

ANNEX - QUESTIONS TO THE COMMISSION

- ▶ Question no 63 by Caroline Lucas ([H-0549/05](#))

Subject: Shellfish toxin testing

[H-0549/05](#)

There is growing concern about the implementation of Council Directive 91/492/EEC⁽¹⁾, which lays down the health conditions for the production and placing on the market of live bivalve molluscs and prescribes a mouse bioassay for shellfish toxin testing as reference method.

It is recognised that DG SANCO via the Community Reference Laboratory in consultation with ECVAM has started validation activities to replace the animal test. However, it appears that the Food and Veterinary Office (Ireland) will insist on the implementation of the mouse bioassay, even if Member States successfully apply in vitro methods or refinement or reduction of the in vivo method for several years.

Since this is clearly contrary to Directive 86/609/EEC⁽²⁾ on the protection of animals used for experimental and other scientific purposes, could the Commission explain how it plans to respond?

(EN)The Commission considers as a priority the replacement of biological tests using rodents to verify the absence of biotoxins in shellfish. It is working very closely on this with the European Centre for the Validation of Alternative Methods, ECVAM.

Intoxication with biotoxins of bivalve molluscs is quite a serious form of food poisoning that can be picked up from shellfish. Member States are required to test for their presence and, if detected, the shellfish production areas are closed until the problem has been resolved.

There are many different shellfish toxins and validated non-animal tests are available for many but not for all types. Consequently the reference method to detect all these toxins and prevent toxic shellfish being harvested remains the mouse bioassay.

The Commission has been active in attempting to replace biological tests by alternative tests for many years. The Commission has more recently asked the Community Reference laboratory in Vigo (Spain) to develop, in cooperation with ECVAM and with the assistance of the National Reference Laboratories, alternative methods by the end of 2005. This process will of course also take account of international developments, and notably recent work in the United States on a chemical test method for PSP, currently undergoing validation in

Europe.

Current legislation allows Member States to use validated non-bioassay tests where they exist. However, alternative chemical methods can replace biological methods only if they give equivalent results in the matter of sensitivity and diagnostic reliability.

The Commission would encourage Member States to continue work in this area and to share their results, methods and reference materials.

When enough alternative methods have been validated so as to cover all toxins, the Commission would be very pleased to propose that Community legislation be modified to move entirely away from the mouse bioassay for good.

[\(1\)](#)OJ L 268, 24.9.1991, p. 1.

[\(2\)](#)OJ L 358, 18.12.1986, p. 1.