

02 July 2010

**Re: Call for replacement of animal tests used to test for Biotoxins in shellfish**  
(Directive 91/492/EEC and EFSA Opinion (Question No. EFSA-Q-2006-065A))

Dear Minister of Justice,

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. The animal test, the mouse bioassay, is the method laid down in Directive 91/492/EEC for determining the presence of biotoxins. This is a very distressful test, which includes death as an endpoint. Opinions adopted by the EFSA over the past 2 years highlight the shortcomings of the mouse bioassay, on most occasions stating it as being inappropriate at detecting the presence of biotoxins and therefore inadequate in ensuring human safety.

The requirement to use of the mouse bioassay is contradictory to Article 13 of the Lisbon Treaty, which provides that Member States and the EU have the legal obligation to pay full regard to the welfare requirements of animals when formulating policies. Additionally, Council Directive 86/609/EEC<sup>1</sup>, Article 7(2), states that: 'An experiment 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'.

Alternatives to the mouse bioassay exist and have been used in Germany since the 1980s. These are chemical assays (such as the HPLC method or combinations of fluorimetric and chromatographic assays) or biological test methods (cell culture methods, enzyme inhibition assays). These tests are very reliable, highly sensitive and highly reproducible.

It is our understanding that the Commission is preparing to revise the directive, which they have started discussing with Member States during meetings of the Standing Committee on the Food Chain and Animal Health. The Danish Animal Welfare Society request from you the position of Denmark regarding the use of the mouse assay to test for marine biotoxins and the implementation of alternative non-animal methods.

To ensure the end of redundant animal testing, The Danish Animal Welfare Society and Eurogroup for Animals continue to call for the speedy implementation of alternative non-animal methods into legislation as soon as possible, with the removal of the mouse and rat bioassays as the prescribed reference methods for biotoxin testing in the EU.

Yours sincerely,

Britta Riis, Director  
Danish Animal Welfare Society, Dyrenes Beskyttelse

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

Date : 28 June 2010  
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Annex: Briefing. Biotoxins. June 2010 (2 pp.)