



NOTE TO THE ADVISORY FORUM

State of Play on the question from Germany regarding alternative tests for marine biotoxins¹

1. European Commission Decision 2002/225/EC² sets rules for the implementation of Council Directive 91/492/EEC³ as amended by 97/61/EC⁴ as regards maximum levels and the methods of analysis of certain marine biotoxins in bivalve molluscs, echinoderms, tunicates and marine gastropods.

2. According to Commission Decision 2002/225/EC, three groups of marine biotoxins must be determined by the food producers and competent authorities: Paralytic Shellfish Poison (PSP), Diarrhetic Shellfish Poison (DSP) and Amnesic Shellfish Poison (ASP). The total ASP content has to be analysed using a chemical analytical method, (i.e. high performance liquid chromatography, HPLC), whereas biological testing methods, the mouse bioassays (MBA), is indicated as reference method to determine the content of PSP and DSP. Commission Decision 2002/225/EC permits, in principle, the use of alternative methods such as chemical methods and *in vitro* assays, if it is demonstrated that the performance of the chosen methods is not less effective than the performance of the biological method and that their implication provides an equivalent level of public health protection. However, the prerequisite for this option is the validation of such methods and the availability of an internationally accepted protocol. Article 5 of Commission Decision 2002/225/EC states that, if there are discrepancies between the results obtained by the use of the different methods, the MBA shall be the definitive reference method.

3. Last year the German Federal Institute for Risk Assessment (Bundesinstitut für Risikobewertung, BfR) sent a request to EFSA to consider if the mouse bioassay, from a scientific point of view, deserves the status of a method of reference and whether it provides sufficient health protection of the consumer, taking into account the results of a Joint FAO/IOC/WHO ad hoc expert consultation on biotoxins in bivalve molluscs which took place in Oslo from 26-30 September, 2004.

¹ 'marine biotoxins' means poisonous substances accumulated by bivalve molluscs feeding on plankton containing toxin (91/492/EEC)

² OJ L 75, 16 March 2002, p. 62-64

³ OJ L 268, 24 September 1991, p. 1-14

⁴ OJ L 295, 29 October 1997, p. 36-36

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4. EFSA forwarded the question to its Scientific Panel on Contaminants in the Food Chain (CONTAM) for further consideration. The CONTAM Panel discussed the question at its 16th plenary meeting (3 to 5 April 2006) and concluded that a small group of Panel members should discuss this question in more detail and draft a Terms of Reference to be reviewed by the Panel at its next meeting (June 2006). This meeting took place on 28 April 2006 in the presence of a representative of the European Commission (EC) responsible for the community legislation in this area.

5. The group mentioned in para 4, was informed by the Commission's representative about the latest developments in the legal area within the EU, as well as about developments in the Codex Committee on Fish and Fishery products (CCFFP). On 10 – 13 April 2006 an *ad hoc* WG of the CCFFP met in Ottawa, Canada, and there was a general consensus to regulate the maximum levels for marine biotoxins. The aforementioned group was also informed that the Commission intends to send a request to EFSA to consider the acute reference doses for eight different toxin groups as proposed by the Joint FAO/IOC/WHO *ad hoc* expert consultation on biotoxins in bivalve molluscs in September 2004⁵.

6. In view of the before mentioned developments, EFSA will propose to the CONTAM Panel to address the relevant issues in relation to marine biotoxins as follows:

- To provide an opinion on the acute reference doses for the eight different toxin groups as proposed by the Joint FAO/IOC/WHO *ad hoc* expert consultation on biotoxins in bivalve molluscs in September 2004;
- To consider whether the mouse bioassay still deserves the status of reference method for the relevant marine biotoxins at EU level taking trends and developments in the performance and applicability of alternative test methods for the detection of marine biotoxins into consideration.

7. EFSA is seeking the views of the members of the Advisory Forum if the proposed mandate for the CONTAM Panel is adequately covering their needs in the area of marine biotoxins.

⁵ Report available at URL: unesdoc.unesco.org/images/0013/001394/139421e.pdf