

WRITTEN QUESTION E-4872/07  
by Caroline Lucas (Verts/ALE)  
to the Commission

Subject: Use of validated non-animal methods for detection of amnesic shellfish poisoning

Two precise analytical methods are currently available to detect amnesic shellfish poison in the edible parts of molluscs. The high performance liquid chromatography method (HPLC) method of ASP detection has been validated for over a decade and is regarded as the reference method. The ELISA method has been published in the AOAC journal as of 2006, been accepted by the European Commission as a validated method and is cost-effective, simple and highly reliable. These methods provide far stronger assurances of human safety than the mouse bioassay which also causes substantial suffering to animals.

In light of the requirement under Article 7 of Directive 86/609/EEC<sup>1</sup> that 'an experiment shall not be performed [on an animal] if another scientifically satisfactory method of obtaining the result sought, not entailing the use of an animal, is reasonably and practicably available' will the Commission ensure that Chapter II of Annex III to Regulation (EC) N° 2074/2005<sup>2</sup> is amended to specify the use of the HPLC and ELISA methods only for the detection of ASP, or that it specifically prohibits use of the mouse bioassay?

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Answer given by Mr Kyprianou  
on behalf of the Commission  
(14.11.2007)

The Honourable Member's question concerns the methods used for the analysis of amnesic shellfish poisons (ASP) under Commission Regulation (EC) No 2074/2005<sup>3</sup>.

The reference method for the ASP analysis in Regulation (EC) No 2074/2005 is the high-performance liquid chromatography (HPLC) method. Since the Regulation is demanding the detection of "the total content of ASP in edible parts of molluscs" the method used should be quantitative and therefore the use of qualitative animal bio-assay tests are not foreseen under Commission Regulation (EC) No 2074/2005 for ASP analysis.

For screening purposes the 2006.02 ASP ELISA<sup>4</sup> method has recently received a favourable vote in the Standing Committee on the Food Chain and Animal Health but has not yet been adopted in Commission Regulation (EC) No 2074/2005.

The Commission fully shares the Honourable Member's opinion that animal tests should be avoided whenever there are other scientifically satisfactory methods available. ASP has been the first marine biotoxin for which alternative non-animal methods are available and EU legislation has been amended accordingly.

<sup>1</sup> OJ L 358, 18.12.1986, p. 1.

<sup>2</sup> OJ L 338, 22.12.2005, p. 27.

<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 Parliament and of the Council and for the organisation of official controls under Regulation (EC) No 854/2004 of Parliament and of the Council and Regulation (EC) No 882/2004 of Parliament and of the Council, derogating from Regulation (EC) No 852/2004 of Parliament and of the Council and amending Regulations (EC) No 853/2004 and (EC) No 854/2004 (Text with EEA relevance), OJ L 338, 22.12.2005.

<sup>4</sup> AOAC Journal, June 2006.