Commission Regulation (EU) No 15/2011 of 10 January 2011 amending Regulation (EC) No 2074/2005 as regards recognised testing methods for detecting marine biotoxins in live bivalve molluscs (Text with EEA relevance)

COMMISSION REGULATION (EU) No 15/2011

of 10 January 2011

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

(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[(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 recognised 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 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 the official methods for the detection of lipophilic biotoxins. The Panel on Contaminants in the Food Chain

Changes to legislation: *There are currently no known outstanding effects for the Commission Regulation (EU) No 15/2011. (See end of Document for details)*

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) A liquid chromatography-mass spectrometry (LC-MS/MS) method was validated under the coordination of the European Union Reference Laboratory on marine biotoxins (EU-RL) in an inter-laboratory validation study carried out by the Member States. This method is publicly available for consultation in the web page of the EU-RL (http://www.aesan.msps.es/en/CRLMB/web/home.shtml). This validated 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.

(6) Any other recognised method, 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 EU-RL. Such methods should be intra-laboratory validated and successfully tested under a recognised proficiency test scheme. If the results are challenged, the reference method shall be the EU-RL LC-MS/MS method.

(7) 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.

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

(9) 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 20th day following its publication in the *Official Journal of the European Union*.

It shall apply from 1 July 2011.

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

***Changes to legislation:** There are currently no known outstanding effects for the Commission Regulation (EU) No 15/2011. (See end of Document for details)*

Done at Brussels, 10 January 2011.

For the Commission

The President

José Manuel BARROSO