesticide residues, in accordance with Regulation (EC) No 396/2005.

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(2) 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 and on pesticide residues, in accordance with Regulation (EC) No 396/2005.

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#### *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*  
*[...]*

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