WRITTEN QUESTION E-3458/07
by Caroline Lucas (Verts/ALE)
to the Commission

Subject: Reducing animal tests used to identify certain marine biotoxins

In answer to Question H-0549/05[1] , the Commission confirmed that it 'considers as a priority the replacement of biological tests using rodents to verify the absence of biotoxins in shellfish'.

Would the Commission please describe all methods being used at this time to gather data on the presence of cyclic amines of the diarrhetic shellfish poison (DSP) group, and comment on the perceived need for such data gathering in the light of the level of hazard posed to the human population? Is it correct that the mouse bioassay is still identified as the reference method for detecting the presence of these toxins?

Does the Commission acknowledge that at the Joint FAO/WHO Food Standards Programme Codex Committee on Fish and Fishery Products (Twenty-Eighth Session, Bejing, China, 18-22 September 2006), experts agreed, and asserted in their 'report of the working group meeting to assess the advice from the joint FAO/WHO/IOC Ad Hoc expert consultation on biotoxins in bivalve mollusks' that: 'It is important to note that there is not evidence of harmful effects in humans caused by cyclic imines, as seen for other marine biotoxins and that the toxic potential of cyclic imines by oral administration is significantly lower than after intraperitoneal administration. The significance of these toxins to food safety is unclear.?

Given that mice are acutely affected by cyclic amines while humans are not, would the Commission agree that use of the mouse bioassay to detect these toxins is wholly inappropriate on both scientific and ethical grounds, and that in the case of detection of cyclic amines, the mouse test does not provide data that are necessary in order to protect human health?

Lastly, will the Commission provide an update on current progress towards the collection of reference material for use in developing non-animal methods to entirely replace the use of the mouse bioassay to detect marine biotoxins?

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Answer given by Mr Kyprianou
on behalf of the Commission
(2.10.2007)

The Commission reiterates the commitment to replace the biological methods as soon as alternative validated methods, giving the same level of public health protection, are available.

The detection methods, biological and alternative, for the toxins belonging to the Diarrhetic Shellfish Poisoning (DSP) group, are set out in Annex III, Chapter III to Commission Regulation 2074/2005[2].

Regarding the recommendations of the recent Codex Committee on Fish and Fishery Products (Beijing, China 18-22 September 2006) the Commission underlines that the proposal to deregulate certain toxins belonging to the DSP group is not already a Codex standard and, consequently, further discussion is needed.

[1] Written answer of 5 July 2005.

[2] 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 Parliament and of the Council and for the organisation of official controls under Regulation (EC) No 854/2004 of the Parliament and of the Council and Regulation (EC) No 882/2004 of the Parliament and of the Council, derogating from Regulation (EC) No 852/2004 of the Parliament and of the Council and amending Regulations (EC) No 853/2004 and (EC) No 854/2004; OJ L 338, 22.12.2005.

However, in 2006, the Commission asked European Food Safety Authority (EFSA) to assess the current limits and methods of analysis for marine biotoxins as established in the EU legislation, in the light of the publication of the report of FAO/IOC/WHO[3] ad hoc Expert Consultation on Biotoxins in Bivalve Molluscs (Oslo, 26-30 September 2004). The scientific opinion of EFSA is expected by December 2007.

On the basis of this opinion, the Commission is ready to modify the current legislation on marine biotoxins, including the detection methods, if appropriate.

Regarding the collection of reference materials, the Commission, under the Sixth Research Framework Programme Thematic Priority 5, Food Quality and Safety, is funding several projects involving the main marine research laboratories in Europe, which aims at providing new detection methods for marine biotoxins. These projects will concur to ensure high-quality and safe seafood (easy to use, fast and sensitive methods) and would ultimately provide a support to the process of replacing animal-based tests with non-animal tests. Results will be made available to the public within the respective time frame of these projects. Further references can be found on the following site: http://www.marine-biotoxins.org/biotoxins/index.html.

[3] The United Nations Food and Agriculture Organisation, the Intergovernmental Oceanographic Commission of UNESCO and the World Health Organisation