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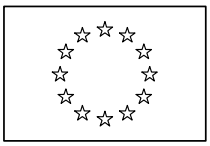

COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels,

Draft

COMMISSION REGULATION (EC) No …/..

of […]

amending Regulation (EC) No 2074/2005 as regards recognized testing methods for detecting marine biotoxins in live bivalve molluscs

(Text with EEA relevance)

Draft

COMMISSION REGULATION (EC) No …/..

of […]

amending Regulation (EC) No 2074/2005 as regards recognized testing methods for detecting marine biotoxins in live bivalve molluscs

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

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[1], and in particular Article 11(4) 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[2], and in particular Article 18(13)(a) 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 hygiene rules for food of animal origin. Implementing measures for those Regulations as regards recognized testing methods for marine biotoxins are set out in 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[3]. It is necessary to modify those implementing measures in the light of new scientific evidence.

(2) In July 2006 the Commission requested the European Food Safety Authority (EFSA) to provide a scientific opinion to assess the current limits and methods of analysis with regard to human health for various marine biotoxins as established in the Community

1 OJ L 139, 30.4.2004, p.55.
2 OJ L 139, 30.4.2004, p.206.
3 OJ L 338, 22.12.2005, p. 27.

legislation, including new emerging toxins. The last of a series of opinions was published on 24 July 2009.

(3) The mouse bioassay (MBA) and the rat bioassay (RBA) are is the official methods for the detection of lipophilic biotoxins. The Panel on Contaminants in the Food Chain of EFSA noted that these bioassays have shortcomings and are not considered an appropriate tool for control purposes because of the high variability in results, the insufficient detection capability and the limited specificity.

(4) Recently developed alternatives to the biological methods for the determination of the marine biotoxins with lower limits of detection (LOD) have successfully been tested in prevalidation studies.

(5) The technique of liquid chromatography (LC) mass spectrometry (MS) should be applied as the reference method for the detection of lipophilic toxins and used as matter of routine, both for the purposes of official controls at any stage of the food chain and own-checks by food business operators. The performance criteria of that technique should be stipulated after a successful prevalidation. It is appropriate that the performance criteria be established by the Community Reference Laboratory on marine biotoxins and that an interlaboratory validation is carried out by the Member States.

(6) In the long term, an interlaboratory validation of the method should be made, following an internationally agreed protocol. The Community Reference Laboratory on marine biotoxins should facilitate such a validation process.

(7) Other detection methods, different from the liquid chromatography (LC) mass spectrometry (MS), could be applied for the detection of lipophilic toxins provided that they fulfil the method performance criteria stipulated by the Community Reference Laboratory on marine biotoxins. Such methods should be intralaboratory validated and successfully tested under a recognised proficiency test scheme.

(8) To allow Member States to adapt their methods to the chemical method, the biological methods should continue to be used for a limited period of time. After this period, the biological methods should be used not as a matter of routine and only during the periodic monitoring of production areas for detecting new or unknown marine toxins.

(9) Therefore, Regulation (EC) No 2074/2005 should be amended accordingly.

(10) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS REGULATION:

Article 1

Annex III to Regulation (EC) No 2074/2005 is amended in accordance with 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*.

It shall apply from [……..].

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

Done at Brussels, […]

For the Commission
[…]
Member of the Commission

ANNEX

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

"CHAPTER III

LIPOPHILIC TOXIN DETECTION METHODS

A. Chemical methodology

(1) Liquid chromatography (LC) mass spectrometry (MS) shall be the reference methodology for the detection of marine toxins as referred to in Chapter V(2)(c), (d) and (e) of Section VII of Annex III, to Regulation (EC) No 853/2004. The methodology shall determine at least the following compounds:

- okadaic acid group toxins, including their esters

- pectenotoxins group toxins : PTX1 and PTX2,

- yessotoxins group toxins: YTX, 45 OH YTX, homo YTX, and 45 OH homo YTX,

- azaspiracids group toxins: AZA1, AZA2 and AZA3.

(2) Total toxicity equivalence shall be calculated using toxicity equivalent factors (TEFs) as recommended by EFSA.

(3) If new analogues of public health significance are discovered, they should be included in the analysis. Total toxicity equivalence shall be calculated using toxicity equivalent factors (TEFs) as recommended by EFSA.

(4) The liquid chromatography (LC) mass spectrometry (MS) procedures used as detection method must follow an interlaboratory validation process coordinated by the Community Reference Laboratory (CRL) on marine biotoxins. The CRL on marine biotoxins shall define performance criteria for these procedures on the basis of prevalidation data.

(5) As long term objective, an interlaboratory validation of the method should be made following an internationally agreed protocol. The CRL on marine biotoxins shall support activities toward inter-laboratory validation and standardization of the procedures.

(6) Other detection methods, such as high-performance liquid chromatography (HPLC) with fluorimetric detection, immunoassays and functional assays, such as the phosphatase inhibition assay, can be used as alternatives or supplementary to the liquid chromatography (LC) mass spectrometry (MS) method, provided that:

(a) either alone or combined they can detect at least the analogues as identified in point A (1) and respect the conditions of point A(4) of this Chapter; more appropriate criteria shall be defined when necessary;

(b) as a long term objective, an interlaboratory validation of the method should be made following an internationally agreed protocol; the CRL on marine biotoxins shall support activities toward inter-laboratory validation of the technique to allow for formal standardization;

(c) their implementation provides an equivalent level of public health protection.

B. Biological methods

(1) To allow Member States to adapt their methods to the chemical method as defined in point A(1) of this Chapter, a series of mouse bioassay procedures, differing in the test portion (hepatopancreas or whole body) and in the solvents used for extraction and purification, may be still used until 31 December 2012 for detecting marine toxins as referred to in Chapter V(2)(c), (d) and (e) of Section VII of Annex III, to Regulation (EC) No 853/2004.

(2) Sensitivity and selectivity depend on the choice of solvents used for extraction and purification and this should be taken into account when a decision is made on the method to be used in order to cover the full range of toxins.

(3) A single mouse bioassay involving acetone extraction may be used to detect okadaic acid, dinophysistoxins, azaspiracids, pectenotoxins and yessotoxins. This assay may be supplemented, if necessary, with liquid/liquid partition steps with ethyl acetate/water or dichloromethane/water to remove potential interferences.

(4) Three mice shall be used for each test. Where two out of three mice die within 24 hours of inoculation with an extract equivalent to 5 g hepatopancreas or 25 g whole body, this shall be considered a positive result for the presence of one or more toxins as referred to in Chapter V(2)(c), (d) and (e) of Section VII of Annex III to Regulation (EC) No 853/2004 at levels above those laid down.

(5) A mouse bioassay with acetone extraction followed by liquid/liquid partition with diethylether may be used to detect okadaic acid, dinophysistoxins, pectenotoxins and azaspiracids but it cannot be used to detect yessotoxins as losses of these toxins may take place during the partition step. Three mice shall be used for each test. Where two out of three mice die within 24 hours of inoculation with an extract equivalent to 5 g hepatopancreas or 25 g whole body, this shall be considered a positive result for the presence of okadaic acid, dinophysistoxins, pectenotoxins and azaspiracids at levels above those laid down in Chapter V(2)(c) and (e) of Section VII of Annex III to Regulation (EC) No 853/2004.

(6) A rat bioassay may be used to detect okadaic acid, dinophysistoxins and azaspiracids. Three rats shall be used for each test. A diarrhetic response in any of the three rats shall be considered a positive result for the presence of okadaic acid, dinophysistoxins and azaspiracids at levels above those laid down in Chapter V(2)(c) and (e) of Section VII of Annex III to Regulation (EC) No 853/2004.

C. After the period established in point B(1) of this Chapter, the mouse bioassay shall be used only during the periodic monitoring of production areas and relaying areas for detecting new or unknown marine toxins on the basis of the national control programmes elaborated by the Member States."