EUROPEAN PARLIAMENT

FORM FOR TABLING PARLIAMENTARY QUESTIONS

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To the: **COUNCIL** ☐
COMMISSION ☒

ORAL QUESTIONS		**WRITTEN QUESTIONS**	
Oral Question with debate (Rule 108)	☐	Written Question (Rule 110)	☒
Question Time (Rule 109)	☐	Priority Written Question (Rule 110 (4)	☐

AUTHOR(S): Caroline Lucas

SUBJECT: (please specify) Choice of testing methods for marine biotoxins

TEXT:

In the Answer given by Mr. Kyprianou, on behalf of the Commission, to Written Question P-0542/06EN, it is confirmed that Article 7.2 of Directive 86/609 EEC[1] must be applied with respect to choice of test method for the detection of marine biotoxins. The Article 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.'

Would the Commission confirm that non-animal High Performance Liquid Chromatography (HPLC) methods for detection of two diarrhetic shellfish poisoning (DSP) toxins, okadaic acid (OA) and dinophysis toxins (DTX), have been accepted for use in Germany, where the HPLC methods have in fact been the preferred means of protecting the public from contamination by OA and DTX?

Moreover, would the Commission confirm that in Germany, non-animal methods have, indeed, been the preferred means of testing for all marine biotoxins? In view of the need for implementation of Article 7.2 of Directive 86/609, would the Commission explain why Regulation 2074/05 does not require use of HPLC tests for the detection of the two DSP toxins (OA and DTX) throughout the EU? Furthermore, would the Commission explain why Regulation 2074/05 does not also require the use of non-animal methods for the detection of lipophilic toxins?

Does the Commission have plans to amend regulations setting out approved methods for detection of OA and DTX specifically, as well as those tests intended to detect lipophilic toxins, so that non-animal methods are used instead of the non-validated biological test?

[1] OJ L 358, 18.12.1986

Signature(s): Date:
28/04/06

E-2083/06EN
Answer given by Mr Kyprianou
on behalf of the Commission
(29.6.2006)

There are many different marine biotoxins and validated non-animal tests are not available for all types. For this reason, the Commission is obliged to use the mouse bioassay which detects all shellfish toxins. This method has a low specificity (cannot differentiate toxins) but a high sensitivity (can detect all toxins). The validation of the biological test for the detection of Diarrheal Shellfish Poisoning (DSP) toxins is very difficult because of the interferences of some toxins (yessotoxins) in the final results. However, a defined protocol has been established and it is used by the laboratories in the Member States

In addition to biological testing methods, current legislation allows the use of alternative, internationally validated, detection methods such as chemical methods and in vitro assays. The most difficult point which has not been achieved for certain toxins, in particular lipophilic toxins, is to demonstrate the equivalence between the reference method and the proposed alternative chemical method. Moreover, the lack of reference materials for all toxins is an important limitation in the development of the alternative methods. Development and validation of alternative methods in this respect are the result of a long procedure that needs initial fundamental scientific work to identify reference materials. Under the Sixth Research Framework Programme Thematic Priority 5, Food Quality and Safety, the Commission is funding the development of new detection methods for marine biotoxins in three specific targeted research projects (STREPS) and part of one Integrated Project (IP). The first results will be available end 2007. More information can be found on the following site: http://www.marine-biotoxins.org/biotoxins/index.html.

This is the picture of the current situation. Unfortunately, for the moment, alternative tests, internationally validated, covering the whole range of toxins are not available.

The Commission reiterates its commitment to replace the biological methods as soon as alternative validated methods, giving the same level of public health protection, are available. The validation of an alternative method for marine biotoxins is under the responsibility of organisations such as AOAC (Association of Official Agricultural Chemists), ECVAM (European Centre of Validation of Alternative Methods) and the CRL (Community Reference Laboratory).