

INTRODUCTION OF A NEW CHEMICAL SCREEN TEST TO THE UK STATUTORY MARINE BIOTOXIN MONITORING PROGRAMME

Issue

1. To update the Board on progress towards the implementation of alternative methods to the mouse bioassay for the detection of paralytic shellfish poisoning toxins in shellfish within the Agency's statutory marine biotoxin monitoring programme.

Background

2. Filter-feeding bivalve molluscs, e.g. mussels and scallops, can accumulate naturally occurring biotoxins produced by certain marine algae. Some of these algae produce potent neurotoxins that in consumers may cause paralysis and, in certain cases, can be lethal. These are known as paralytic shellfish poisoning (PSP) toxins.
3. EU legislation requires that bivalve molluscs for human consumption are regularly monitored for biotoxins and lays down the maximum permitted levels of toxins in live bivalve molluscs placed on the market. The FSA, as the competent authority within the UK, is responsible for implementing and managing this monitoring programme, which is entirely publicly funded; Local Food Authorities pay for the sampling¹ and the FSA pays for the transportation and testing of the samples.
4. The mouse bioassay (MBA) is stipulated in EU legislation as the reference method for the detection of PSP toxins and its use in the UK is subject to licensing by the Home Office (as the competent authority for regulations on animal experimentation and for ensuring that animal use for scientific purposes is reduced to a justifiable minimum).
5. The Agency has for some time been committed to seeking alternative test methods to the MBA that will protect public health and reduce reliance on animal testing. Consequently, there has been a need to develop and validate alternative (chemical) methods that will be suitable for use in the UK statutory monitoring programme.

HPLC Method Development

6. In recent years significant progress has been made by the Agency and others in developing alternative methods. An analytical method, known as the AOAC² High

¹ In Northern Ireland (NI) both sampling and testing is paid by FSA NI.

² AOAC is an internationally recognised scientific body in America which, among other things, lays down validation and quality assurance guidelines for analytical methods.

Performance Liquid Chromatography (HPLC)³ has recently been validated through an international inter-laboratory trial for the detection of specific toxins in selected shellfish species. This method provides the best prospect as an alternative method to the MBA for detecting the amount of the individual PSP toxins (quantitative), an opinion shared by the Committee on the Toxicity of Chemicals in Food, Consumer Products and the Environment (COT).

7. However, following ring trials in several member states (including the UK) co-ordinated by the EU Community Reference Laboratory, the European Commission concluded that in view of the technical difficulties encountered it was not at that time able to recommend the use of this AOAC HPLC method as an alternative to the MBA⁴ as an official control and reference method. The Agency shares this view and, of particular concern to the UK, the method has not been validated for shellfish species such as cockles, which make up a sizeable part of our biotoxin monitoring programme.
8. While the issues with the AOAC HPLC method preclude its use at this time as a quantitative method, the FSA commissioned a study to evaluate its potential for detecting just the presence of any toxin (i.e. use as a qualitative screening method). Subsequent assessment of the results has allowed implementation of the method within the UK statutory monitoring programme where it has been used on over 95% of the samples submitted. Since the 1 November 2006 only bivalves testing positive in the screen are put into the MBA and this has reduced mouse usage for PSP testing by over 70% for England, Wales and Scotland (equates to around 7,000 mice per year, depending on the level of positive samples). The screen was implemented in Northern Ireland on 1 December 2006 with an estimated 93% reduction in mice usage due to the lower incidence of PSP toxins in NI waters.
9. The UK is one of the first countries in Europe to take such an approach, as most Member States still rely solely on the MBA for PSP toxin testing. The Agency will discuss the use of the HPLC screen with the Commission in the coming months in order to facilitate an agreed position throughout the European Union.

Impact on Stakeholders

10. The reduction in reliance on animal testing meets the objectives of both the Agency and the Home Office. However, the HPLC screen is a more resource intensive method than the MBA, entailing higher running costs for the Agency and requiring a greater investment of time. This will potentially affect the Agency, Local Authorities and Industry by delaying the time from sampling to the declaration of results.

³ Lawrence *et al.*, 2005. J. AOAC Internat. 88(6): 1714-1732.

⁴ Ben-Gigirey *et al.*, 2007. J. Chromatogr. A. 1140(1-2): 78-87.

Future Work

11. The Agency continues to focus resources on implementing a full reliable quantitative HPLC method replacement, and the AOAC HPLC method is currently undergoing single laboratory validation (according to IUPAC guidelines⁵) in the UK monitoring laboratories. This will be followed by a period of real-time testing using samples submitted to the monitoring programme to assess the logistics and robustness of the method. It is hoped to complete this work by the end of 2007.

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⁵ Thompson *et al.* 2002. Pure Appl. Chem. 74(5) 835-855.