



House of Commons
Environment, Food and Rural
Affairs Committee

The Food Standards Agency and Shellfish: Government Reply to the Committee's Report

Ninth Special Report

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The Environment, Food and Rural Affairs Committee

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NINTH SPECIAL REPORT

The Environment, Food and Rural Affairs Committee reported to the House on *The Food Standards Agency and Shellfish* in its Fifth Report of Session 2003–04, published on 20 February 2004 as HC 248. The Government’s Reply to the Report was received on 7 May 2004.

Government response

Following an intervention from the Cabinet Office at official level on whether the enforcement of the regulations should be subject to an RIA, we confirm that the Agency would develop a Regulatory Impact Assessment (RIA) in the usual way should the developments of alternative testing methods result in amendments to the legislation in the future.¹

Introduction

The UK Government welcomes the Report of the Environment, Food and Rural Affairs (Efra) Committee Inquiry into “*The Food Standards Agency and Shellfish*” (HC 248, published on 20 February 2004), as a helpful contribution to The Agency’s on-going investigations into the atypical Diarrhetic Shellfish Poisoning (DSP) findings which have been obtained with some UK cockle and mussel samples.

The Food Standards Agency was set up by the Government in April 2000, under the Food Standards Act 1999, to protect public health and other consumer interests in relation to food, address the perceived imbalance in favour of food producers in risk assessment, risk management and risk communication, and to address a consumer belief that there was a lack of openness on food safety issues. The Agency is accountable through Health Ministers to the Westminster Parliament and devolved administrations in Scotland, Wales and Northern Ireland.

Since summer 2001, unexplained (atypical) responses have been observed when some shellfish, principally cockles, have been tested for Diarrhetic Shellfish Poisoning (DSP) toxins in the mouse bioassay (MBA). These are positive DSP results within the terms of EU law. The atypical response involves mice dying more quickly than they do when known DSP toxins are present. The reasons for this response has been investigated in considerable detail, but it has not so far been possible to identify the cause. Nevertheless, all the independent international experts who have been consulted consider that the response might be due to a novel toxin. The Agency has recommended, on a precautionary basis, that Temporary Prohibition Orders be placed on beds by local authorities where atypical responses have been generated in the MBA. These Orders

¹ From the letter covering the Government Reply.

remain in effect until two successive tests, from samples collected at least seven days apart, produce negative results.

The Department of Agricultural and Rural Affairs (DARD) in Northern Ireland started to use the MBA to check cockle samples in January 2001. The first atypical response was detected at DARD on 22 August 2001 in a cockle sample from Dundrum Bay. The laboratory continued to detect atypical responses until May 2003. In England and Wales, the Centre for Environment, Fisheries and Aquaculture Science (CEFAS) began testing shellfish in England and Wales on 4 June 2001 and detected the first atypical response with cockle samples on 8 June 2001. The laboratory continued to detect atypical responses until the end of October 2003. The Fisheries Research Service (FRS) which is responsible for undertaking the test for Scotland, and was responsible for the test for the whole of Great Britain between September 1996 and June 2001, has not reported finding any atypical responses.

The UK Government has given careful consideration to each of the “Conclusions and Recommendations” of the Efra Committee Report and its response is set out below.

Recommendation 1

It is both astonishing and unacceptable that the three laboratories conducting statutory toxin monitoring used different methods, and more importantly, did not appear to have a common standard for determining whether a result was positive or negative. (Paragraph 22)

The Government agrees that it would have been preferable if the three laboratories carrying out statutory testing in the UK had been using a common standard operating procedure (SOP) from the beginning, although it notes that some differences in methodology are permitted in EU law. It is clearly undesirable if differences in the way the method is applied can give different test results, particularly if this might mean that something of potential significance to public health could be missed.

The UK National Reference Laboratory (UK NRL) for shellfish biotoxins is responsible under EU law for co-ordinating the activities of the monitoring laboratories across the UK. Testing for shellfish biotoxins is both complex and demanding. There is no standardised international procedure for carrying out the MBA for DSP toxins, nor does European legislation prescribe the method in full detail. This has meant that certain aspects of the testing methodology have had to be interpreted by the laboratories. The UK laboratories all applied a method in accordance with EU law, based on that developed in 1984 by the world’s leading expert on shellfish toxins, Professor Yasumoto.

Notwithstanding these difficulties, the Agency’s clear objective since questions began to arise about different approaches has been to see a harmonised UK test method put in place which adequately protects human health, detects all known DSP toxins, and which is applied and interpreted in a consistent manner.

A great deal of work has been carried out, to investigate the effects of differences between the methodologies then in use in the statutory monitoring laboratories in the UK. The results of all of these studies have been published on the Agency website. As a consequence of what was learned, a single method based closely on that in use in DARD, was adopted by all three laboratories from November 2003.

All three statutory laboratories have been, and are, working to a common interpretation of the MBA end point which, for atypical DSP responses, is death within a very short space of time.

In addition, the Agency has been pressing the European Commission since mid 2002 for agreement on a harmonised DSP MBA testing method, and to develop alternative non-animal based tests. As a consequence of this lobbying, these matters are now receiving attention, and work has been started by the National Reference Laboratories in Europe to develop an EU DSP Standard Operating Procedure and an alternative chemical test methodology based on liquid chromatography – mass spectrometry (LC-MS). The Agency will continue to maintain pressure for a resolution of these issues as soon as possible.

Recommendation 2

The FSA was slow to recognise that the atypical results merited further investigation, slow to take account of the industry's suggested explanations and was slow to investigate the possibility that the methodology could be at fault. The flaws highlighted in the methods applied by the laboratories, even if they do not explain the atypical results, suggest that the FSA should, at the very least, have paid closer attention to quality control in its investigations. These delays have meant that this crisis has been unduly prolonged. (Paragraph 23)

As the Efra Committee has acknowledged, the issues involved are complex. Although an extensive investigative programme of work has been carried out since the Agency became aware of the extent of the problem (it was first notified of the atypical issue in October 2001), the Government takes the view that, with the benefit of hindsight, more rapid progress may have been possible, if additional resources had been devoted to this work and had there been closer co-operation with the industry at an earlier stage. The time taken to resolve issues at the cutting edge of science can however be lengthy as shown by experience in the Irish Republic when an unusual DSP response in shellfish was detected in 1995. Their investigative work eventually resulted in the identification of a new shellfish toxin (azaspiracid). That matter took 6 years to resolve fully and the toxin concerned is now the subject of EU public health legislation.

Recommendation 3

The FSA does not appear to recognise that the extent to which the industry believes that the atypical results can be explained by the solvent and methodology hypothesis. As a result it has not done enough to communicate what it has done to investigate this hypothesis and on what evidence it has rejected it, if indeed it has. In such a

delicate situation as this, where the risk of a threat to public health must be balanced against the risk of severe and lasting damage to individuals' livelihoods and to businesses, it is imperative that the Agency take all possible steps to ensure that reasonable hypotheses are rigorously researched and that the outcomes of such research are made clear to the other parties involved. (Paragraph 24)

The Agency has been left in no doubt that the industry believes that the methodology, particularly solvent carry over, is responsible for the atypical responses. It has taken this possibility very seriously from the outset, but has always kept an open mind about the possible cause of the responses, especially as international experts have said that a novel shellfish toxin cannot be ruled out. The Agency has commissioned a great deal of work to investigate whether solvents may play a role, but the findings from the studies have not shown a direct causal link between solvents and the atypical response.

Significant new resources have been allocated to the investigative work. Somewhere in the order of £200,000 was spent on studies into the atypical DSP problem during 2003/4, and £159,000 for work on non-animal test methods. Since 2000, approximately £1million has been spent in the UK on research on shellfish biotoxin issues.

The Agency has always sought to explain its thinking, the uncertainties surrounding the issue, and the basis for its decisions. It has tried to involve all the key stakeholders in the process. In 2003 alone it held 12 meetings with industry and the enforcement authorities to up-date them on developments and to listen to their views. In addition, up-dates on the atypical investigations were provided at 5 open Board meetings, and responses were provided to more than 50 pieces of correspondence, many from industry. Where new information with a bearing on earlier reported findings has come to light, the Agency has reviewed the evidence base and taken it into account, as appropriate. Stakeholders have been given advance notice of the findings of all investigations into the atypical issue, prior to publication on the Agency website:

http://www.food.gov.uk/science/research/microbioSafety/b16programme/shellfish_toxins

The Agency does not yet know whether the atypical response is caused by an artefact of the testing procedures or by a novel toxin. However, it will continue to commission research aimed at resolving this.

The Agency will be exploring what more can be done to improve communications in the stakeholder forum which will be established in the near future (see recommendation 8 below).

Recommendation 4

We recommend that the FSA pursue its research into the causes of the atypical response with urgency and it should inform us of the outcome of such research. The FSA should inform us of its strategy for responding to any future atypical results should further research prove inconclusive. (Paragraph 25)

The Agency fully accepts this recommendation, and is continuing to pursue its research into the atypical DSP issue and to assess the implications of it for human health as a high priority.

Public health protection is the Agency's first consideration. Until it has sufficient information to be able to make a robust assessment of the public health implications of the atypical DSP response, the Agency will continue, as a precautionary measure, to recommend the temporary closure of beds when shellfish produce an atypical response in the DSP MBA.

Preliminary toxicology studies have been undertaken in order to assess the public health implications of the atypical DSP testing response. The results of this work were presented to the Government's independent advisory Committee on Toxicity of Chemicals in Food, Consumer products and the Environment (COT). Based on the data presented, Members of the Committee considered that the repressed respiratory function exhibited in the MBA may be due to paralysis of the diaphragm or a neurotoxic mechanism. In the light of this, the Agency has sought advice from two independent experts on how best to explore this further. Having considered their advice and made some enquires about the feasibility of experimental approaches some short-term, non-animal based studies are now planned to determine the potential neurological activity (which will include electro-physiology work) and cytotoxicity of the cockle extracts that give rise to atypical responses.

In addition, to address industry suggestions about the possible role of biogenic amines, the Agency is exploring if it is possible to measure the concentrations of these types of compounds in cockle extracts. Although independent analysts do not consider that biogenic amines, if present, would be carried through into the final extract, the Agency considers that this matter is still worthy of further investigation.

Depending on the outcome of these studies, further work may be undertaken, some of which could be subject to Home Office licensing, under the Animals (Scientific Procedures) Act 1986. Research outcomes will continue to be placed in the public domain when complete.

If, as a result of all this work, it is considered by the COT that the atypical response is likely to pose a threat to public health, the Agency may need to carry out further investigations to identify the causative agent and fund work to develop a specific test to detect it. However, should it be shown that the atypical response raises no public health concerns, the Agency will immediately review its policy in relation to the advice it offers local enforcement authorities in relation to the temporary closure of harvesting areas when atypical responses have been observed.

The UK Government shares the Committee's desire to see an end to the uncertainty about the possible risks from the atypical DSP response as soon as possible.

Recommendation 5a

We welcome the FSA's decision to allow zoning of shellfish beds in order to mitigate the effects of closures on the shellfish industry. (Paragraph 29)

The UK Government welcomes the acknowledgement of the Agency's work to minimise the impact of the atypical issue on the cockle industry, while still protecting public health.

Recommendation 5b

The Government should consider what avenues are available to it to compensate shellfish harvesters and processors for their loss of earnings during prolonged closures. (Paragraph 29)

The Government has no plans to introduce a scheme of financial compensation to shellfish harvesters and processors for loss of earnings during recurring temporary suspensions, necessary for the protection of human health due to contamination of a fishery by biotoxins. Action has been taken to zone shellfish beds whenever possible in order to reduce the impact of atypical findings on the industry.

Recommendation 6a

It is important that the respective roles of the Food Standards Agency and food authorities are clarified. (Paragraph 30)

The Food Safety Act 1990 and the Food Safety (Fishery Products and Live Shellfish) (Hygiene) Regulations 1998 set out the respective roles and responsibilities of the Agency and local food law enforcement authorities. Guidelines have been issued to the enforcement authorities on the taking of samples for biotoxin monitoring, and their transport to the laboratories.

Recommendation 6b

The Government should require the FSA to explain fully, and in public, the reasons behind its decisions in respect of closures. (Paragraph 30)

The Agency is the UK Government authority responsible for food safety. It has a commitment to openness.

The Agency has regularly explained its policy of recommending the temporary closure of harvesting areas where atypical responses to the DSP MBA are found. This has included explaining its view of the uncertainties involved.

The Agency has made its views known in written communications and at meetings with industry, the enforcement authorities, laboratories, and other Government Departments. It has also answered questions during open Board meetings, and these are recorded in the minutes available on its website.

However, the Agency will be seeking views from the stakeholder forum (see recommendation 8 below) on what more might usefully be done in relation to information needs.

Recommendation 7

The Government should examine the way that food authorities are funded to carry out their work. All the costs of the statutory shellfish toxin monitoring programme should be met by the FSA. (Paragraph 31)

The UK Government already funds a significant proportion of the statutory shellfish monitoring programmes, paying for all analytical work and the dissemination of results. This amounted to approximately £2 million in 2003/4. The Agency has also invested significant resources in a programme of investigative work and studies to determine the cause of the atypical response and its implications for public health.

The cost of food law enforcement is met by local authorities from their local resources. There are no plans to change these funding arrangements. It is for each local authority to determine how much of its available resources should be spent on food law enforcement work, including that involving shellfish.

Recommendation 8

The issues surrounding the atypical results are complex. We have already emphasised the importance of providing a clearer explanation of the research that has already been carried out into this issue. However, the failure of communication in this case extends beyond scientific issues to the heart of the relationship between the three principal parties involved. The FSA needs to show greater sensitivity to the needs of the industry and local authorities, closer co-operation with them and greater openness. We recommend that the FSA establish a working group comprised of representatives of all the stakeholders in this issue in order to identify ways to improve co-operation and to agree a forward programme of research on the causes of atypical results and a common approach to any future similar incidents. The group should report progress on such matters before the next main shellfish harvesting season begins in summer 2004. (Paragraph 35)

The UK Government welcomes the Committee's recognition that the issues surrounding the atypical issue are complex.

The Agency will establish a forum with representative stakeholders to consider what more can be done to improve co-operation and communication with industry and local enforcement authorities, and also with others with an interest such as consumer organisations and other Government Departments. This forum will also consider what further research might be needed to resolve the atypical DSP issue.

The terms of reference for the forum will be agreed with stakeholders as soon as possible and published on the Agency website.

Recommendation 9a

It would be desirable to move away from the routine use of the mouse bioassay in shellfish toxin monitoring and we encourage the FSA and industry to work together on any new regime. (Paragraph 38)

The UK Government fully agrees that it would be desirable to move away from the routine use of the mouse bioassay in shellfish biotoxin monitoring. The Agency has been actively seeking the development of alternative chemical tests at a national and European level since it was established in 2000. Work has now started in the EU to develop chemical tests for DSP based on Liquid Chromatography-Mass Spectrometry (LC-MS). When alternative tests have been fully validated, and shown to give public health protection at least equivalent to the current tests, they will be submitted for approval of the Member States by the European Commission. Approval of such tests could result in a significant reduction in reliance on mouse testing.

Recommendation 9b

Operating a voluntary regime in parallel with the current method would merely exacerbate existing disagreement and confusion. (Paragraph 38)

The UK Government welcomes the industry's recognition of its own responsibility for taking appropriate measures to monitor product safety, as required by existing legislation. However, it shares the Committee's concerns about the introduction of a voluntary regime in parallel with the statutory monitoring programme.

Recommendation 9c

We welcome the research being carried out on alternatives to MBA and we recommend that the Government work to achieve European agreement on a single operating procedure as soon as possible. (Paragraph 38)

The UK Government accepts this recommendation and welcomes the acknowledgement of the Agency's research work. Matters will continue to be progressed as a priority, and in this context the Agency welcomes the fact that the European Commission has asked the Community Reference Laboratory to establish a detailed standard operating procedure for the biological test for DSP toxins by September 2004.