

FORM FOR TABLING PARLIAMENTARY QUESTIONS

To the: **COUNCIL**   
**COMMISSION**

ORAL QUESTIONS	WRITTEN QUESTIONS
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AUTHOR(S): Caroline Lucas

SUBJECT: Shellfish toxin testing  
 (please specify)

TEXT:

Animal tests used to assess the presence of marine biotoxins in shellfish destined for human consumption are extremely painful and should be replaced with non animal alternatives. EC Directive 86/609, Article 7(2), states that: ‘An experiment [on live animals] shall not be performed if another scientifically satisfactory method of obtaining the result sought, not entailing the use of an animal, is reasonably and practicably available’.

In the case of detection of paralytic shellfish poison (PSP) toxin, the non-animal Lawrence method of high performance liquid chromatography (HPLC), has been accepted for use by the AOAC (Association of Analytical Communities). However, Commission Regulation (EC) No 2074/2005 states that ‘the biological testing method or any other internationally recognised method’ should be used. Furthermore, the Regulation actually requires use of the biological (animal) method as the reference method to be used if results are challenged.

Could the Commission explain why the Lawrence method is not specifically required for identification of PSP toxins rather than the biological test; why this non-animal method has not been identified as the reference method for detection of PSP toxins, and why the Commission has not specified that in order to comply with Article 7.2 of Directive 86/609, the animal method should not be used?

In the case of detection of amnesiac shellfish poisons (ASP), the HPLC method is required and set as the reference method. However, Regulation 2074/2005 also allows use of ‘any other recognised method’, which could include animal tests. Why has the Commission not specified that in order to comply with Article 7.2 of Directive 86/609, animal methods must not be used to identify ASP toxins?

With regard to diarrhetic shellfish poisons (DSP)/lipophilic toxin detection, could the Commission explain the grounds on which biological methods are considered to be valid, whereas non-animal alternative methods are not?

Finally, does the Commission have plans to amend regulations setting out approved methods for identification of marine bio-toxins in shellfish so that testing requirements comply fully with Article 7.2 of Directive 86/609?

Signature(s): \_\_\_\_\_ Date: 1/2/06

Answer given by Mr Kyprianou  
on behalf of the Commission  
(29.6.2006)

The limits of Diarrhetic Shellfish Poisoning (DSP)/lipophilic toxins groups in live bivalve molluscs are established in Annex III, Section VII, Chapter V (2) of Regulation (EC) No 853/2004 of the Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin<sup>1</sup>.

These limits were established on the basis of the results of working groups meetings held in Brussels in 2001. The participants to the working groups (representatives of the European Laboratory network on marine biotoxins, the Director of the Community Reference Laboratory (CRL) for marine biotoxins in Vigo, private scientists universally recognised as expert in the field of marine biotoxins) provided the Commission with the scientific basis and an appropriate risk assessment for fixing the limits currently established in the Community legislation.

The Commission is aware of the results of the Joint Food and Agriculture Organisation (FAO)/ Intergovernmental Oceanographic Commission (IOC)/ World Health Organisation (WHO) ad hoc expert consultation on biotoxins in bivalve molluscs held in Oslo in September 2004.

The Commission's Directorate-General for Health and Consumer Protection (DG SANCO) organised, in March 2006, a meeting to discuss the report of the Joint FAO/IOC/WHO and, in particular, the limits proposed for marine biotoxins, with the participation of representatives of some Member States (Spain, Ireland, Lithuania, Germany and the United Kingdom) and the Director of the Community Reference Laboratory (CRL) for marine biotoxins. This group, following the analysis of the report, proposed to maintain the current limits for lipophilic toxins with the exception of yessotoxins and pectenotoxins which were proposed for deregulation. The outcomes of this meeting were discussed during a CODEX ad hoc working group<sup>2</sup> held in Ottawa (Canada) in April 2006 where the European proposal to maintain the current limits for marine biotoxins (with the exception for yessotoxins and pectenotoxins) was unanimously accepted by the participants.

The results of this CODEX ad hoc working group will be discussed in the forthcoming next CODEX Committee for fish and fishery products (September 2006). Only once all the steps for a formal adoption of the report by the CODEX are completed, will the Commission envisage the possibility to change its legislation for pectenotoxins and yessotoxins.

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1 OJ L 139, 30.4.2004

2 The CODEX working group was composed by representatives of Canada, Chile, EC, Denmark, France, Ireland, Japan, New Zealand, Norway, South Africa, Thailand, United Kingdom, United States and FAO