



Council of the  
European Union

Brussels, 24 July 2017  
(OR. en)

11471/17

AGRILEG 146  
DENLEG 61  
VETER 68

#### COVER NOTE

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From:	European Commission
date of receipt:	20 July 2017
To:	General Secretariat of the Council
No. Cion doc.:	D050358/04
Subject:	COMMISSION REGULATION (EU) .../... of XXX amending Annex III to Regulation (EC) No 2074/2005 as regards paralytic shellfish poison (PSP) detection method

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Delegations will find attached document D050358/04.

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Encl.: D050358/04



Brussels, **XXX**  
SANTE/10108/2017  
(POOL/G4/2017/10108/10108-EN.doc)  
D050358/04  
[...](2017) **XXX** draft

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

**of **XXX****

**amending Annex III to Regulation (EC) No 2074/2005 as regards paralytic shellfish  
poison (PSP) detection method**

(Text with EEA relevance)

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

of **XXX**

**amending Annex III to Regulation (EC) No 2074/2005 as regards paralytic shellfish  
poison (PSP) detection method**

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to 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<sup>1</sup> and in particular point (4) of Article 11 thereof,

Having regard to Regulation (EC) No 854/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption<sup>2</sup>, and in particular point 13(a) of Article 18 thereof,

Whereas:

- (1) Regulation (EC) No 854/2004 lays down specific rules for the organisation of official controls on products of animal origin and Regulation (EC) No 853/2004 lays down specific requirements concerning hygienic rules for food of animal origin. Implementing measures for those Regulations as regards recognised testing methods for marine biotoxins are set out in Annex III to Commission Regulation (EC) No 2074/2005<sup>3</sup>.

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<sup>1</sup> OJ L 139, 30.4.2004, p. 55.

<sup>2</sup> OJ L 139, 30.4.2004, p. 206.

<sup>3</sup> Commission Regulation (EC) No 2074/2005 of 5 December 2005 laying down implementing measures for certain products under Regulation (EC) No 853/2004 of the European Parliament and of the Council and for the organisation of official controls under Regulation (EC) No 854/2004 of the European Parliament and of the Council and Regulation (EC) No 882/2004 of the European Parliament and of the Council, derogating from Regulation (EC) No 852/2004 of the European Parliament and of the Council and amending Regulations (EC) No 853/2004 and (EC) No 854/2004 (OJ L 338, 22.12.2005, p. 27).

- (2) Point 2 of Chapter I of Annex III to Regulation (EC) No 2074/2005 provides that if the results of the paralytic shellfish poison (PSP) detection method are challenged, the reference method is to be the biological method.
- (3) During the thirty-sixth session of the Codex Alimentarius committee on methods of analysis and sampling (Budapest, Hungary 23 – 27 February 2015)<sup>4</sup> it was confirmed to maintain the biological testing method in Section I-8.6.2 of the Codex as Type IV<sup>5</sup>.
- (4) All Codex methods, including Type IV methods, can be used only for control, inspection and regulation (Principles for the establishment of methods of analysis) and when parties so agreed, for resolution of disputes (Guidelines for Settling Disputes on Analytical (Test) Results (CAC/GL 70-2009) but not as reference method.
- (5) Considering that a Type IV method cannot be used as reference method , it is important to adapt the current Union rules to the international standards.
- (6) Taking into account the so-called Lawrence method as published in AOAC Official Method 2005.06 (Paralytic Shellfish Poisoning Toxins in Shellfish) is currently used for the detection of paralytic shellfish poison (PSP) content of edible parts of molluscs, it is opportune that this method is used as reference method for the detection of those toxins.
- (7) Chapter I of Annex III to Regulation (EC) No 2074/2005 should therefore be amended accordingly.
- (8) In order to allow the Member States to adapt their methods to the chemical method, the biological testing method may be still used as reference method until 31 December 2018.
- (9) 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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<sup>4</sup> [http://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FMeetings%252FCX-715-36%252FREPI5\\_MASe.pdf](http://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FMeetings%252FCX-715-36%252FREPI5_MASe.pdf)

<sup>5</sup> Paragraph 56 of the Report.

HAS ADOPTED THIS REGULATION:

*Article 1*

Chapter I of Annex III to Regulation (EC) No 2074/2005 is replaced by the following:

"CHAPTER I

PARALYTIC SHELLFISH POISON (PSP) DETECTION METHOD

1. The paralytic shellfish poison (PSP) content of edible parts of molluscs (the whole body or any part edible separately) must be detected in accordance with the biological testing method or any other internationally recognised method.
2. If the results are challenged, the reference method shall be the so-called Lawrence method as published in AOAC Official Method 2005.06 (Paralytic Shellfish Poisoning Toxins in Shellfish)."

*Article 2*

This Regulation shall enter into force on the third day following that of its publication in the *Official Journal of the European Union*.

It shall apply from 1<sup>st</sup> January 2019.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels,

*For the Commission*  
*The President*  
*Jean Claude JUNCKER*