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August 2011

**Re: Call for urgent take up of alternative non-animal method used to test for Biotoxins in shellfish**  
(Regulation 15/2011/EU)

Dear Henrik Høegh, Minister of Agriculture &  
Lars Barfoed, Minister of Justice

The animal test used to assess the presence of marine biotoxins in shellfish destined for human consumption is extremely painful, inappropriate and should be replaced with the validated non-animal alternative method as soon as possible. The new Regulation (15/2011/EU)<sup>1</sup> which applied from 1<sup>st</sup> July 2011 allows for the use of an alternative non-animal method over the animal test.

The animal test, the mouse bioassay, was the method laid down in Regulation (EC) No 2074/2005 for determining the presence of biotoxins. Following the publication of numerous EFSA opinions on marine biotoxins, which outlined the shortcomings and inappropriateness of the assay in ensuring human safety, the Regulation has recently been revised to withdraw the mouse bioassay and replace it with alternative, non-animal method.

Member States have until the 31<sup>st</sup> December 2014 to implement the new test. We consider this time exaggerated for implementation of the simple alternative methods, while they continue to use up to 600 000 mice in the EU each year in a test that is considered unreliable and inappropriate in ensuring human safety. We call on you to ensure the take up of the alternative method as soon as possible.

The continued use of the mouse bioassay is contradictory to requirements of the Lisbon Treaty where in the EU it is a legal obligation to pay full regard to the welfare requirements of animals as stated under the Lisbon treaty, Article 13. Additionally, Directive 2010/63/EU<sup>2</sup>, Article 4(1), states that: *'Member States shall ensure that, wherever possible, a scientifically satisfactory method or testing strategy, not entailing the use of live animals, shall be used instead'.*

<sup>1</sup> OJ 11/01/2011. Commission Regulation (15/2011/EU) OF 10 January 2011 amending Regulation (EC) No 2074/2005 as regards recognised testing methods for detecting marine biotoxins in live bivalve molluscs.

<sup>2</sup> OJ 20/10/2010. Directive 2010/63/EU of the European Parliament and of the Council of 22 September 2010 on the protection of animals used for scientific purposes.

To ensure the end of redundant animal testing, the Danish Animal Welfare Society calls on Denmark to speed up the implementation of the alternative non-animal method as soon as possible, with the replacement of the mouse bioassay as the prescribed reference methods for marine biotoxin testing into their law.

Yours sincerely,

A handwritten signature in black ink, consisting of a large, stylized 'R' followed by a smaller 'i' and a period.

Britta Riis, Director  
Danish Animal Welfare Society (Dyrenes Beskyttelse)  
Member of Eurogroup for Animals

cc.: Members of the Food Committee of the Danish Parliament (Folketingets Fødevareudvalg)