



30 November 2012

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

Att.: Danish Minister for Food, Agriculture and Fisheries

Dear Mette Gjerskov,

Legislation has existed now for over a year allowing the use of a reliable alternative non-animal method over the extremely painful and scientifically questionable animal test used to assess the presence of marine biotoxins in shellfish destined for human consumption. Regulation 15/2011/EU¹ applies since 1st July 2011 and allows the use of the validated non-animal alternative method immediately.

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

Although Member States have until the 31st December 2014 to implement the new test, we consider this time exaggerated for implementing a simple alternative method, while up to 600 000 mice are used in the EU each year in a test that is considered unreliable and inappropriate in ensuring human safety.

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 Article 13. Additionally, Directive 2010/63/EU², 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'*.

When the Regulation was adopted in January 2011, Denmark was carrying out safety testing on shellfish using the animal test for the paralytic shellfish poisons (PSP) and diarrhetic shellfish poisons (DSP). However it is our understanding that Denmark planned to commence with the alternative non-animal method on the 1st of July 2011 when the Regulation started to apply. Could you confirm this to

¹ 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.

² 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.

be accurate information? Is any shellfish which are foreseen to be imported into Denmark for human consumption, first subject to safety testing using the animal test in other Member States?

Thank you in advance for answers.

Yours Sincerely

A handwritten signature in blue ink, consisting of a large, stylized 'R' with a horizontal line through it, followed by a small dot.

Britta Riis
Director

A handwritten signature in blue ink, consisting of a large, stylized 'S' followed by a horizontal line and a small '2'.

Søren Kent Pedersen
Project manager, DVM

Danish Animal Welfare Society (Dyrenes Beskyttelse)
Member of Eurogroup for Animals

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