



**COUNCIL OF  
THE EUROPEAN UNION**

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Delegations will find attached Commission document D025799/04.

Encl.: D025799/04



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[...](2013) **XXX** draft

**COMMISSION REGULATION (EU) No .../..**

**of **XXX****

**amending Annex III to Regulation (EC) No 853/2004 of the European Parliament and of the Council as regards the permitted limits of yessotoxins in live bivalve molluscs**

(Text with EEA relevance)

**COMMISSION REGULATION (EU) No .../..**

**of XXX**

**amending Annex III to Regulation (EC) No 853/2004 of the European Parliament and of the Council as regards the permitted limits of yessotoxins 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<sup>1</sup>, and in particular Article 10(1)(d) thereof,

Whereas:

- (1) Regulation (EC) No 853/2004 lays down specific rules on the hygiene of food of animal origin for food business operators. That Regulation provides that food business operators are to ensure that live bivalve molluscs placed on the market for human consumption do not contain certain marine biotoxins in total quantities, measured in the whole body or any part edible separately, that exceed the limits set out in point 2 of Chapter V of Section VII of Annex III thereto. Point 2(d) of that Chapter sets out the maximum limit for yessotoxins at 1 milligram of yessotoxin equivalent per kilogram.
- (2) In December 2008, the European Food Safety Authority (EFSA) adopted an Opinion of the Scientific Panel on Contaminants in the Food chain on a request from the European Commission on marine biotoxins in shellfish – yessotoxin group<sup>2</sup>. According to that Opinion, in a series of acute toxicity studies following oral administration of yessotoxins, no lethality and no clinical signs of toxicity were observed. In addition, EFSA concluded that a portion of shellfish should not contain more than 3.75 milligrams of yessotoxin equivalent per kilogram. That level is above the current limit set out in point 2(d) of Chapter V of Section VII of Annex III to Regulation (EC) No 853/2004.
- (3) The 32<sup>nd</sup> Session of the CODEX Committee on Fish and Fishery Products (1-5 October 2012) confirmed the exclusion of yessotoxins from the list of marine biotoxins that should be tested at international level.
- (4) In the light of the EFSA Opinion and of the conclusions of the 32<sup>nd</sup> Session of the CODEX Committee on Fish and Fishery Products, it is appropriate to increase the current limit for yessotoxins to 3.75 milligram yessotoxin equivalent per kilogram.
- (5) Annex III to Regulation (EC) No 853/2004 should therefore be amended accordingly.
- (6) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health and neither the European Parliament nor the Council has opposed them,

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

<sup>2</sup> The EFSA Journal (2009) Journal number, 907, 1-62.

HAS ADOPTED THIS REGULATION:

*Article 1*

In Annex III to Regulation (EC) No 853/2004, point 2(d) of Chapter V of Section VII is replaced by the following:

"(d) for yessotoxins, 3.75 milligram of yessotoxin equivalent per kilogram;"

*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*  
*José Manuel BARROSO*