House of Commons

Environment, Food and Rural Affairs Committee

The Food Standards Agency and Shellfish

Fifth Report of Session 2003–2004

Report, together with formal minutes, oral and written evidence

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Environment, Food and Rural Affairs Committee

The Environment, Food and Rural Affairs Committee is appointed by the House of Commons to examine the expenditure, administration, and policy of the Department for Environment, Food and Rural Affairs and its associated bodies.

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A list of Reports of the Committee in the present Parliament is at the back of this Report.

Committee staff

The current staff of the Committee are Gavin Devine (Clerk), Fiona McLean (Second Clerk), Dr Kate Trumper and Jonathan Little (Committee Specialists), Andy Boyd and Louise Combs (Committee Assistants), Anne Woolhouse (Secretary) and Rebecca Flynn (Intern).

Contacts

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Report

Summary

Since 2001, statutory monitoring for toxins in shellfish, particularly cockles, has produced unexplained, atypical positive results. On a precautionary basis the Food Standards Agency (FSA) has recommended the closure of shellfish beds that produce these results. The prolonged closures have had a severe impact on the shellfish industry in England and Wales, despite efforts by Defra and the FSA to minimise the areas closed.

There has been a fierce debate about the cause of the atypical results. The shellfish industry believes that flaws in the test method used in England and Wales explain the results. The FSA is of the view that there is no evidence that that is the case and that further research is needed to identify the cause. It is imperative that the remaining research be completed as soon as possible. The FSA should develop and publish a strategy for responding to any future atypical results should further research prove inconclusive.

In this case, the FSA has not lived up to its core value of being open and accessible. Communication and co-operation between the FSA, the industry and local authorities, which enforce closures, has been poor. The result is an atmosphere of distrust and, at times, hostility. The three parties should form a joint working group to develop common solutions in time for next year's main harvesting season.

These problems have highlighted discrepancies in testing across Europe and drawbacks with the animal testing methods used. The Government should work towards a common European method, which moves away from testing on mice towards primarily chemical testing.

1 Introduction

1. Under the terms of the European Community's Shellfish Hygiene Directive,[1] Member States are required to monitor shellfish harvested for human consumption for toxins, and seawater around shellfish harvesting areas for algae that are known to produce such toxins. Three types of poisoning can result from eating contaminated shellfish: paralytic shellfish poisoning (PSP), amnesiac shellfish poisoning (ASP) and diarrhetic shellfish poisoning (DSP). This inquiry is concerned with the United Kingdom's monitoring programme for DSP. The test method is the Mouse Bioassay, whereby shellfish extract is injected into mice.

2. The Food Standards Agency took on responsibility for toxin monitoring on its establishment in 2000. In 2001, it transferred the contract for laboratory testing for toxins in England from the Fisheries Research Service in Aberdeen to the Centre for Environment, Fisheries and Aquaculture Science (CEFAS), in Weymouth. In the summer of that year, the FSA began to record positive test results for DSP from different areas of England and Wales. The positive results were mainly found in cockles. It became apparent that the symptoms in the mice used in the test were more severe, and mice died more quickly, in these cases when compared to 'normal' cases of DSP, so the new cases came to be called 'atypical DSP'.

3. As a result of the positive tests, the FSA recommended the temporary closure of several cockle beds, which the relevant food authorities (County and Borough Councils) actually implement. Normally, incidents of DSP are short-lived and shellfish beds re-open rapidly. In many of these 'atypical' cases, though, shellfish continued to test positive and many beds remained closed for months at a time.

4. After the atypical results had persisted for some time, the shellfish industry began to express scepticism about their cause. It has expressed doubts about the test methodology as it is applied in England and Wales and contended that the 'atypical results' were artefacts of the test procedure and did not provide evidence of a toxin in shellfish which posed a threat to human health. It has also expressed grave concerns about the impact that such long periods of closure have had on shellfish gatherers and processors.

5. We therefore decided to set up a sub-committee to examine the issues surrounding the atypical results, under the chairmanship of Austin Mitchell MP. Our terms of reference were:

> "Taking account of the reports published by the Food Standards Agency on 2 October 2003 into the testing of UK shellfish for toxins, the Committee will look into the implications for public health and for the shellfish industry of the 'atypical results' revealed by statutory testing of shellfish in the past two years, and the way in which those results have been interpreted and acted upon."

[1] Council Directive 91/492/EEC of 15 July 1991 laying down the health conditions for the production and the placing on the market of live bivalve molluscs

6. We received written memoranda from 19 organisations and individuals. We held a single session of oral evidence on 19 January 2004, during which we heard from the Shellfish Association of Great Britain and Kershaws Quality Foods Limited, and from the Food Standards Agency. We are most grateful to all those who submitted evidence and otherwise assisted us in our inquiry.

7. It would be wrong for us to produce a report about the cockle industry at the moment without recording our shock at the death of 19 cockle pickers in Morecombe Bay on 5 February 2004. Our thoughts are with those killed, and with their families.[2]

2 The shellfish toxin monitoring system

8. The Food Standards Agency (FSA) is the competent authority in the United Kingdom in the terms of the Shellfish Hygiene Directive and as such is responsible for the monitoring and control of marine biotoxins, that is, toxins produced by algae.[3] Where monitoring test results show that placing shellfish on the market may constitute a hazard to human health, the FSA recommends closure of the beds the shellfish came from. It is then for the relevant food authority (the local authority) to impose a Temporary Prohibition Order, which closes the beds to harvesting until the tests have returned negative results for two consecutive weeks.[4]

9. The laboratory testing of shellfish is carried out under contract. Monitoring in England, Wales and Scotland was originally carried out by the Fisheries Research Service (FRS) and its predecessors, in Aberdeen.[5] In 1999 the European Commission's Food and Veterinary Office criticised the United Kingdom for carrying out insufficient sampling, in terms of the number of areas and species sampled.[6] The FSA decided to increase the numbers of shellfish tested and to put the monitoring contract out to competitive tender.[7] As a result, in 2001 statutory testing for shellfish toxins in England and Wales was transferred to the Centre for Environment, Fisheries and Aquaculture Science (CEFAS), in Weymouth. FRS still conducts the monitoring programme in Scotland.[8] The Department for Agriculture and Rural Development (DARD) has conducted the testing programme in Northern Ireland since the Directive was implemented.[9]

[2] The Committee produced a report on *Gangmasters* in September 2003 (Fourteenth Report of Session 2002-03, HC 691), which is relevant to the Morecombe Bay tragedy. We will be returning to the topic shortly.

[3] Ev 32

[4] Ev 33

[5] Ev 83

[6] Q54, Ev 84

[7] Q57

[8] Ev 33

[9] Ev 55

3 Atypical results

10. The method used to test for Diarrhetic Shellfish Poisoning (DSP) in the United Kingdom is the Mouse Bioassay (MBA),[10] whereby shellfish extract is injected into mice. European legislation established the MBA as the reference test for DSP, that is other methods are allowed provided that they are as effective as MBA and where there are discrepancies between the results of different tests, the MBA result is definitive.[11] EU Decision 2002/225 stipulates that if two of three test mice die within 24 hours of the injection, the shellfish sample is deemed to be positive for DSP.[12] Aside from the atypical results that are the main subject of this report, we have some concerns about the mouse bioassay itself, which will be discussed in greater detail later in the report.

11. Since June 2001, atypical results have been recorded for shellfish (mainly cockles) being tested for DSP with the mouse bioassay.[13] Although the symptoms and speed of death in the atypical results differed from normal positive DSP results, the mice nevertheless died within the period set out by the Directive and therefore the FSA is of the view that the atypical results were positive DSP results as defined by European Union law.[14]

12. The atypical results were mainly found in cockles from England and Wales in tests conducted by CEFAS, but DARD also found atypical results in shellfish from Northern Ireland. At the time of writing, there have been no further atypical results since November 2003.[15]

13. The FSA does not know what caused the atypical results, nor what are their implications for human health.[16] No-one has documented the presence of any known DSP toxins in samples showing the atypical response.[17] However, the FSA point out that

> in recent years, a number of new shellfish toxins have been described from many areas of the world. For example, in 1995, toxins in Irish shellfish exported to other countries caused human illness. It took four years of investigations before the Irish authorities identified azaspiracid as the cause, and a further two years to complete the assessment of risks to public health. This shellfish toxin is now controlled under EU legislation.[18]

14. Furthermore, the FSA says that shellfish toxins do not always produce an acute response and may instead give rise to chronic effects.[19] It recommended closure of shellfish beds which produced atypical results as a precautionary measure. It explains its reasoning as follows:

[10] Ev 33
[11] Ev 33
[12] Ev 32
[13] Ev 34, Ev 55, Ev 84
[14] M15 para 9
[15] Qq 21, 76
[16] Ev 35
[17] Ev 84
[18] Ev 32
[19] Ev 35

> on the basis that something is being detected in the MBA which is killing mice more quickly than DSP, the Agency recommends closure of affected shellfish beds, as a precautionary measure to protect consumer health. To do otherwise would be to ignore the conclusions of the Phillips Inquiry into BSE on the handling of potential threats to health arising from the food chain. The Phillips report lays great stress on the need to take precautionary action when the risk is uncertain.[20]

15. Although the FSA recommends closure of affected beds, some shellfish from these beds may still reach the market. This is because it can take four days from the time of sampling to finding the result of the test, and in the interim shellfish can still be sold.[21] It is rare for a product recall to be issued in these cases, and in any case, the fresh shellfish will already have been consumed. The FSA says that although its primary aim is to protect public health, it wants to act in a precautionary way. It takes the view that consuming small amounts of shellfish over a short period of time, as may happen in the period between sampling and getting the test result, is not likely to cause a problem.[22] However, to the shellfish industry, the lack of product recalls and the absence of any known occurrences of poisoning in people who have eaten shellfish from beds that have produced atypical results, suggest that there is no true threat to public health.[23]

16. The FSA has commissioned a number of investigations into the cause of the atypical results. The Laboratory of the Government Chemist was funded to study whether Liquid Chromatography Mass Spectrometry could be used to detect and, if possible, identify whatever substance was responsible for producing the atypical response. The results of this study are expected to be published early in 2004.[24] The FSA will also conduct a toxicology study to "inform the Agency's consideration of the associated public health implications …[and] policy on the closure of shellfish production areas that generate atypical results in the MBA."[25]

4 Alternative explanations for the atypical results

17. At first, the shellfish industry accepted that the atypical positive DSP results might represent the presence of something that was, or could be, a threat to public health.[26] However, as the period of closures continued, the industry began to doubt the presence of a toxin, as normal episodes of DSP are generally short-lived.[27] Furthermore, they argued

[20] Ev 35
[21] Ev 77, Q22
[22] Q51
[23] Q22
[24] Ev 34
[25] Ev 35
[26] Ev 12
[27] Ev 67

that outbreaks of DSP are usually associated with an algal bloom, but that this was not the case in the atypical results.[28]

18. The industry noted that the atypical results began to be found when CEFAS took over monitoring for England and Wales, although DARD began to find some atypical results at around the same time. Moreover, the atypical results appear to have stopped since a common method was introduced at all three laboratories in November. The industry put forward the hypothesis that the results were an artefact of the method used at CEFAS and DARD rather than the presence of a novel toxin.[29]

19. When testing was transferred to CEFAS, the laboratory adopted a different scientific protocol for the MBA to that used at FRS (DARD used a third version of the method). The industry's suggestion is that CEFAS's method resulted in solvents used in the preparation of the shellfish extract remaining in the material that was injected into mice, and that it was these solvents that caused the symptoms and death observed in the atypical results. For example, the CEFAS method involved a more vigorous extraction method, which the industry suggests may increase the likelihood of emulsion formation, which in turn could result in greater volumes of solvent remaining in the final extract.[30]

20. Because none of the laboratories concerned found atypical results in other shellfish as often as in cockles, despite using the same procedure, the industry accepts that some factor associated with cockles was involved too, perhaps the presence of stress-induced compounds, but maintains that there was no evidence of any risk to human health.[31] The industry also criticises other aspects of the way in which the mouse bioassay was carried out, which it believes may have allowed certain cockle compounds to remain the final material and thus contaminate the results.[32]

21. The FSA has investigated the possibility that solvent carry-over from the production of the extract to the material that is injected into the mice is responsible for the atypical symptoms. However no relationship was found between the amount of solvent present in the injected material and atypical results: some samples which contained a lot of solvent did not produce the atypical result and some with little solvent did. FSA says that it is not possible to ensure that solvent is completely removed and therefore have not been able to show that samples that are completely free of solvent may still produce the atypical response. The FSA has also found no link between the type of solvent used and the atypical response. It has concluded that there is no evidence that solvent carry-over explains the atypical response.[33]

22. The atypical results prompted closer scrutiny of the methods used at the three laboratories and an audit was carried out by Professor Hugh Makin. This highlighted the fact that originally the three labs were using three separate versions of the MBA and identified some poor scientific practice, principally a lack of quality assurance. Of

[28] Ev 12

[29] Ev 1, Ev 12, Ev 67, Ev 86

[30] Q3

[31] Qq27-28

[32] Qq23, 25-26

[33] Investigations To Assess Whether Diethyl Ether Or Acetone Carry - Over During The DSP Standard Operating Procedure Is Responsible For The Atypical Response In Mice, FSA Report, 01 October 2003

particular concern was the fact that there were different approaches to determining whether a particular test result was positive or negative.[34] The FSA and the laboratories concerned have taken steps to address those issues, adopting a common method since November 2003. **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.**

23. **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.**

24. **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.**

25. The industry's hypothesis is supported by the fact that the period during which atypical results were found coincided with the period during which a new version of the test was in use. The problem of atypical results lasted from the summer of 2001 to late autumn 2003, and if further atypical results are discovered, it seems unlikely to be resolved unless the cause of the results can be discovered. There is an urgent need for further investigation of the cause of the results and what, if any, are the implications for human health. We understand that the FSA has commissioned research with this aim. **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.**

[34] An audit of methods and procedures for lipophilic toxin analysis used by laboratories at CEFAS, FRS and DARD, which undertake the statutory monitoring of shellfish toxins in the UK. Hugh L. J. Makin, 1 October 2003, Section 9, para 5.

5 Impacts on the industry

26. The Shellfish Association of Great Britain estimates that the cockle industry employs about 2000 people in the United Kingdom and generates sales worth about £20 million a year.[35] The shellfish industry says that the closures of cockle beds as a result of atypical DSP results have had a severe economic impact on fishermen, processors and marketing companies.[36] For example, Kershaws Quality Foods told us that the FSA's actions in recommending closures have resulted in a direct loss of 75 jobs and the loss of a profitable export market.[37] In addition to the direct impact, the industry believes that the reduction in harvesting has led to a longer-term deterioration in the cockle stock, as older, larger cockles that would normally be harvested have been left in place and are smothering the younger ones. The impact of this will not be seen for a few years.[38]

27. However, Defra questioned how significant the effect of closures had been. It told us that "in spite of the intermittent closure of cockle beds in both fisheries [the Thames and Wash], following the detection of atypical DSP, there has been a very high uptake of the total allowable catch of cockles agreed annually by each SFC [Sea Fisheries Council] for its area". It gives figures of 92% and 99% for the Thames fishery and 99% and 114% for the Wash fishery.[39]

28. The industry says that fact that a high percentage of the total allowable catch was taken does not mean there was no economic impact. Kershaws said

> the fishery officers [for the Thames estuary] were forced to change management opinion allowing the industry to fish on juvenile stocks to keep the industry alive rather than the true management structure of conserving stocks.[40]

Kershaws said that as a result of fishing on the juvenile stocks, smaller, lower quality cockles are harvested, which do not attract as high a price as the larger cockles.[41]

29. In an attempt to mitigate the impact of closures on the shellfish industry, the FSA eventually permitted the zoning of shellfish beds. Thus even if shellfish from a particular part of an estuary, for example, tested positive, harvesting could carry on in other areas that tested negative. **We welcome the FSA's decision to allow zoning of shellfish beds in order to mitigate the effect of closures on the shellfish industry. The Government should consider what avenues are available to it to compensate shellfish harvesters and processors for their loss of earnings during prolonged closures.**

[35] Ev 4
[36] Ev 4
[37] Ev 10, Q10
[38] Q11
[39] Ev 89
[40] Q11
[41] Q10

6 Local Authorities

30. As described above, local authorities, in their capacity as food authorities, are responsible for closing shellfish beds, although they do so on the recommendation of the Food Standards Agency.[42] Local authorities have raised concerns about the way that responsibilities for shellfish complying with legislation are split between them and the FSA.[43] In particular they are concerned that although food authorities have no influence on the testing scheme, because they implement closures they are legally accountable for the choices made.[44] Indeed, six local authorities who submitted evidence to the Committee believe that they are likely to be the subject of a judicial review brought by some in the shellfish industry who contest the grounds for closing the beds.[45] **It is important that the respective roles of the Food Standards Agency and food authorities are clarified. The Government should require the FSA to explain fully, and in public, the reasons behind its decisions in respect of closures.**

31. The FSA says that it meets the costs of the statutory monitoring programme.[46] However the local authorities say that the problem of atypical results has become a "major drain on resources",[47] and that they receive no additional funding to fulfil their responsibilities in this area.[48] They say that sampling is expensive, as is the enforcement of closures and dissemination of information about the problem. In addition, the dispute over the cause of the atypical response has led local authorities to appoint their own legal and scientific advisors.[49] **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.**

7 Communication

32. It is clear that communication between the parties involved has been poor. The food authorities have expressed concern about the way information is passed between industry, the FSA and themselves, describing themselves as a 'piggy in the middle'.[50] For example, Carmarthenshire County Council says "a major cause for concern was the exchange of information between all three parties. There has been little openness or transparency".[51]

[42] Ev 33
[43] Ev 76, Ev 80
[44] Ev 80
[45] Ev 76, Ev 78
[46] Ev 33
[47] Ev 80
[48] Ev 63
[49] Ev 64, Ev 72
[50] Ev 81
[51] Ev 77

The Borough Council of Kings Lynn and West Norfolk says "the present situation has led to an increasing level of mistrust between the three groups".[52]

33. The Shellfish Association of Great Britain (SAGB) has been highly critical of the FSA's approach to resolving the issues raised by the atypical DSP response. It said

> the precautionary principle has been mis-applied by FSA, used as a scapegoat for its inability to address the procedural/artefactual causes of the MBA response. Industry believes that the Agency now believes its own spin, seeking control to camouflage extremely poor science. It is paranoid about the release of information.[53]

The SAGB also said

> industry has very actively sought compromise and offered willingness to work with the FSA but this has been repeatedly rejected outright with contempt.[54]

34. The FSA believes that it has handled the issues correctly but expressed sympathy for the position of the shellfish industry and said that it understood the sensitivities surrounding the events since 2001.[55] The Agency's Chief Executive said

> I would certainly hope things have not got to the point where we do not have a working relationship [with the shellfish industry]. … I think we need to redouble our efforts, I might say on both sides, to ensure that we work together to get a solution as quickly as we can. I can understand the frustration at the time this takes and we are doing all we can to get things moving and make sure we get to an end as quickly as we can. No purpose is served by being at war. I hope that is not the position we are at. I do not recognise that position and we would want to continue to talk and work with all the parties that are involved in this.[56]

35. **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 principle 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.**

[52] Ev 65
[53] Ev 5
[54] Ev 27
[55] Q108
[56] Q109

8 The mouse bioassay

36. A European Commission Decision established the mouse bioassay (MBA) as the 'reference method' for DSP testing.[57] The use of other tests is allowed provided that they can detect certain specified toxins and that their use provides the same degree of public health protection as the MBA. However, where there are discrepancies in the results of different methods, the MBA result is taken to be definitive.[58] The FSA says that the MBA also provides "early warning" of new toxins which may have implications for human health and which cannot be detected by chemical methods.[59] However, the routine use of the MBA in toxin monitoring has been criticised on animal welfare grounds.[60]

37. Not all European Community Member States use the MBA as the routine test; Holland uses a rat oral toxicity test which does not result in death and Germany uses chemical testing.[61] Even those Member States that do use the MBA do not use an agreed, Europe-wide, protocol, although the FSA is pressing for one.[62] These differences have led to complaints from the United Kingdom industry that their product was effectively discriminated against by the FSA, since imported shellfish did not have to undergo the same tests.

38. The FSA and CEFAS are researching chemical testing and other alternatives to the MBA. The industry would also like to move towards chemical testing and have proposed a voluntary testing initiative based on Liquid Chromatography Mass Spectrometry. **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. Operating a voluntary regime in parallel with the current method would merely exacerbate existing disagreement and confusion. 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.**

[57] Commission Decision 2002/225/EC

[58] Ev 33

[59] Ev 33

[60] Ev 52, Ev 53

[61] Ev 81

[62] Ev 33

9 Conclusions and recommendations

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)

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)

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)

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)

5. We welcome the FSA's decision to allow zoning of shellfish beds in order to mitigate the effect of closures on the shellfish industry. 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)

6. It is important that the respective roles of the Food Standards Agency and food authorities are clarified. The Government should require the FSA to explain fully, and in public, the reasons behind its decisions in respect of closures. (Paragraph 30)

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)

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 principle 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)

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

Formal minutes

Wednesday February 2004

Members present:

Mr Michael Jack in the Chair

Mr Colin Breed	Alan Simpson
Mr David Drew	David Taylor
Mr Mark Lazarowicz	Paddy Tipping
Mr Austin Mitchell	Mr Bill Wiggin

The Committee deliberated.

Draft Report [*The Food Standards Agency and Shellfish*], proposed by Mr Mitchell, brought up and read.

Ordered, That the draft Report be read a second time, paragraph by paragraph.

Paragraphs 1 to 38 read and agreed to.

Summary read and agreed to.

Resolved, That the Report be the Fifth Report of the Committee to the House.

Ordered, That the Chairman do make the Report to the House.

Ordered, That the provisions of Standing Order No.134 (Select committees (reports)) be applied to the Report.

Several papers were ordered to be appended to the Minutes of Evidence.

Ordered, That the Appendices to the Minutes of Evidence taken before the Committee be reported to the House.–(*The Chairman*).

Several memoranda were ordered to be reported to the House.

The Committee further deliberated.

[Adjourned till Wednesday 3 March at a quarter past Two o'clock.

Witnesses

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List of written evidence

List of unprinted written evidence

Additional papers have been received from the following and have been reported to the House but to save printing costs they have not been printed and copies have been placed in the House of Commons library where they may be inspected by members. Other copies are in the Record Office, House of Lords and are available to the public for inspection. Requests for inspection should be addressed to the Record Office, House of Lords, London SW1 (tel: 020 7219 3074). Hours of inspection are from 9:30am to 5:00pm on Mondays to Fridays.

The Shellfish Association of Great Britain (appendices)

Dr CG Askew (appendices)

Rory Parsons (appendices)

Carmarthenshire County Council (appendices)

Kershaws Frozen Food Ltd (appendices)

Canterbury City Council (appendix 2)

JH Loose (annex)

Food Standards Agency (annex 3)

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Oral evidence

Taken before the Environment, Food and Rural Affairs Committee

on Monday 19 January 2004

Members present

Mr Austin Mitchell, in the Chair

Ms Candy Atherton	Mr David Drew
Mr Colin Breed	Alan Simpson

Memorandum submitted by the Shellfish Association of Great Britain (M5)

SUMMARY

Transfer of DSP testing to CEFAS, Weymouth, in June 2001 coincided with false, "atypical" positive response to mouse bioassay. The mice died within minutes as a result of a convulsive CNS reaction symptomatic of solvent carryover. The response could not be duplicated on the same material at other EU laboratories. Similar procedural or artefactual responses have been recorded in many countries but eliminated or replaced by chemical testing. An empirical approach to quickly determine the implication to human health was ignored by the FSA which pursued a supposed novel toxin. The intent of the EU Directive is to monitor for specific named toxins associated with specific planktonic algae. CEFAS showed lack of due diligence in modifying the established bioassay and there was no basis for the FSA presumption of a new toxin and the closure of cockle fisheries. The economic impact on the cockle industry was huge. After two years, the FSA submitted to independent audit and solvent studies. These identified widespread procedural malpractice and the carryover in the bioassay of ether and acetone solvents, and "dirty water" from the cockle matrix, all of which the test is designed to remove if conducted properly. The presence of solvents is consistent with the anaesthesia and rapid death in mice. Independent peer review confirmed the serious non-conformance, outside the terms of the licence to conduct the test. The Home Office demanded the immediate elimination of solvent carryover. A comprehensive technical analysis by FRAME confirmed the gross misuse of animals and ill-judged application of science; it recommended actions to ensure the abuse could never happen again. Industry has proposed a bio-security programme (CIVIT) which uses only best practice non-animal methodologies and gives better consumer safety than the mouse bioassay. The FSA misapplication of the precautionary approach, poor science and lack of transparency has serious implication for all FSA/CEFAS food safety work, and the lack of control on the use of animals to wider testing programmes.

1. *Background*

Diarrhetic Shellfish Poisoning (DSP), together with Paralytic Shellfish Poisoning (PSP) and Amnesic Shellfish Poisoning (ASP), testing on cockles and other bivalve molluscs in England, Wales and Scotland was conducted by Fisheries Research Services (FRS, Aberdeen) operating under the National Reference Laboratory (NRL) for toxins from 1996 to June 2001. Following tender, the contract for England and Wales was awarded to the Centre for the Environment, Fisheries and Aquatic Sciences, Weymouth (CEFAS) in June 2001. CEFAS unilaterally modified the testing methodology, failing to include safeguards adopted to minimise false positives, and from the beginning produced what they described as "positive" results. Industry registered concern at the integrity of the results. For one year, the Food Standards Agency (FSA) did not declare that the responses were atypical and the results were recorded as positive DSP. In June 2002, the FSA advised that the mice had been dying as a result of a convulsive central nervous system response within minutes of injection. The normal diarrhetic positive response is death between 2 and 24 hours. The mice died long before a DSP test was completed and thus false positive results could have camouflaged positive results for real DSP which would have triggered product recall. Cockle fisheries in England and Wales were closed on FSA advice following the atypical positive results; the FSA advocated a precautionary approach to the possible existence of a novel toxin but continued to describe the result as "atypical positive for DSP". Industry queried how the transfer of testing to CEFAS coincided with areas as far apart as South Wales, the Thames and the Wash becoming simultaneously contaminated.

2. *Failure to Duplicate Results*

FRS continued to conduct DSP testing on Scottish cockles after June 2001 using its established method. The atypical false positives at CEFAS, Weymouth, were not experienced at FRS Aberdeen and duplicate cockle samples sent to Aberdeen from closed fisheries in England and Wales could not replicate the atypical result. Industry also undertook duplicate testing in Holland and France using split samples, and has never replicated an atypical response. From the beginning, the NRL requested the FSA to undertake tests on possible solvent carryover but the FSA failed to do this. Industry also advised FSA that the death was symptomatic of solvent carryover response. The "atypical result" has never been experienced when a proper extraction procedure has been in place.

3. *Non-uniformity in Testing*

The FSA accepted that the FRS test was in accordance with the EU Directive. Product from Scotland, Holland, France or New Zealand is brought into England and Wales without being subjected to the CEFAS test. Ninety percent of UK cockles are exported to EU Countries.

4. *International Modification to Testing Methodology*

Similar anomalies using the DSP intra-peritoneal mouse injection (MBA) have been recorded in most countries, particularly on cockles. All modified the test to address the random procedural or artifactual responses, or changed to chemical testing (by liquid chromatography mass spectrometry (LCMS)), having established the necessary reference standards. Holland and Germany do not use the mouse test on animal abuse principle. France, Spain, Portugal, Ireland, Italy, New Zealand and Canada have modified procedures to ensure that solvent is not carried over. Ireland, New Zealand, Canada, and the US have adopted LCMS for the monitoring programme, retaining a modified mouse test for background screening only. FRS is equipped to undertake a similar LCMS programme. Yasumoto, the Japanese chemist responsible for devising the mouse test, has publicly recorded at international conference that the test is unreliable, particularly with cockles, and should be replaced for routine monitoring by LCMS as quickly as possible.

5. *Identification of Implication to Human Health*

In January 2003, the Shellfish Association of Great Britain (SAGB) presented FSA an empirical approach to identify whether the atypical response was procedural, artifactual, toxic only to mice, or toxic to humans. The principle that human toxicological risk of the causative agent of the atypical MBA result can be reasonably assessed by oral application of test material to rats was accepted by the FSA. Yasumoto had agreed to conduct the testing at no cost in October 2002 but the FSA has yet to supply the material. The SAGB also arranged for the Dutch Authorities to conduct oral testing to any FSA prescribed operating procedure. The SAGB also queried sample transport conditions without ice, noting that cockles were mailed (Post Office) live and dry in polythene bags causing stress and likely degradation. The Agency undertook to implement the empirical work at a meeting on 15 January 2003. A reputable drug company could complete this work in four weeks. The FSA also agreed to consult closely with industry on proposed experimental work and modification to standard operating procedures. The FSA did not do this and instead pursued possible routes towards identification of a novel toxin with implication to human health and did not attempt to rule out solvent carryover or an artifactual reaction in mice to something emerging from the cockle matrix.

6. *Intent of EU Directive*

The intent of the relevant Directive 91/492 to permit free trade in bivalve molluscs within Europe, without disparity, whilst protecting public health in a consistent way throughout Europe. Article 2 defines "Marine Toxins" as poisonous substances accumulated by bivalve molluscs feeding on plankton containing toxins, naming the specific toxins. It requires avoidance of malpractice with regard to origin and destination, checks on microbiological quality, checks for toxin producing plankton and biotoxins in live bivalve molluscs, and for chemical contaminants.

7. *Absence of Associated Algae*

At no stage during the 30 month period have the algae associated with DSP (*Dinophysis* spp or *Prorocentrum lima*) been significantly present in any waters testing atypical positive. In France, testing for the DSP toxin only begins when a relevant associated algal bloom is present. CEFAS appears not to have undertaken any additional phytoplankton monitoring in order to identify any DSP causative organisms.

8. *Abuse of Power*

The SAGB contends that the FSA has no powers to enact a precautionary closure if it is not for a named biotoxin covered by the Directive or a contaminant as separately defined. The Home Office licence is issued to conduct the specific DSP mouse bioassay and the killing of mice to seek a possible novel toxin appears to be an abuse.

9. *Lack of Due Diligence*

The Shellfish Association of Great Britain (SAGB) suggests that CEFAS had not shown due diligence in modifying the mouse bioassay (MBA) from that used under NRL supervision by the FRS, with regard to:

— Possible solvent carryover resulting from the removal of the overnight stand and other safeguards;

— Possible particulate matter carry-over from inadequate filtration;

— Possible increase in aqueous-soluble fraction resulting from vigorous shaking in a separating funnel;

— Fifty percent increase in ether volume without proportionate increase of distilled water backwash.

Aqueous fractions are not the subject of the DSP test and should not be present in the final injected extract. The final water backwash is specifically to remove water-soluble fractions. The CEFAS method uses the least water volume of all member states and appears to be insufficient to remove all aqueous fractions.

10. *Discrepancy in Interpretation of Directive*

Commission Decision 2002/225/EC of 15 March 2002 lays down the rules for the chemical detection of named marine biotoxins including the DSP complex. The latter consists of Okadaic Acid, Dinophysistoxins, Yessotoxins, Pectenotoxins and Azaspiracids. Article 5 states that when the results of the analyses performed demonstrate **discrepancies** between the different methods, the mouse bioassay should be considered the reference method. When chemical analysis has demonstrated the absence of all the above DSP complex, but mice die rapidly in a way which is totally inconsistent with DSP poisoning and prior to the end-point of a DSP test having been reached, there is *per se* a **"discrepancy"** between the methods. In such circumstances, the FSA is incorrect in insisting that the mouse test has priority as the reference method.

11. *Lack of Basis for the Presumption of a New Toxin*

Prior to the meeting convened by the FSA on 1 October 2003 to present the results of its findings, the SAGB strongly contended the FSA presumption of a new toxin in the light of:

— Consequences of the CEFAS modification to the MBA test;

— A multitude of substances definitely non-toxic to humans, are known to give positive reactions during mouse bioassay;

— Other Countries, including other EU Member States, have not presumed procedural or artifactual mouse bioassay problems to be due to a new unknown human toxin;

— Failure by the FSA to initiate studies to either verify the presence of a novel toxin or to investigate its source organism;

— Dutch cockles, not subject to mouse bioassay, are not subject to the same investigation on importation;

— No human response has been observed among those consuming cockles throughout the thirty month period;

— The failure by FSA to verify results using duplicate testing and controls;

— Parallel industry testing conducted on CEFAS "atypical positives" produced confirmed negative results at all other laboratories;

— An FSA modified MBA operating procedure imposed on FRS in June 2003 produced rapid mouse deaths at the FRS laboratory;

— Confirmation by CEFAS and FRS technicians that there was a clear solvent smell when mice died rapidly. This was also identified by the Rowett Vetinerary staff who concluded that the mouse deaths are symptomatic of central nervous system disorder due to solvent presence;

— There is absolutely no evidence that the unknown agent which is causing the mice to die is toxic to humans.

12. *Implications to Industry*

The closures of the main cockle fisheries in Burry Inlet (South Wales), the Thames (Leigh on Sea) and Wash has had huge economic impact on fishermen, processors and marketing companies. It has decimated an industry employing more than 2,000 people and with final value added sales around £20 million per year. Burry Inlet was totally closed for 14 months, with the exception of two weeks, before industry initiated zoning was accepted by the FSA. The repeated closures in the three major fisheries have resulted in overexploitation of small cockles and failure to take, and subsequent loss of, large cockles. Stock structures are no longer in equilibrium with optimum exploitation. The value of small cockles is less than half that of large cockles. The discontinuity of regular supply for contracts resulted in loss of premium prices and the customer in some cases. Business planning became impossible. The closures have also damaged the reputation for the integrity of the product in the market.

13. *FSA Reports*

Independent audit of the three laboratories (CEFAS, FRS and DARD (Department of Agriculture and Rural Development)) by Professor Makin and studies on solvent carryover by the Macauley Institute and Central Science Laboratories (CSL) were published by the FSA on 1 October 2003.

14. *The Makin Report*

This identified many areas of quality assurance concern and lack of quality controls. Makin identified significant variations in procedures between and within the three laboratories, many operator deviations from the standard operating procedures (SOPs) and different MBA end points at each site. He expressed specific concern relating to the DSP analyses at CEFAS and surprise that the deviations from the SOP had not been addressed by CEFAS quality management or the United Kingdom Accreditation Authorities (UKAS). Makin criticised the failure to use control samples or any attempt to demonstrate reproducibility. Critically, he noted the formation of emulsions and "dirty water" carryover at CEFAS. This would inevitably result in the transfer of compounds from the cockle matrix into the mouse injection extract. He observed the clinical symptoms in mice which were wholly consistent with an anaesthetic effect.

The FSA has yet to explain how a confirmed DSP negative audit mussel homogenate produced positive symptoms or death at all three laboratories, as observed by Makin.

15. *Misleading Conclusion*

Makin's overall conclusion that "no evidence emerged from the audit that the atypical response is due to the presence of ether" does not correspond with the detail of his observations and is misleading. On 13 November 2003, Makin verbally agreed that he could equally have concluded "that no evidence has emerged that a novel toxin is responsible for the atypical response". He denied FSA influence in reaching his earlier conclusion. The FSA retains total editorial control and ownership of contracted research apparently without provision for peer review.

16. *Solvent Carryover Reports*

The Macauley and CSL reports both showed conclusively that there was substantial ether and acetone carryover occurring in the DSP MBA, particularly at CEFAS. Although variable, the solvents were often at high levels. On 16 October 2003, the Home Office confirmed its concern at the high level of solvent (ether and acetone) found in the material injected into mice. It stated that a high level of ether, sufficient to cause the clinical signs, was found in many samples, while levels above the LD50 were found in some samples. The Home Office stipulated that it is essential that immediate steps be taken to eliminate the problem of solvent carryover and requesting what measures are being taken to ensure that ether and acetone are not present in the injectate used in the mouse bioassay for DSP.

17. *Independent Peer Review*

Industry sought independent "high level" peer review and analyses of the FSA reports which were undertaken by Mackenzie, Cockrill, Parsons and Askew, Appendices III to VI [Not printed]. All were presented at a meeting with Local Health Authorities on 15 October 2003; the FSA was invited but declined to attend. The papers confirmed a liturgy of malpractice, multiple solvent and cockle juice carryover and resultant anaesthesia, yet rapid recovery of animals that did not die. The synergistic effect of acetone and ether combined, transfer of cockle water and a possible cockle factor were the very likely cause of the atypical response. It constituted serious non-conformance with the MBA protocols and the atypical positives should have been totally disregarded as in other Countries. The DSP MBA was specifically designed to exclude solvent, water and cockle juice and tests should have been immediately suspended until

nil solvent carryover was demonstrated; to continue without this, the assay is useless. The New Zealand Authorities advised the FSA on 13 June 2003 that vacuum drying of extracts to constant weight was required to remove the risk of solvent residues affecting results.

The SAGB contends that the standards expected of Government Laboratories falls far short of those expected from private Laboratories.

18. *Procedural Mechanism for the Malfunction of the Bioassay*

The procedural mechanism by which water transferred to the injectate has been described separately by Askew. The cockle factor may be associated with the stress caused in transporting the samples which are **mailed (GPO),** live and dry in polythene bags from the fishery to the laboratory. Cockles tend to stress more than other molluscs because of their small size and low tolerance to dessication. Such stress can cause the production of biogenic amines (eg histamines or other neuroactive compounds extracted by the acetone (Mackenzie)). In other countries, cockles are delivered by the quickest route **in ice** with temperature recorders; samples are rejected if the cockle meat ever exceeds 10°C (Smales, pers com).

19. *Non-conformance*

Mackenzie has presented a further paper "What is different about cockles? Methodological hypotheses for the atypical response" (Appendix VII)[Not printed]. He concluded that failure to ignore seriously non-conforming data was a significant departure from good analytical practice and from UKAS accreditation. The paper analyses the competing hypotheses and overwhelmingly concludes that an artefact is responsible for the atypical response. The FSA is actively "spinning" against this despite weight of evidence for it. There is absolutely no evidence for the presence of a cockle toxin, the mouse response corresponds closely to human solvent abuse deaths, and Occam's razor points to artefact as the cause.

20. *Misuse of Laboratory Animals*

Industry has repeatedly advised the FSA that the lack of reproducability, absence of controls and non-conforming data constituted a failed result outside the terms of the licence to conduct the test, and hence a misuse of laboratory animals. This advice has been treated with contempt. A comprehensive peer reviewed technical paper describing the gross misuse of animals and of scientific methodology has now been independently produced by the Fund for the Replacement of Animals in Medical Experiments (FRAME) (Combes, ATLA, 31, 1-16, 2003 at Appendix VIII.)[Not printed]. The paper critically assesses the development, regulatory use and methodological deficiencies of the MBA. It discusses how testing for DSP toxins could and should have been improved and made more humane by applying the Three Rs concept of Reduction, Refinement and Replacement, and by the proper validation of the test method used. It concludes that the MBA should not have been developed for the routine screening of shellfish samples, as it has a substantially severe endpoint (death) and is not used as part of a tiered-testing strategy with non-animal methods. It states that during the UK monitoring programme for DSP toxins, the assay has been used without an optimised and universal protocol, and apparently without due regard to the principles of basic scientific methodology. In view of this, the atypical results obtained for cockle samples cannot be relied on as evidence of a human health hazard. It recommends how to replace this gross misuse of animals and ill-judged application of science to ensure that it is never allowed to occur again. Subsequent to this, the SAGB notified the Parliamentary Bioethics Committee of its concerns over the FSA response to its alerts on animal ethics aspects (Appendix IX)[Not printed]

21. *Industry Initiative*

Throughout the 30 month period of closures, industry has actively sought to be positive and proactive towards a resolution despite the negative and single minded FSA self-justification of its own mal-administration. Industry seeks only to ensure the safety of its cockle products and the growing problems of the Government monitoring has required the development of its own bio-security programme, CIVIT, Cockle Industry Voluntary Initiative on Toxin Testing (Appendix X)[Not printed]. CIVIT will provide a state of the art consumer protection, comfortably exceeding that provided by Government monitoring. It will put the UK cockle industry in the lead with regard to consumer safety within Europe, based on the most advanced non-animal methodologies in line with best international practice. The FSA has yet to comment on the CIVIT proposal. The FSA is resisting acceptance of chemical testing despite FRS being equipped to undertake the work.

22. *Misapplication of the Precautionary Principle to a Flawed Test*

The precautionary principle has been misapplied by the FSA, used as a scapegoat for its inability to address the procedural/artefactual causes of the MBA response. Industry believes that the Agency now believes its own spin, seeking control to camouflage extremely poor science. It is paranoid about the release of information. For the past 10 years, Industry has worked closely with FRS, the NRL, and with

Environmental Health Officers, but the FSA has banned communication, going so far as to threaten Officers under the Official Secrets Act. The FSA has introduced new SOPs (June and November) supposedly to prevent solvent carryover but "unofficial" communication with the laboratories indicates that this is not being achieved. The FSA fails to accept that the basic methodology is flawed and has deviated so far from the prescribed method as to fail to meet the Directive. The developed World is now using non-animal chemical methods; New Zealand Government recently introduced its fully validated chemical testing regime, stating that the use of mice is fraught with scientific validity and animal welfare issues. It stated that the mouse bioassay also produces false negatives which is an even greater risk to food safety.

Is it reasonable to apply a precautionary principle after 30 months without any substantiated evidence?

23. *Implications to Other Areas of Work*

There is concern that the poor scientific, transparency and consultative standards demonstrated on the DSP MBA issue applies to other areas of the FSA/CEFAS food safety work. Although the need for FSA independence is appreciated, it is imperative that central FSA control on funding does not jeopardise the integrity of scientific research. DEFRA must also be independent to represent industry. The lack of control on the use of animals also has major implication to the integrity of the diverse animal testing programmes conducted in the United Kingdom. Most foodstuffs subjected to 30 months of intensive analysis for a novel toxin would yield a result, but cockles have not.

6 January 2004

Memorandum submitted by Dr C. G. Askew (M6)

TESTING REGIME FOR DSP SHELLFISH TOXINS IN GREAT BRITAIN

Executive Summary

"Atypical DSP" is a response which to date has only been observed in injected mice when laboratories have used extraction methods with known failings.

The Makin and FSA/Macaulay reports show clear evidence of four major failings in the extraction procedures in use at the time;

- Solvent carryover
- Water carryover
- "Dirty" extract produced at CEFAS
- Minimal water backwash.

When testing began at CEFAS, 5 significant changes were made to the extraction technique, but only three of these have been highlighted by FSA. Prof Makin's report provides the evidence that a more vigorous shaking in a conical flask, rather than swirling in a round bottom flask, was instituted at CEFAS. The relative volume of the distilled water backwash was reduced, because of an increase in the volume of ether used. These two changes probably greatly increased the potential for "cockle juice" carry-over, resulting in this being injected into mice, instead of a pure ether extract as intended using this test. This would have invalidated the tests. The apparent toxicity to mice under the extreme conditions of the DSP bioassay does not imply a human health threat.

FRS Aberdeen had not observed the reaction using their standard procedure, which used a gentle extraction and a final over-night stand as their means of ensuring freedom from solvent carryover.

The change to a standard "Interim SOP" has reduced solvent carryover and stopped the practice of vigorous shaking at CEFAS, which produced the dirty extract.

Whilst there remain further clear shortcomings in the method used at all laboratories, and these may be sufficiently severe as to represent a deviation from "the customary" bioassay demanded by Directive 91/492/EEC, no case of "Atypical DSP" has been reported since the solvent carryover and dirty extract issues were confronted.

There is therefore currently no evidence for the existence of a new toxin and no reason to invoke anything other than former procedural failings (solvent carry-over and/or dirty extract) to explain the "atypical" response.

Until such time as the "atypical" response has been observed following proper extraction (in line with the "customary" method, with a full water backwash to remove water soluble compounds) combined with proper ether removal, there is no evidence that a toxin exists.

FSA's key statements suggesting that the CEFAS, DARD and Interim SOPs are better at extracting the as-yet unidentified toxin have no scientific validity.

Prof Makin's headline conclusion that there was no evidence that atypical DSP was caused by ether was dismissed at the meeting with FSA on 13th November and its use by FSA was misleading and unfounded. The Minutes of that meeting as currently circulated by FSA contain many errors and omissions.

The Macaulay Institute study showed evidence that water and ether carry-over were linked. They recommended that the extraction method be examined in detail. This has not been done and there appears to be nothing in current FSA research proposals to do so.

Mouse bioassay is time consuming and permits up to 5 days' catch of shellfish to be released onto the market and consumed prior to results being available. It is, therefore, only partially effective as a basis for toxin controls.

Chemical methods are now permitted by the EU. Being quicker these are more effective in protecting the public. Under Decision 2002/225/EC the mouse bioassay remains only as a reference method in case of conflictive results.

1. *History of False Positive Results using Mouse Bioassay (MBA)*

1.1 During the early 1990s, when MBA was carried out at the Torry Laboratory, Aberdeen, the Shellfish Association complained that the number of positive results for DSP was excessive and did not accord with known plankton blooms. In 1996 testing passed to FRS Aberdeen, who continued to use the method developed by Torry. At the Mollusc Committee meeting of 25 March 1998, Mr G Howard agreed that testing in the early 1990s had been subject to false positive results, but that improvements made by Torry had largely overcome these. (Ref 1) It is not clear whether these improvements, specifically designed to avoid false positives, were incorporated into the method introduced at CEFAS in June 2001.

1.2 The reasons for CEFAS undertaking a markedly different extraction procedure independent of the National Reference Laboratory (NRL), Aberdeen is unclear. Changes to protocols should only have been made with the agreement (NRL) and the European Central Reference Laboratory (CRL) Vigo. There was no suggestion initially that the Aberdeen method was unsatisfactory in sensitivity for the lipophylic substances it is intended to detect, though it differed from Yasumoto's 1984 description in having only one acetone extraction stage instead of three. The view that the CEFAS and DARD methods were more sensitive and hence able to detect a new unknown toxin only appeared *post hoc* as an FSA hypothesis after they had already been closing cockle fisheries for over year. As no atypical response has been reported since steps were introduced to reduce ether carry-over, there is to date no evidence for the existence of any unidentified toxin, nor any valid reason to invoke one.

2. *Changes in Method between FRS and CEFAS*

2.1 Until the publication of the FSA Updating Report of December 2002 no detail was available of the differences in methods being used. This report highlighted three changes which they considered significant;

1. From a single stage acetone extraction using 225 ml acetone to a two-stage extraction, each of 100ml.(Closer to Yasumoto's 1984 description of 3 stages).
2. From a two stage to a three stage ether extraction. (Closer to Yasumato's description)
3. Different procedure for removing ether from the final extract, deleting the over-night stand used at Aberdeen to ensure freedom from solvent (ether) carry-over.

However, Prof. Makin's Report showed other significant differences, including a change in the extraction method from gentle swirling in a round-bottom flask to shaking for up to 20 seconds in a conical separating funnel. This risks formation of emulsions, which would make the technique invalid. The 50% increase in ether volume also further reduced the already "token" water backwash, increasing the potential for false positive results.

Following reports by lab staff at FRS/Rowett of ether being smelt in the extract immediately prior to injection, the possibility that the atypical response was being caused by ether was raised by shellfish industry representatives. By this time, cockle fisheries had been closed many times by FSA on a presumption that the atypical response indicated a new unidentified toxin.

2.2 The conclusions reached by FSA in the Dec 2002 Updating Report had no scientific basis: they were selectively made on a presumption of a new toxin. The key statements that "This confirms that a single extraction using a large volume of acetone produces negative results" and "it was clear that the use of two extractions increased the sensitivity of the method to detecting toxicity" have not been justified by a controlled comparison changing this factor alone. The change was only one of several and whilst the 2-stage acetone extraction now being employed is more correct and is closer to the "customary" method, there is no evidence that this change has any bearing on the "atypical DSP" problem. Overall, the changes made at CEFAS greatly increased the possibility of false positives (See Annex) [Not Printed]. The implication in the Dec 2002 Updating Report that, because the two-stage acetone extraction is better, the whole of the CEFAS method is better, is highly misleading. Over-riding failings which led to the production of dirty extract at CEFAS emerged in the Makin and FSA/Macaulay Reports.

2.3 Similarly, the assertion that solvent carry-over was unlikely because ether is highly volatile was subsequently shown to be untrue by their own work (FSA/Macaulay). The great difficulty all labs are now having in attempting to ensure freedom from solvents is evidence of this.

2.4 Nothing was done to investigate the likelihood of false positives. The key statements made in the December 2002 Updating Report have no scientific basis.

Detail of other changes in method, some of which are now seen as highly significant, were not made available until the Makin and FSA/Macaulay reports were released on 1 October.

2.5 These reports together showed clearly that water was being carried over and injected into mice. The fact that the extracts at CEFAS were also described by Prof Makin as "dirty" shows that substances other than the desired ether extract had been picked up at the solvent extraction stages and were being injected into mice at CEFAS Weymouth. The "water" being carried over was actually "cockle juice", containing aqueous soluble fractions which proper extraction is designed to exclude.

2.6 Scrutiny of Prof Makin's report identified a major unreported change in method which would account for the increase in "juice carryover" and hence increase the probability of false positive results. This change appeared minor, from gentle swirling of the shellfish extract with ether in a round bottom flask, to shaking them in a conical separating funnel. However, in combination with Prof Makin's own comment that emulsions can form when water is shaken with ether in a separating funnel, it becomes clear that this change increases the probability of emulsion formation, which would directly account for the cockle juice carryover. It is now clear that the method adopted unilaterally at CEFAS (up to 20 seconds of shaking in a separating funnel) greatly risks emulsion formation. This accounts for the "dirty" extract, which should never have been injected into mice. Prof Makin suggested this ("This suggests the possibility that CEFAS are getting water carry-over, perhaps because of the way that CEFAS carries out the extraction (slightly more vigorously shaken than FRS and DARD, who use gentle swirling action). (Appendix I) [Not Printed].

2.7 Examination of the linkage between the original "Yasumoto 1984" method and those used in the UK (the "original" Torry/FRS method and the CEFAS and DARD methods), together with observations of necessary modifications made in other European member states, showed that the UK has drifted a long way from the "customary" mouse bioassay required by the Directive 91/492. Furthermore, the changes summate to producing greatly increased risk of false positives and contain no precautions to avoid emulsion formation and "juice carryover". The most significant observations are:

1. The reference given by FSA to Yasumoto 1984 is not to a working method; it simply gives a 9 line description of mouse bioassay involving 3-stage extraction with acetone followed by ether. The UK does not use a 3-stage acetone extraction. (Ref. 2) [Not printed].

2. The internationally "most commonly used assay method for DSP toxins" (ie the "CUSTOMARY" Method), was that published by the Japanese Ministry of Health and Welfare (1981), developed by Prof. Yasumoto and described in the Intergovernmental Oceanographic Commission Manual and Guidelines No 33, Manual on Harmful Marine Algae (UNESCO 1995). (Ref.3) [Not printed] This details a fundamental relationship between the weight of sample analysed, the volumes of solvents to be used and the final distilled water backwash to remove aqueous soluble compounds. For a 100g sample of shellfish flesh (as used in the UK) a water backwash of 100 ml is specified. The volume of water used in the UK is 5 ml, but in practice is not even measured and is simply "a squirt from a wash-bottle".

3. The origin of the minimal 5 ml water backwash used in Britain has not been provided. All other member states use much larger volumes of water. There is no suggestion that a larger volume of water backwash in any way decreases the sensitivity of the method to DSP toxins.

4. The problem of emulsion formation is specifically recognised in other member states. The Standard Operating Procedure used in Italy states that it is essential to pre-saturate the solvents with distilled water, otherwise dark emulsions can be formed. Pre-saturation would reduce the uptake of shellfish juice by the solvents. Again, there is no suggestion that it would reduce the sensitivity of the assay to the toxins it is intended to detect. It would reduce the likelihood of false positive results.

5. The Italian SOP also stresses the importance of carrying out the ether extraction delicately.

2.8 Examination of the Makin Report and the FSA/Macaulay reports shows technical shortcomings of all three methods used into the UK up until the introduction of the "Interim SOP", which is essentially the DARD SOP. These are:

FRS Appropriate gentle extraction technique was used but this was followed by inadequate backwashing which can create an emulsion. The evaporation stage was inherently poor but compensated for by the over-night stand.

CEFAS Excessive shaking in a separating funnel at the ether extraction stage creating high risk of emulsion formation. Insufficient time to clear, not in accordance with SOP. Distilled water backwash at best inadequate and if emulsion has formed non-functioning. Solvent evaporation inadequate to remove bound solvents. Poor solvent removal.

DARD Less vigorous shaking in a separating funnel. Still evidence of emulsion formation. Backwash too small and probably too gentle to function completely.

The new Standardised SOP confronts only the problem of solvent removal and avoids the excessive shaking used by CEFAS. The other shortcomings identified in the DARD SOP inherently remain in the new SOP (risk of emulsions plus inadequate backwash). Simply removing solvent at the end also removes evidence of associated water/juice carryover if all originate from the same basic problem of emulsion formation.

New Zealand has confronted this problem in a simple way, by vacuum drying extracts to a constant weight. FSA was advised of this by Helen Smale of the Marborough Sound Quality Programme in June this year.

3. *Failure to use a "Customary" Assay as Required by Directive 91/492*

3.1 The original directive 91/492 (ChV .7) states "the Customary biological testing methods must not give a positive result to the presence of Diarrhetic Shellfish Poisoning(DSP) in the edible parts . . ." The word "customary" must place some limitation on the freedom to use new methods, otherwise they will not be "customary". Whilst the Annex of EU Decision 2002/225 does not refer to "customary" methods, the decision is not concerned with changing the bioassay regime; it is simply setting numerical standards to be applied when chemical methods are used. The reference to "the mouse bioassay" in Art 5 is therefore to the "customary biological testing methods" in the original Directive and in the first "Whereas" of the decision.

3.2 The DARD SOP is a new bioassay method, developed without reference to Yasumoto's original method, (At the FSA meeting on 13 November the DARD representative said he had not seen the UNESCO International Manual). That method is described as being "The most commonly used assay method for DSP toxins". A prime principle of the method is that there is a relationship between the sample weight, the volume of solvents and the volume of distilled water for the backwash. The new SOP loses this relationship, because it modifies the volumes of solvent without compensating the volume of water, which is now too small by a factor of 20 (See Annex II) [Not printed]. It has also changed from the established FRS method because the ether extraction is carried out in a separating funnel, not a round-bottom flask as FRS. It is therefore not the "customary" method in either UK terms or international terms.

4. *Failure to Protect Public Health*

4.1 The mouse bioassay relies on samples taken on a Monday being analysed and reported by Thursdays or Fridays. During the intervening period the fisheries remain open (unless closed by a previous weeks positive result). If a toxin were present, the many tonnes of cockles harvested in the intervening days would have caused illness among consumers. None has ever been reported. The fact that FSA have rarely insisted on product recalls for those days suggests that they do not consider the "new toxin" to present a significant consumer risk. It is apparent that the Local Authority EHOs are unconvinced of the evidence for a new toxin. This has led to the entire toxin monitoring system, particularly in respect of DSP, losing credibility. In the event of a genuine DSP alert it is now less likely that appropriate action would be taken. The overall effect is a lowering of the effectiveness of public health controls for DSP.

4.2 The one justification quoted by FSA is the "Precautionary Principle", backed by Prof Yasumoto's observation of a possible new mouse toxin. His observation of the presence of a "polar" (water soluble) substance toxic to mice by injection is entirely consistent with Prof Makin's observation of "dirty" extract at CEFAS. This would contain water soluble compounds, including many neuro-active ones liable to be toxic to mice by injection under the extreme dose used in the DSP test. Such substances simply should not have been present in the extract tested for DSP. The test involves a massive injected dose (equivalent to injecting an extract made from over 100kg of cockle flesh, i.e. 1/2 tonne of live in-shell cockles into a 12 stone human being) so very small quantities of biologically active compounds such as histamines can be fatal to mice when injected in this way. It does not imply any human health threat.

4.3 Prof Yasumoto's further observation after his visit to CEFAS, that the substance he was observing could be partitioned into a chloroform fraction (implying that it is an organic-soluble, not water soluble compound) is questionable in the light of Prof Makin's later evidence of poor fractionation techniques employed at CEFAS.

5. *Is the FSA Hostage to its own aspirations?*

5.1 From its inception the FSA has gone to great lengths to stress its independence, transparency and scientific decision-taking process. These are laudable intentions, but carry risk if the reality becomes subject to criticism. What may have begun as a simplistic assertion of potential consumer risk if a new toxin had appeared, has after 30 months without evidence of a toxin, exposed severe shortcomings in the control of mouse bioassay in the UK. Some of these shortcomings date back to the Torry method (eg Minimal water backwash, failure to pre-saturate solvents), but others arose with the failure of NRL to oversee the methods introduced at CEFAS and DARD, as criticised in the EU Mission Report.

5.2 Prof. Makin may be independent, but his conclusion that "No evidence emerged from this audit to support the view that the atypical response is due to the presence of ether . . ." was guided by the wording of the question he was presented in his terms of reference. He admitted this at the meeting with FSA on 13th November, when he agreed that the opposite conclusion could also have been stated, i.e. there was no evidence that it was not caused by ether. In reality his audit contained no evidence concerning the cause of atypical response, because it did not appear in the analyses of the audit homogenate samples undertaken; (he did observe the response "in passing" as a cockle sample happened to be undergoing assay during the

time he was at the CEFAS laboratory). Nevertheless, FSA used his headline conclusion uncritically in a misleading way. It certainly had no scientific basis and may be regarded as a subversion of scientific principle. FSA are now faced with having to acknowledge these mis-uses of claims purporting to be scientific. This will be an embarrassment in the light of their aspirations, but to continue trying to justify such misleading claims will be even more damaging, to FSA, industry and all involved. It is vital that truly independent organisations are used to uncover the truth and resolve the situation.

5.3 Conclusions drawn by FSA in the Dec 2002 Updating Report and FSA's quotation of Prof. Makin's unfounded conclusion all point to attempts to justify the pre-conceived assumption of a new toxin, to the exclusion of the more likely hypothesis of juice and or solvent carryover. In the meantime the "transparency" credentials of FSA are also evaporating, as staff have now been instructed not to discuss the question. The latest proposals from FSA to identify the cause and test for oral toxicity to mice continue to lack scientific rigour, being based solely on the presumption of a new toxin and are prejudiced by a presumption of the outcome. (Appendix III) [Not printed]

6. *Considering Future Options Free of Prejudice*

6.1 In the long term the greatest damage being done is that FSA now seem unable to consider progressive solutions to the toxin monitoring question as they are so deeply entrenched in the view that "we are right". EU decision 2002/225/EC clearly opens the way to permit testing by chemical methods rather than mouse bioassay. The methods used can detect lower levels than the mouse test, and so give a view of developing toxic algal bloom situations, giving a degree of advance warning. Prof. Yasumoto said in June 2002 that the time had come to rely on chemical methods and some countries have already moved to this.

6.2 Chemical testing returns quicker results. This is the most important factor in protecting public health. As mentioned above, very few product recalls have been demanded following publication of positive results at the end of a week, so the reality is that the current controls leave open a wide window for product to go onto the market without being subject to toxin controls.

6.3 Leading shellfish producing countries such as Ireland and New Zealand have reacted progressively to the development and routine use of chemical testing (LC-MS) as their prime method of control. Mouse bioassay continues to be used on a much smaller scale for research. Professor Yasumoto is on record as saying that the time has come to rely on LC-MS. The EU permits the import of New Zealand Green Lip Mussels tested only by chemical means, without resort to mouse bioassay. In the meantime, FSA staff have stated (FSA Meeting Aviation House 1st October 2003), "I think you are wrong to assume that chemical testing will replace it (the mouse test). It won't, ever."

6.4 The argument that we do not have access to a complete set of chemical standards has been put forward by FSA for at least eighteen months since Prof. Yasumoto made his statement about placing reliance on LC-MS. Whilst other countries have progressed this, the UK has concentrated all effort getting its three laboratories to adopt a standard method for mouse bioassay and have only succeeded in producing a fundamentally flawed "Interim SOP", which may not constitute a "customary" method as required by Directive 91/492. This situation is unsatisfactory in respect of protection of public health, animal welfare and compliance with the pertinent EU Directive. The course being taken by FSA, solely aimed at justifying former actions and decisions appears to have no route to resolution.

6.5 To date there is no evidence for the existence of a new toxin. No atypical responses have been reported since steps were introduced to reduce ether carry-over and CEFAS' vigorous shaking was stopped. All reports of "atypical DSP" are linked to assays with clear faults.

C G Askew M.Sc. Ph.D

January 2004

Memorandum submitted by Kershaws Frozen Food Ltd (M10)

SUMMARY

— Kershaws, along with the rest of the cockle industry, has been adversely affected by FSAs actions. In our case this has resulted in a direct loss of 75 jobs.

— FSA cite the "precautionary principle" to justify their actions. However, this has not been applied within the recommended guidelines of the Commission of the European Guidelines COMM (2000) issue 1. FSA has failed to demonstrate proportionality, non-discrimination, consistency and the requisite cost/benefit analysis; as well as failing to take account of scientific developments and addressing the issue of burden of proof.

— If there was a true risk from cockles, FSA should have stopped all imports from the Netherlands harvested some 60 miles from the Thames estuary and which would have certainly failed the tests applied by FSA to UK cockles.

— FSA ignored the advice of the experienced FRS and, despite public statements in favour of transparent openness, Industry partnerships and collaborative approaches, they have been combative, dismissive and adversarial to Industry's initiatives for resolving this issue. Their public statements on the affair have not matched the scientific results.

— FSA have failed to make a genuine attempt to get to the truth of the atypical response. They have instead applied unlimited resources in an increasingly desperate and unfruitful search for evidence to support their assertion that there is a toxin present in cockles.

— FSA have used poor scientific methodology and misused animals. Animal welfare has not been properly considered as required by the Animals (Scientific Procedures) Act 1986 and they did not inform The Home Office of solvent carry-over until October 2003.

— We consider that the Industry position that the alleged toxin is nothing more than a spurious artefact caused by negligent application of the mouse bioassay has been fully vindicated by the lack of any atypical results since solvent carry-over was eliminated in November 2003. FSA only acknowledged solvent carry-over after considerable pressure from industry and still continue to deny this is the cause of the atypical response. This proves bias on the part of FSA or at least incompetence in scientific interpretation.

— Had the FSA followed the advice from industry and FRS, this problem would have been resolved within at most a few months rather than the two and a half years it has taken.

— We believe that Industry should receive appropriate compensation from the FSA for the unnecessary damage they have caused the industry. We also believe that scientific procedures within the FSA need to be radically overhauled to prevent this happening again.

1. Mr David Kershaw is a director of 3 companies. He has spent 32 years working in the shellfish industry, ensuring we place a safe product on the international market.

Mr Andrew Rattley is operations manager of Kershaws, he has spent 31 years working in the food industry, and was trained under the guidance of the Royal Society of Hygiene, the Institute of Meat and the Institute of Environmental Health Officers.

We are both highly trained and qualified in our field of food safety.

2. We attach to this submission appendices of documents marked "AR" [Not printed]. Numbers in brackets in this letter refer to the appendices numbers marked in the bottom right corner of the documents. We confirm that we wish to attend to give oral evidence to the select committee to expand on the points we make in this letter.

3. Margaret and Edwin Kershaw formed Kershaws Quality Foods in 1946. We are now market leaders in our Industry ensuring a high quality product in the United Kingdom as well as the international market. We have gained International respect and awards through our determination to be at the forefront of food safety. We are proud to be able to export 95% of our products in an industry worth more than £20 million year in export sales. However, our industry's credibility in the international market is now seriously undermined by the actions of the FSA.

June 2001—CEFAS take over the cockle tests

History of the cockle bed closures

4. The cockle industry was one of the success stories of modern Britain. Approximately 3,000 people participate in the cockle industry, mainly small businesses and self employed individuals in rural coastal areas, generating a turnover in excess of £20 million a year. The major fisheries are in the Burry Inlet, the Thames and The Wash. Our company, Kershaws Quality Foods, employs 200 people on the Thames Estuary; Rory Parsons runs a processing plant which employs 200 people in the Burry Inlet and John Lake is part of an industry in The Wash that supports another 1,600 people. These fisheries have been closed for long periods during the previous two and half years causing significant hardship and bankruptcies to those in the industry. Kershaws have made 75 people redundant and along with other companies has been forced to import Dutch cockles at a grossly inflated price in order to remain in business in the UK markets. Total losses, across the industry are estimated at £250,000 a week.

5. The crisis for the cockle industry began when the FSA transferred its testing for Shellfish toxins from the Fisheries Research Services ("FRS") Aberdeen for England and Wales to the Centre for Environment, Fisheries and Aquaculture Science ("CEFAS") in Weymouth. The algal toxin monitoring and surveillance programme for England and Wales which FRS had undertaken on behalf of MAFF since 1996 had been put out to tender by the FSA. The new programme in England and Wales started in June 2001 and CEFAS assumed responsibility for it at that time (page 1)[Not printed]. The FRS continued with the monitoring programme in Scotland. Immediately after the programme had been transferred to CEFAS, we became aware that they were obtaining an abnormally high number of positive results for DSP which led to the issue of temporary prohibition orders by the local authorities and the closure of various cockle beds. Shellfish collection bans have been in place frequently and for various periods of time since then.

6. At this stage the results were not described as being atypical. It was widely reported in the press that shellfish beds along the Thames Estuary had become contaminated with dangerous poisons (pages 2 and 3) [Not printed].

7. During the first season of cockle closures between June and December 2001, there was no question that those in the industry believed that a new toxin had been discovered. This was based on the information we were receiving from the FSA. It was only as the closures continued and further investigations were carried out by Kershaws that we began to have concerns that the results were not necessarily indicative of the presence of a new toxin, but could be due to procedural problems in the testing carried out by CEFAS. Kershaws repeatedly informed the FSA of these concerns throughout the latter part of 2001.

8. The method of testing for cockle toxins involves injecting live mice with large doses of solvent extracted cockle flesh. At CEFAS if more than two out of three mice die within a certain period then a "positive" result is reported (often this was only one out of two as CEFAS incorrectly applied the assay to only two mice if there was insufficient extract obtained). Mice were going into a fit immediately with death soon after. The evidence from abroad was that the mouse test was far from precise and was associated with false positives. Various other EU member states had refined the mouse test, as had the FRS over the years, and other countries had switched to alternate methods of testing. There was no evidence of human illness caused by the cockles.

Despite the number of atypical results,Dr Jonathan Back, Head of Food and Microbiology at the FSA, told the Shellfish Association's annual conference in May 2002 that: "The mouse bioassay is not a perfect test. But it's the only one we've got. We cannot change to a different test merely in order to get negative results. We know that there is a toxin in these shellfish which is killing mice within 5 minutes, with neurological symptoms." (page 3A) [Not printed]. Dr Back informed the conference that work was being done by CEFAS to identify the toxin but the results were some way off. The FSA have found no evidence of a toxin.

9. We do not believe that the FSA adopted a reasonable or responsible approach when the atypical results occurred. The immediate reaction of the FSA can be criticised since they were aware, or should have been aware, of the fact that the mouse bioassay test is known for producing false positives. The initial assumption of the FSA was that a normal DSP toxin episode had occurred and they proceeded with investigations to determine which toxin it was. Having ruled out known toxins they concluded that the atypical results were being caused by a new toxin. There was no review of the methodology employed at the CEFAS laboratory to check whether this was the cause. The FSA appeared to accept that it was possible that the transfer of testing to CEFAS had coincided with areas as far apart as South Wales, the Thames and The Wash becoming simultaneously contaminated. This was despite the fact that there was no evidence linking the atypical reaction of the mice with the known reaction to DSP toxins and there was no evidence of the presence of algae which are known to produce DSP toxins. Water samples, as well as cockle samples, are taken by the local councils. Throughout the last two and a half years these have not produced any evidence of poisonous algae being present in the water.

10. We have also seen no evidence of any inter-laboratory collaboration prior to the transfer of the contract to CEFAS. It appears that the introduction of the methodology at CEFAS was carried out without any reference to the previous methodology undertaken by the FRS at Aberdeen. Once the atypical results had appeared, there was no consultation with the Aberdeen laboratory.

11. By the summer of 2002, it had become Kershaws' view that the atypical results were being caused by a variation in the methodology between the CEFAS laboratory and the FRS laboratory. The FRS laboratory continued to have only negative results and the Scottish cockle beds had remained open continuously since 2001. At Kershaws' request local authorities agreed to carry out duplicate testing of the cockle samples and therefore those samples which produced atypical results at CEFAS were subject to tests at other laboratories. Independent tests of duplicate samples have also been carried out in other countries and negative results have ALWAYS been produced. None of the duplicate tests indicate the presence of any toxin in the cockles. All the tests were carried out in accordance with the European Directive and the FSA accepts that the methods are valid for detecting known toxins. The FSA gave instruction to the Local Authorities to ignore all results obtained by Industry.

12. In October 2002, further pressure from industry resulted in the FSA asking FRS to undertake a detailed paper comparison of the methodology used by the statutory testing laboratories in the UK, to ascertain what could be causing the conflicting results. In addition, the FSA asked CEFAS to organise a trial to compare the testing procedures at CEFAS, the FRS and DARDNI (the Department of Agriculture and Rural Development Veterinary Sciences Division), the statutory testing laboratory in Northern Ireland. Cockle samples were obtained from areas in the Burry Inlet and the Thames which were expected to produce atypical results. These were sent to Weymouth, split and sub-samples sent on to Aberdeen and Northern Ireland. All three laboratories undertook testing using their standard methodology and a member of the CEFAS staff travelled to Aberdeen to use the CEFAS methodology, but with the FRS laboratory equipment and mice.

October 2002 Comparative Trial between the 3 UK Laboratories

13. As one would expect there were significant similarities between the methods used by the different laboratories because they all based their mouse test on the method of Professor Yasumoto. However, there were significant differences between CEFAS, DARDNI and FRS in the procedures. The results of the trial were that FRS obtained negative results, while, CEFAS, DARDNI and the CEFAS method used at Aberdeen gave atypical results.

14. Rather than carrying out further investigations into the methodology, the conclusion of the FSA was that the method used at Aberdeen did not detect the alleged new toxin which was picked up by the CEFAS test. Most impartial observers would have thought that the FRS test should have been given greater consideration, as they were responsible for regulation many years prior to June 2001. However, the FSA stated that the FRS test methodology was wrong, as it did not detect the alleged toxin that CEFAS and DARDNI did. Despite this the FRS continued to use their methodology in Scotland on Scottish cockles and have continued to obtain no atypical results. These cockles are freely available for consumption throughout the UK. There has been no incidence of human toxicity reported.

December 2002—The FSA's "updating report"

15. On 12 December 2002 the FSA published its "updating report" in relation to the cockle bed closures. Following their analysis of the methodology used by CEFAS, FRS and DARDNI, the FSA decided that it should continue its precautionary approach in protecting consumers from the potential risk of what they believed was a new toxin. The report highlighted the studies which had been carried out and indicated at paragraph 9 that "There was no evidence to suggest that the tests giving the positive results are in any way flawed. The possibility that the positive results are due to chemicals used in the extraction process has been ruled out". Their conclusion was that "Our investigations have eliminated a number of possible causes of the atypical DSP positives observed from cockles", i.e. there was no doubt in the FSA's mind that the criticisms from Industry were unfounded (a) there was nothing wrong with the methodology at any of the laboratories (other than FRS) and (b) there was no solvent carryover. Further, when announcing the report, the newly appointed interim Deputy Chair of the FSA and the chair of the Agency's Advisory Committee for Wales said "The Agency must protect public health. This toxin could be harmful to people and that may not be apparent for many years. We have carefully considered the tests and have no doubts about the methodology used by our laboratories." (pages 4 and 5) [Not printed]. Following the points raised by the industry, this was not the response which we were expecting.

16. Having seen some of the background material which resulted in the December report being published, it appears to us that the final report does not reflect the findings of the FRS laboratory.

17. We refer to pages 6 and 7 [Not printed] which refer to the comparison of the extraction methods between CEFAS and FRS. This illustrates the differences in methodology between FRS and Weymouth. In particular there is overnight holding to ensure no solvent carryover; there is a different application of Tween 60 to put the extract into suspension and there are differences in the acetone extraction methods.

18. An initial report was compiled by CEFAS in Oct 2002 which was then commented upon by FRS (pages 8 to 12) [Not printed]. We have not seen a copy of CEFAS' initial report. Points 1 to 10 of the FRS document emphasise that the test, originally designed to detect shellfish biotoxins has not been validated and the design of the test together with the high number of variables in the methodology between laboratories means that if an atypical response is encountered, interpretation can only be speculative. The absence of a procedural control (a mouse injected with extract from a toxin-free matrix put through the extract procedure) means that it is impossible to reach a meaningful conclusion. Point 11 makes it clear that FRS did not believe that the centrifugation used by the CEFAS member of staff was adequate to remove all particulate matter.

19. It is clear from paragraphs 12 to 14 that solvent carryover is a critical issue. In layman's terms if there is even a trace amount of solvent in the injectable it may cause death. Certainly the level would be difficult to detect by smell, so if you do smell it, there is too much solvent. FRS, the Home Office, the Department of Health and the observer from CEFAS all reported smelling solvent in the extracts produced by the CEFAS method. It was also reported at this time that a member of staff from CEFAS observing the procedure at FRS confirmed that the same solvent smell in the extract was encountered at CEFAS.

20. A competent laboratory would go to exhaustive lengths to eliminate any possibility of solvent carryover and perform a simple analysis for DEE and acetone. Solvent carryover can be detected in a matter of minutes by the simplest of methods but CEFAS did not do this. Even now the FSA are not directly investigating whether solvent carryover is responsible for the atypical results.

21. Despite the references to solvent carryover, both in the FRS report and the "discussion issues" document (page 13) [Not printed], the FSA formal statement issued in November 2002 states that whilst "solvent contamination has been suggested by the industry as a potential cause of the differing results, the agency believes this is 'highly unlikely' to be the case" (page 14) [Not printed].

22. This view is further reported by the FSA in correspondence (pages 15 and 16) [Not printed]. In a letter of 13 November 2002, Joy Whinney of the FSA states that "all were agreed that solvent carryover was highly unlikely to be the cause of the atypical mouse deaths and it is concluded that "the methods used at CEFAS and DARDNI may just be better at extracting the toxic substance" (pages 17 and 18) [Not printed].

23. The information coming out of FRS Aberdeen through conversations with Godfrey Howard MBE who has served 36 years as a shellfish biologist and held the post senior shellfish hygiene manager for the past 14 years at the laboratory was different to the information being reported by the FSA. Godfrey Howard stated in a telephone conversation with Dr Clive Askew of the Shellfish Association of Great Britain towards the end of October 2002 that he believed that the way the mice were dying was consistent with solvent carryover.

24. On 31 October 2002 Godfrey Howard confirmed to Dr Peter Hunt of the Shellfish Association of Great Britain that there appeared to be solvent carryover in the Weymouth testing which pre-empted any conclusion to the DSP toxin testing (page 19) [Not printed]. A further conversation was had with Godfrey Howard on 27 November 2002 (pages 20 to 22) [Not printed] after the relevant parties had seen Joy Whinney's letter to Mr Parsons. Dr Hunt asked Godfrey Howard whether he agreed that solvent carryover was highly unlikely to be the cause of the atypical mouse deaths. Godfrey Howard replied that in his opinion the Aberdeen laboratory did not agree with this conclusion and he had not written the response to the FSA which was submitted by his colleague Dr Liz Smith. Godfrey Howard said that the Aberdeen laboratory had asked for another series of tests to eliminate the differences in methodology between the two laboratories as he believed it was the differences in extraction techniques that were causing the conflicting results. Such investigations were not carried out by the FSA until July 2003 and only then once additional pressure had been brought to bear by the industry.

25. There is no reason why comparative testing and the investigation of solvent carryover as a possible reason for the death of the mice could not have been carried out in the autumn of 2001.

26. It is clear that despite the fact that the FRS had carried out tests for over 15 years before the testing switched to CEFAS in June 2001, the FSA were more prepared to stand by the methodology at the Weymouth laboratory. They had become blinkered with the idea that it was a new toxin and were not prepared to consider the fact that it could be something else.

27. Throughout the period from January 2003 to June 2003 there were ongoing discussions between industry and the FSA with regard to issues arising from the atypical results and we believed that some progress was being made. However, none of the tests which we suggested should be put in place were accepted by the FSA.

In January 2003, following a meeting with the FSA, we arranged for a presentation to be given by Jim Cockrill (Toxicologist JRF International) at the SAGB office Fishmongers Hall London, which detailed various alternative (and more probable) explanations for the atypical response. These comprised artefactual and procedural effects (associated with the variables of the method) or possibly a non-toxic component of cockle origin to which mice reacted during the test but which had no adverse health implications to consumers. We were led to believe, from this meeting that the FSA accepted the validity of these alternative hypotheses and that they would devote (at least) equal efforts to investigating these as probable causative agents. Sadly the evidence of the last year has proved this not to be the case. Solvent carry-over (DEE and acetone), water-soluble cockle components (which must be excluded from the test extracts) and the provision for the correct cockle sampling (shipped to the Labs in good condition without deterioration) are only some of the procedural issues, which required priority investigation. These matters remain uninvestigated in whole or in part while every effort appears to have been applied to pursue the justification of the "novel toxin" concept proposed by CEFAS and the FSA.

We observe that the other competent authorities who have addressed this and the wider issue of false positives in shellfish toxin testing programmes have all made significant progress in method adaptation and animal test replacement by addressing such procedural test issues, sample collection and the quality of sample processing.

June 2003—Introduction of the new standardised test

28. In the early summer of 2003 we learned that the FSA had proposed that all UK monitoring laboratories would use the same operating procedure as from 3 June 2003. This new SOP was to be based predominantly on the CEFAS method. The position at this time is set out in an email from Ms Clare Boville of the FSA to Dr Peter Hunt of the Shellfish Association of Great Britain (pages 23 to 27) [Not printed]. Ms Boville also confirmed that the new procedure will not include any controls because the same methodology as used on other shellfish species acts as an adequate control of the methodology and she claimed that the Home Office will not allow additional tests on mice. (The Home Office deny ever making this statement).

29. As the cockle season began again in June, there were immediate closures and it became apparent that despite the ongoing discussions with the FSA, no progress had been made at all. Nothing had been done by the FSA to resolve the questions of the atypical results since the publication of the December 2002 report. By this time Kershaws and its scientists were certain that there was no known or new toxin present, but that the atypical results were being produced by the methodology carried out by CEFAS.

30. There was further support for this view when the standardised (new CEFAS) method was introduced by FRS in Scotland. It immediately produced a reaction similar to that experienced by CEFAS: the mice died very quickly.

31. Acting on instruction from the FSA Scotland and the Home Office, FRS immediately abandoned the test and reverted to their previous methodology. (Because the whole of the Scottish shellfish industry would have closed overnight) There have been no atypical results in Scotland since that time.

32. Again, there have been telephone conversations between members of the Shellfish Association of Great Britain and Godfrey Howard in June 2003 concerning the discontinuance of the new standardised protocol by FRS Aberdeen (page 28 and 29) [Not printed]. In conversations Godfrey Howard said that FRS Aberdeen was conducting an independent analysis of the methodology and hoped to have the results within one month. Godfrey Howard made it clear that the FSA had previously blocked any analysis of the methodology which was why the tests were now being carried out by the FRS. We understand from a conversation we had with him that the decision to revert to the previous testing method had been taken on advice from the Home Office advisor, the supervising vet and the Scottish FSA who had informed FRS that they should revert back to the previous method for all tests.

33. Three weeks later in July 2003 Godfrey Howard informed Dr Hunt that the formal tests which had been conducted by the Mcauley Institute to ascertain the presence or absence of solvent in the extract had demonstrated clear solvent carry-over (page 30) [Not printed].

34. For a period of over two months Industry sought a copy of the Macaulay Institute report from the FRS, the Macaulay Institute and the FSA. The position of the FSA was that the Macaulay Institute report was a small pilot study and that investigations to assess whether the methods in use at CEFAS, DARDNI and FRS resulted in ether carry-over were continuing. Only once the whole programme of work to investigate the ether carry-over issue had been completed would the results be made available. We were therefore refused access to this report for a number of weeks.

35. Despite these developments the FSA maintained a different position in their correspondence with the outside world. A good example of this is a letter from Sir John Krebs of the FSA to Chris Leftwich, the Chief Fisheries Inspector dated 6 November 2003. This states that "the agency always aims to operate in an open and transparent manner" and their general practice has been "in keeping with the Agency's policy of releasing information at the earliest possible opportunity" (pages 33 and 34) [Not printed]. The letter refers to the audit of the laboratories by Professor Makin and other recent developments.

Summer 2002—Independent audit of the laboratories

36. In July 2003, under pressure from industry the FSA finally commissioned two reports to investigate the methodology being used at the laboratories and to determine whether or not the atypical results were being caused by solvent carryover.

1 October 2003—Meeting with the FSA

37. On 1 October 2003 representatives from industry and local councils attended a meeting at the FSA in London. A presentation was given by Professor Makin who had carried out the independent audit of the CEFAS laboratory, FRS and DARDNI on behalf of the FSA. A presentation was also given by Ms Claire Boville on behalf of the FSA. Both reports, together with a schedule setting out the FSA's response to the findings of Professor Makin's report were distributed at the end of the meeting and were made generally available on the FSA website.

FSA Change in policy following the publication of the reports

38. The reports indicated that the FSA now accepted that there was, in fact, solvent carryover but not that the solvent carryover was the cause of the atypical response. This was a major volte face as the FSA had previously denied that there was any solvent carryover. The FSA also finally accepted that the three laboratories were not operating the same testing procedures and that they needed to address the quality and consistency of their performance and procedures. This is clearly something which the FSA could have investigated and dealt with two and half years ago. It became clear from the report that steps were finally being taken to minimise solvent levels (conclusion 1) and operating procedures were being tightened up (conclusion 2). Further, the operating procedure currently being used by DARD was to be implemented in all three laboratories from the end of October 2003.

39. This contrasts with the view of the FSA in December 2002 when they stated that they had "no doubts about the methodology used by our laboratories". This stark change in policy, which continues to be denied by the FSA, is clearly due to the criticisms of CEFAS in Professor Makin's report:

Criticisms of CEFAS in Professor Makin's Report [Not printed]

40. At page 15 Professor Makin states—*The SOPs specifically relating to DSP analyses at CEFAS leave a great deal to be desired. They must be re-written so as to present the procedures in a clear unambiguous way, removing extraneous matters which are not immediately relevant.*

41. At page 16—He is surprised "*that the deviations from the SOPs have not already been spotted by the CEFAS quality manager but also by UKAS"*. These deviations are not listed anywhere in the report.

42. At page 26—Crucially "*the extracts prepared during the visits, which were obtained after the ether had been evaporated were significantly different between CEFAS and the other laboratories for all the samples. The CEFAS extracts were often very dirty and contained liquid whereas the FRS and DARD residues (that I saw) were usually dry with little or no liquid (ie, no water present). This suggests the possibility that CEFAS are getting water carry-over, perhaps because of the way that CEFAS carries out the extraction (slightly more vigorously shaken than FRS and DARD who use a gentle swirling action)".*

43. The FSA had come to the conclusion that the DARD method was preferable and also that there needed to be one body overseeing the methodology at the three laboratories; This role was given to the National Reference Laboratory. **They had been previously excluded**.

44. Despite the FSA's conclusions in the reports (1) that solvent carry-over was not the cause of the atypical response and (2) that no evidence has emerged from the audit that supported an argument that the cause of the atypical response is due to methodology, efforts were immediately made to ensure that (1) there was no solvent carry-over in the future and (2) that the methodologies at the three laboratories were the same and that (3) CEFAS used a different procedure as from the end of October 2003.

Expert conclusions on the two FSA reports and Professor Makin's audit

45. Following receipt of the reports, Kershaws instructed Dr Doug McKenzie of Integrin Advanced Biosystems Limited prepare an independent review of Professor Makin's audit and the FSA report. Amongst other things his report addresses the question of whether the cause of the atypical results is more likely to be a new toxin or a methodological problem. His views are:

- It is a central part of the FSA case that there is a toxin present in the cockles and it follows that it should always be found in positive samples and never in negative samples. [As] the same sample [of cockles] produces a mix of positive and negative results then this strongly indicates that a methodology problem is occurring.
- There is carry-over of solvents into the final extract and at CEFAS this [is] often at very high levels.
- The level of DEE in some CEFAS samples [is] sufficient to kill mice.
- Neither water or any of the solvents should be carried over into the injected extracts. The presence of either solvents or water has been previously associated with false positives in the MBA, including symptoms similar to the atypical response. The observation that the MBA is not being undertaken in an appropriate fashion means that the simplest hypothesis regarding the cause of the atypical response is that poor methodology rather than the presence of an unknown toxin is the cause.
- The conclusion that solvent carry-over is not implicated in the atypical response is not justified by the data given.
- There clearly is something about cockles that is affecting the assay but there is absolutely no supporting evidence of any kind for there being a lipophilic toxin present whereas there is considerable evidence that the DSP MBA is not being conducted properly, both in the FSA and Professor Makin's report.
- Dr Doug McKenzie's conclusion is that "*I think both the FSA and Professor Makin's report go a considerable way in vindicating industry position. The DSP MBA is clearly not being properly applied, particularly at CEFAS". "The burden of proof is pointing towards a methodological problem and it is only a question of for how long the FSA wish to maintain their current position".*

46. Reports were also submitted from Jim Cockrill and Allan Parsons of EC Laboratories Limited.

47. The local authorities and the FSA were provided with a copy of Doug McKenzie's report in draft form on 13 October 2003 and Industry is still waiting for a response. I understand that the local authorities have commissioned their own independent experts to assess the evidence. For some reason this procedure seems to have already taken three months when Industry was able to produce its' reports within two weeks. In the meantime, despite the findings in the reports the local authorities and the FSA continue to rely on the mouse bioassay test and the results from CEFAS.

17 November 2003—Implementation of the new NRL SOP

48. The FSA have now overseen the introduction of the new UK NRL SOP at the three statutory laboratories and we understood that this was fully implemented on Monday 17 November 2003.

There have been no atypical results at any of the laboratories since the new SOP was introduced.

49. At a meeting with the FSA on 13 November, Industry requested confirmation from the FSA that the carryover of solvent has been eliminated and have asked to be provided with the test results for solvent carryover in respect of each and every sample of cockles. Additional information has also been requested by Kershaws from CEFAS and DARD. To date this information has not been provided by the FSA.

The CIVIT proposal

50. Kershaws in the meantime, have taken the initiative, and on 10 November 2003 have provided the FSA, local authorities and other interested parties with the CIVIT proposal. CIVIT stands for Cockle Industry Voluntary Initiative on Toxin Testing. The proposal commissioned by Kershaws and devised by Dr Doug McKenzie sets out a programme of alternative test methods which will produce better public health protection than that currently given by the mouse bioassay. Notwithstanding the local authorities continued reluctance to rely on such alternative tests, Kershaws have asked the local authorities to arrange for additional samples of cockles to be provided to those laboratories involved in the CIVIT scheme. It is proposed that testing of these samples be carried out both under the CIVIT scheme and in accordance with the new mouse bioassay test. Again, despite recent meetings with the local authorities and the FSA they have refused to take this proposal forward.

Conclusions

The FSA has failed to carry out proper investigations

51. Atypical results only began to occur in the summer of 2001 following the transfer of testing to CEFAS. Since then there have been a variety of suggestions as to the cause but not all of these have been investigated. The FSA has persisted with the belief that there is a new toxin and has refused to carry out tests which could have eliminated other causes. Only recently have the FSA carried out a more detailed examination of the differences in the methodologies used at the various laboratories and the possibility of solvent carry-over. Despite this being raised as an issue by the cockle industry in January 2002 and considered by some at the FRS laboratory to be a major problem as long ago as October 2002, the December 2002 FSA report clearly excluded solvent toxicity as an explanation for the results, when the FRS laboratory clearly had a different view. At the very least further tests should have been carried out at that time.

52. The December 2002 report concluded that the FSA is "pursuing analytical work" and "continuing international collaboration". It is indicated that the FSA will investigate "as a priority the effects the toxic substance has" to try "to determine any possible human health implications". None of this work has been carried out. No standard toxicity study or post mortem analysis has been performed.

Contradictions in the FSA policy

53. If it were truly the case that the FSA believed that an unknown toxin were killing the mice they could not have accepted the rejection of the new standardised test in Scotland when it produced the same atypical results in June 2003. Those particular atypical results were never acted upon. Neither could they have accepted the continual import of Dutch cockles into England and Wales when these are harvested from areas only a relative short distance from supposedly Toxic cockles.

54. The logic of allowing beds to be open if two negative results are found in successive weeks, and the zoning of areas of the Wash, Thames and Barry Inlet, introduced in 2002, is also open to question. The precautionary principle adopted by the FSA does not appear to extend to such issues. Surely if there was a real risk of a health scare there should have been an immediate ban of cockle harvesting and a suspension of the mouse test until the toxin could be evaluated. The FSA's approach is therefore totally inconsistent. Either there is a real risk and urgent action is required or there is no risk at all. The FSA's position has been muddled and contradictory throughout.

No evidence of harm to public health

55. There is no evidence of public health incidents arising from the eating of cockles. No human response has been observed among those consuming cockles placed on the market in the days immediately preceding the atypical results. The usual procedure is for samples to be taken on a Monday with the results being declared on a Thursday or Friday. None of the councils have ever taken any action to recall cockles which have been harvested during that period when the tests showed an atypical result from the Monday samples.

The local councils did not recall these allegedly contaminated cockles. These cockles would then have been consumed by the public. There have been no public health problems reported. **It is therefore difficult to see how the FSA can say that this course of action is consistent with their precautionary approach.**

No evidence of a toxin

56. The FSA have no evidence that the unknown agent which is killing the mice is a toxin. On the other hand, despite maintaining for two and half years that there was no solvent carry-over, this has now been shown to exist. This is a major departure from good practice in the mouse bioassay, and is a known source of artefact. The correct scientific response all along was for artefact to become the main hypothesis for explaining the atypical response until it could be shown that the methodology used by the laboratories was 100% correct. This is how other countries have treated such atypical responses. They have not presumed the problem to be due to a new unknown toxin.

Summary

57. In placing the DSP screening contract with CEFAS the FSA failed to exercise proper management, failed to monitor the proper implementation of the testing programme and failed to ensure effective quality management of the screening tests.

58. The FSA have ignored (or failed to act on) scientific advice from multiple sources (UK and international) indicating a probable artefactual/procedural cause for the atypical response. They have therefore failed to apply scientific objectivity and have misused public resources, not to further scientific knowledge or to protect public health but to protect there own untenable position.

We would now ask that the Government insist that the FSA discontinue the mouse test and move towards alternative methods of testing (CIVIT) as a matter of urgency.

January 2004

Witnesses: **Dr Peter Hunt**, Director, **Dr Clive Askew**, Assistant Director, and **Dr Godfrey Howard**, Shellfish Biologist, Shellfish Association of Great Britain; and **Mr David Kershaw**, Director, and **Mr Andrew Rattley**, Operations Manager, Kershaws Frozen Food, examined.

Q1 Chairman: Gentlemen, welcome. The hilarity you heard from the Committee as you came in was not the scale of the audience, it is the fact that we have just discovered we are being televised, not for Mouse Vision but for the BBC committee programme. So, let me welcome and point that out to you. We have Dr Peter Hunt, the Director of the Shellfish Association of Great Britain and Dr Clive Askew, who is the Assistant Director; we also have Mr David Kershaw, the Director of Kershaw Frozen Foods, and Mr Andrew Rattley who is the Operations Manager of Kershaw Frozen Foods. We also have Dr Godfrey Howard from Aberdeen who was responsible for the previous series of tests done by the laboratory in Aberdeen; is that correct?
Dr Howard: I was responsible for monitoring the level of toxins previously to 2000 when it split between England and Wales, and Scotland. Currently, I am here today as an adviser to the Shellfish Association.

Q2 Chairman: I think this is a fascinating but fairly strictly defined inquiry and therefore, if we move at some speed, I hope you will forgive us. Can you tell us first of all what the current situation is regarding what the Food Standards Agency calls atypical DSP results and what you call in your evidence just atypical result. What is the present situation?
Dr Hunt: The current situation is that, following the work that was done in the mid-summer which identified that various solvents and water from the cockle matrix was transferring across in the methodology, the Home Office identified that the levels were above those levels permitted and that would certainly cause the symptoms that had previously been identified and, as such, asked or demanded that such solvents be removed from the methodology. So, two major changes in methodology have occurred: one in June of this year and the final in November of this year. As a result of those changes which were designed to remove the solvent carryover, albeit not fully address the transfer of the matrix from the cockle, as far as we understand, there have been no atypical results since the tests were modified. It is very complex but essentially it indicates that, if a test is conducted properly, then these atypical occurrences do not happen.

Q3 Chairman: Dr Askew, it is your contention from the evidence that, when the tests were transferred from Aberdeen to CEFAS, the methodology was different and there were a series of changes which, in your view, resulted in killing the mice and producing not only a mouse massacre but atypical results. What were those changes that were made?
Dr Askew: Since we have had the two reports, particularly Professor Makin's report, we have become aware that there were actually five changes made. Three of those were admitted or were presented by the FSA. It does appear that those were moves towards the original Japanese method, which is known as the Yasumoto method. It does

appear that previously Aberdeen had been using a method that was really quite divergent from Yasumoto's. The one adopted at Weymouth was closer in three respects: they increased the number of acetone extractions from one to two; the ether separation, the next stage, from two to three; and the other change was in the way the ether was extracted at the end of the process: Aberdeen had had an overnight stand. What was not immediately apparent and only became clear once we had looked at Professor Makin's report very closely was that two other changes took place. One was that, at Aberdeen, they carried out the extraction by a gentle swirling in a round-bottom flask. If you can liken it to a brandy glass and you have your two layers of liquid there and this is a very appropriate way to do it; you have to be careful not to create an emulsion. One of the changes at CEFAS was that they took from doing it in this round-bottom flask to do it in a conical shaped separating funnel, more akin to a champagne flute, and the only way of making the mix in that is by shaking from side to side and, in doing that, they risked creating emulsions.

Q4 Chairman: It was shaken, not stirred!
Dr Askew: Yes. I think it is maybe as simple as that. Also, in increasing the number of ether washes without increasing the volume of water at the final stage because the final stage is a water backwash to remove water-soluble compounds which are not supposed to be there, we have identified that, in the UK, we use by far the least volume of water of any country in Europe. We use five millilitres at each of those washes. If you look back in detail to the original Japanese method, he recommends that the volume of water should be the same as the weight of the sample which, for the 100 gram sample we are using, should be 100 millilitres of water. So, we are only using five. A lot of the time that may work but it means that our method is very, very sensitive to any slight errors and one shake too much of the hand—

Q5 Chairman: Is it your view that these changes were responsible for killing the mice?
Dr Askew: I believe so and, in creating those emulsions, they carried over cockle juice, they carried over the water from the cockles, the water soluble compounds from cockles, many of which are likely to be toxic if injected into mice. Some of these are neuro-active substances. That does not mean that they are a human health risk.

Q6 Chairman: Why do you only kill mice with cockles?
Dr Askew: There is clearly a cockle factor; cockles are different in some way from other shellfish. Cockles are very sensitive when they are removed from the water. They do not survive well out of water. Cockles are fished and are cooked more or less immediately simply because, if cockles are out of water, they quickly gape and they quickly become stressed. Some of these water-soluble compounds which we believe are being carried over are actually stress substance; compounds are released by all animals when they are stressed; they are actually hormones in invertebrates. So, cockles are more stressed than other species when they are out of water. That is one likely cockle factor. There may be other differences which mean that cockles are more likely to create an emulsion, we do not know, but there is a cockle factor which has not been investigated. Page 42 of the Macauley report seems to be the answer to everything; they got that much right.

Q7 Chairman: What does that say?
Dr Askew: They put forward the hypothesis that solvents and water were being carried over together and they recommended that the extraction procedure be examined in detail and that has never been done. So, that is their own hypothesis and that has never been investigated.

Q8 Chairman: Dr Howard, these changes were different to the procedures used in Aberdeen, which I assume did not stress the cockles as much.
Dr Howard: Well, as I understand it, when CEFAS were awarded the FSA contract for the monitoring of algal toxins in England and Wales, they did change the methodology of the Yasumoto method but the Yasumoto method is a variable method, there is no precise recipe for it. There are slight variations anyway. What we are talking about here is a specific atypical DSP response in cockles. You get a normal, if I can call it that, DSP response in other shellfish such as mussels and you do get it in cockles as well. When DSP as we would define it under the terms of the directive containing okadaic acid and dinophysistoxins, known toxins, you get a typical response when the extract you have from this process is injected inter-peritoneally in mice. You get a typical response; you can examine the symptoms that the mice show and normally it is followed by death within two to five or six hours. That is the normal DSP response. What was being found here in these cockles was a so-called atypical response in which death was occurring very rapidly, within a few minutes, not at all typical of a normal DSP response but something that we had previously found in Aberdeen and specifically with cockles because, as Dr Askew was saying, the cockle matrix can produce these artefacts, but we had found it in Aberdeen and our predecessors, in Aberdeen, the Torre Research Station, which did some of the work as well prior to 1995, found this artefact in cockles and it was found to be a result of solvent carryover and this very rapid death is, according to veterinarians, typical of a central nervous system response to a solvent overdose.

Q9 Chairman: Are you saying that the problem was known about in 1995 and that, in Aberdeen, the practices which produced this atypical result were avoided?
Dr Howard: We worked to eliminate these, what we termed then, false positives, yes.

Q10 Chairman: Let us move on. I have taken the first question but my colleagues are eager to come in on the consequences of this. The consequences of this were that grounds were closed. Mr Kershaw, you have given us evidence about the impact of this on the industry but Defra seem somewhat doubtful because their view is that most of the total allowable catch has in fact been taken despite the closures. So, how can you attribute a downturn in the industry to the closures which resulted from these atypical results?
Mr Kershaw: First of all, the impact in Wales, where the beds were closed for 14 months—they were totally closed and only reopened after that—was that we lost a very, very good market in Spain which we had built up through attending exhibitions in Spain arranged with the DTI and Food from Britain. We were selling live cockles to Spain on a daily basis. We had six 40 foot articulated lorries, three on the road at any one time taking between 10, 15 and 20 tons of cockles from South Wales to Spain. That business started in April 2001 and, by August 2001, we had lost it. So, there was a main impact there as well as for all the other cockle producers in South Wales. The beds were closed. There was an impact also when the beds in South Wales were zoned. It is all very well having one of the zones open, for example, but, if the cockles are inferior or smaller cockles, then you get less price for them, you have more people working in smaller areas, so the stocks deplete and basically a worse cockle is produced, so your trade goes down.

Q11 Chairman: What is the effect of the closure on the beds? We had some evidence that the dead cockles litter the beds and limit the productivity of the beds. What is the effect on the beds?
Mr Kershaw: If you take too many cockles, you will strip the bed down.
Mr Rattley: It is basically the same as an agricultural farm. If you do not continue to harvest beds correctly, the cockles, as they go through the year classes, will die and that has happened severely in the Burry Inlet and on the Thames Estuary as well as in the Wash. The older cockles are smothering the young juvenile cockles and killing them and that then chokes the beds. We probably will not see the true effects of that for another two to three years. Just expanding a little further on your original question to David, that Defra were under the impression that 91% of the stocks were fishable. It has been very cleverly read from the Chief Fishery Officer's reports from the Thames Estuary and the Burry Inlet where it says that 91% of the catch was achieved in the years 2001 and 2002. However, they very cleverly disguise the fact that it also states that the fishery officers were forced to change management opinion allowing the industry to fish on juvenile stocks to keep the industry alive rather than the true management structure of conserving stocks. Defra and the Food Standards Agency have very cleverly managed not to include that in the information that they forwarded to you and that is available through Defra's own sites.

Q12 Chairman: So, the figures were spun?
Mr Rattley: Yes.

Q13 Chairman: What was the effect of the closure of beds in this country on imports?
Mr Kershaw: We have been importing cockles from Holland in order to keep our English markets supplied. We supply supermarkets within the United Kingdom whereby we have to keep continuity of supply. All that has really resulted is that you replace one cockle with another.

Q14 Chairman: Were the cockles coming in from Holland mouse tested in the same way?
Mr Kershaw: No, they are not.
Dr Hunt: They are certainly not tested in the same way. In fact, quite the converse. In Holland, the mouse test has been abandoned; they use an oral test of rats which does not kill the rats and, once that product is cleared by rat oral testing, that product has been free to come into the United Kingdom. If there ever was a toxin or anything that could have affected the cockles in the Wash, the Thames and the Burry Inlet simultaneously on the same day that the testing regime changed, then there is no doubt that it would have applied to Holland which is only 60 miles away. So, there is a total disparity in the regulations pertaining to imports. Of course, it must be remembered that 90% of the cockles caught in this country are exported mainly to Spain.

Q15 Chairman: So, export markets were lost?
Mr Kershaw: Yes. I would like to add that, when the beds were closed in England and Wales because of the testing at CEFAS, some of the cockle beds were actually open in Scotland because the cockles were tested at FRS and the beds were open. So, we were allowed to take cockles from Scotland and sell them in England, which seemed a ludicrous notion. The impact on ourselves, taking the fact that we have been unable to fish, fish right sizes, and been pushed into areas where the cockles are just not fit to fish, it has resulted in my company closing down my centre in South Wales by December 2001. In December 2001, I closed my factor in Leigh on Sea and, in June 2003, this last year, I made a further 32 people redundant and closed down my shellfish operations in Southport, Merseyside, which had been in operation since my mother and father had started that in 1946. The impact on other processors have been similar. It is not just ourselves. My company has only been able to survive because we have a very successful business supplying supermarkets with other products/other frozen products, not just seafood, and we have been able to keep our cockle firm going purely by the money we have been able to earn from our other side of the company. With other processors, Rory Parsons, for example in particular, a very large processor in South Wales, has only been able to

keep going because (a) he has been taking cockles from Holland and (b) he belongs to a larger Dutch group. We have found that only the larger producers have been able to stay in business purely because they are either owned by a larger group or, in my case, been able to be propped up by my other successful side of the business.

Q16 Mr Drew: Can I just establish one thing before we go on to look at the arguments over the evidence for a new toxin and that is the degree to which this is a national problem or a European problem or is it a world problem, not that there are not different gradations in different parts of the world but I just think that we need a feel for how much this is really a United Kingdom problem.
Dr Hunt: We did not have a problem until June 2001. Cockles were tested at Aberdeen and the tests had been adjusted such that it gave the right results so far. In actual fact, clearly there is a broader problem in that the European methodology for testing for these toxins is not satisfactory. That is the first point. That is why most countries in Europe and around the world have moved away from the European Union methodologies. Germany refuses to use it, Holland does not use it, Ireland has gone to LCMS. If we look around the world, New Zealand and Canada have moved away from the methodology because of falsehoods. However, that does not mean we can escape from the principal reason for this happening and that is the totally flawed methodology that was used after June 2001 that resulted in this. The mouse test has no status if it is not carried out properly. If the solvents and the matrix of the mouse which are wholly designed not to come across in this operation do come across, then it is totally invalidated and has no meaning whatsoever. So, even though there is a basic overriding problem about the methodology which is recognised worldwide and many countries have resolved it, essentially what we are talking about today is a flawed methodology problem. It is an interpretation. In our opinion, it is extremely poor science, a total lack of scientific objectivity in how it has been handled. Throughout, industry has invested an awful lot of money in consultancies in seeking advice from around the world and it has been totally ignored by the authorities. Right from the beginning, we recommended methodologies whereby we could get at least to distinguish whether it is a procedural or an artefactual or something that is just affecting mice or something that could affect humans and that was totally ignored. The reason for that was that it had gone on for a year before it really became acknowledged that the problem existed as it did, by which time it seemed that the authorities were embedded in their own vision and were not in a position to turn around.

Q17 Mr Drew: Can I move on to look at the evidence for a new toxin. What level of discussion was there in advance of this change in policy with the industry in terms of looking at a new research approach? Obviously, the centres where this research was being carried out, the testing and so on, was altered. Were you fully *au fait* with what was going on or did this come as a complete bolt out of the blue?
Dr Hunt: We certainly were not fully *au fait* with what was going on. We had put through our proposals as to what we thought should be done, but that was substantially ignored, albeit the work that was done could not camouflage the results that eventually did come out and they clearly showed that there was a multiple solvent carryover and carryover from the cockle matrix. We believe a combination of those things is resulting. I think there is a totally different approach to that which is taken by other countries. For instance, samples taken around the British Isles are put in a little polythene bag in a little polythene box and put in the post. These animals are very sensitive; they are the most delicate of mollusc and shellfish and the New Zealand authorities have totally modified it to make sure that the temperature never goes above ten degrees and that the cockles are in a good condition when they arrive, a totally different approach. As to the research that has been done to identify the actual toxin itself, we were asking from day one from the first meeting on 15 January 2003 with Sir John Krebs, to be involved in the drawing up of such research proposals and to be involved in what experimentation was to be done. We were told on 23 December some detail of the research that was being done to identify the toxin. This was fully nine or ten months after we should have been told and, when we looked at what was being done, they have a clear methodological problem there in that the basis for the research that is being done is certainly not scientific, it is unsound, and we have yet to go back substantively on that issue to them because, as I say, we received it on 23 December.

Q18 Mr Drew: So, can I be absolutely clear that all five of you are ruling out the notion that there is a new toxin because you believe that there is no scientific rationale to support that proposition as advanced by the FSA?
Dr Hunt: Absolutely.
Dr Askew: At this moment in time, there is no evidence whatsoever. I have said that in my written report. At this moment in time, there is simply no evidence for it.

Q19 Mr Drew: That is on the record. Presumably relationships with the FSA, notwithstanding the argument over the research disagreement, cannot be very good at the moment. In what way are you trying to rebuild a relationship whereby there is some attempt to come to an agreed position on the science, or are things completely broken down?
Mr Kershaw: I think it is impossible when they have ignored the science that we presented to them. We have employed and paid for a lot of scientific advisers. We have simply said to them, "Find the toxin. Find out what the problem is." All those reports which are mentioned in our submissions point to the fact that it is not a toxin. Yet, when

we present this to the FSA, they totally ignore us. When we have attempted to work with our local EHAs, we have been blocked at every turn. So, we feel that the atmosphere has never been really there from the FSA for us to ever work with them. They have taken a very highhanded approach to us and we feel that we are getting nowhere. They told us as early as December 2001 that they had found a new toxin. Since that date, in two-and-a-half years, they have never presented to us any evidence that they have found the toxin, yet we have produced over and over again evidence, which we presented here and we can present more evidence if you wish it, that it is a matrix cockle mush, whatever it is, of solvent carryover and they have ignored it at every turn. Yet we have said to them, "If it is a toxin, show us, please."

Dr Askew: About a year ago, we thought we were working very closely with the FSA. Our own consultant drew up a very detailed schedule and operating procedures specifically to identify the problem, to identify whether or not there was a toxin problem and to eliminate everything that was not causing a problem. This was very, very detailed: I think it was a 16-lay matrix. This was to be carried out at oral testing with rats. It was agreed when the FSA came to Fishmongers Hall to the Association in May of last year that, if there were any problems with Home Office approval in the UK, we could get it done in Holland. We approach the Dutch national laboratory and they agreed they would do it. The FSA said that they were not then happy with the end points used for experiments in Holland and we went back to Holland and the laboratory there agreed that they would carry out rat oral testing to any protocol which the FSA chose. So, that piece of work could have been put together very, very quickly at that moment in time. Since then, relationships have really deteriorated. There have not been constructive relationships since that time.

Q20 Mr Drew: Has there been a legal challenge advanced by the industry and does that also relate to the decision of the FSA, according to the precautionary principle, to actually shut down the beds? Where are we in the legalities of this?

Dr Hunt: I am not involved in any legal action but certainly Kershaws are proposing to take legal action and that has been deferred pending this inquiry. There is no doubt that we are looking or industry is looking for a route whereby it can finally get this matter resolved.

Q21 Mr Drew: So, there is no current legal action, not even in terms of the beds? Presumably, you voluntarily chose not to carry on?

Mr Kershaw: Yes. It has never been our intent from the beginning. We have tried and attempted in every way to sort this out and put some commonsense into this whole mess, but it is a final, final resort by us.

Mr Rattley: With the fact that we have put on hold the legal challenge, currently all of the cockle beds are open. Amazingly, just going back on where you asked if we could rebuild relationships with the Food Standards Agency, it is very difficult to rebuild a relationship when they have totally ignored the multiple solvent carryovers and will not admit that their methodology is flawed. It begs the question that, since 17 November, when they changed the methodology within the laboratories again, there have been no atypical responses whatsoever. So, it just begs that question. How, if there has been a methodology change and there have been no atypical responses since that date, can they still say that there is an unknown toxin within when it points clearly to what all of our scientific advisers have said, that it was methodology in the first place including multiple solvents?

Q22 Mr Drew: What discussions have you had with the FSA in terms of presumably their main concern which is the impact on human health? Is there any evidence at all that human beings have been affected by what they have eaten, not necessarily in this country but internationally, which caused the FSA to enact the precautionary principle?

Dr Askew: Since the problem began in June 2001, we have had a large number of closures. It did occur to me to sit down and try to extract how many new closures there had been. When I say "new closures", ones that were not preceded by previous weeks' closures. Each of those closures should have been accompanied by a product recall because in fact the cockles are normally collected on a Monday and the results are available on a Thursday or Friday. So, you have normally the best part of a week's product going on to the market. So, something like 50%, possibly, of cockles harvested have actually gone on to the market prior to this testing procedure. I think there have only been one or two product recalls. If the FSA believed in this toxin, they would certainly, on a precautionary principle, carry out product recalls. There is no evidence of illness throughout that time.

Q23 Mr Breed: Perhaps I could move on to the whole area of the evidence of the methodological flaws which is at the heart of all this in a way. You have made it quite clear that you believe that there was very poor scientific methodology in this and that is why we had the atypical results. CEFAS says that they used the same method in other shellfish and that does not give lots of atypical results. So, there must be something clearly very specific about cockles. You said that it was perhaps to do with the way in which they carry out the test or the way that the cockle is looked after because it is very delicate and that sort of thing. Is that the principle area of dispute in terms of the evidence for this methodological flaw or is there other clear evidence that you would present to say that the way CEFAS carries out the tests or rather the way in which it administers the tests is flawed?

Dr Askew: In my written evidence, I have provided a table where I have tried to simplify it showing the differences between the methods used in Great Britain and the original method. The directives that

we all operate to requires us to operate to a customary bioassay. I believe that the word "customary" has to mean something. It seems to have been completely ignored. The word "customary" must mean something. There are two aspects of that. Firstly, it is the question of which version of the original test was the customary method and I have presented in my annex the method published by the International Oceanographic Commission which is Yasumoto's method but it actually gives more detail than the paper nominally referred to as "Yasumoto 1984." So, that shows how divergent we are and particularly in regard to this volume of water which is used at the last stage and, if we have that table to hand, you will see that we are anything up to 20-fold too small in the quantity of water we use at that final backwash stage. I would argue that the methods—and this goes for all the methods used in the UK—are not the customary method. The other aspect of that word "customary" is that it must presumably restrict the extent to which laboratories can undertake new bioassays, to which they can modify bioassays, and what happened here was clearly that CEFAS and DARD in Northern Ireland developed their own versions. We know that, certainly in the case of Northern Ireland, the version that has finally been more or less adopted as the national standard was developed even without reference to the original International Oceanographic commissioned work. So, they have started to use a new method. We maintain that that is not the "customary" method. So, the UK today is not using a customary method as required by the directive.

Q24 Mr Breed: So, the evidence revolves around what is customary and what they have been using, two different ways of tackling it, producing therefore, you would say, different results.
Dr Askew: Yes.

Q25 Mr Breed: What is your response to CEFAS's suggestion that atypical results are found more often by the CEFAS and DARD laboratories than FRS because the protocols that they have used in those labs might be more sensitive? That is their counter to your view.
Dr Askew: I have thought a lot about this. I think that possibly when CEFAS made their changes, when they modified the method, when they took responsibility for it, three of those changes were moved towards the original Yasumoto method. They increased the number of acetone and ether extractions. They saw those as making it more sensitive. At the same time, they happened to make these other changes which Professor Makin's report has made clear. Professor Makin more or less refers to it on page 26 where he refers to the rather vigorous shaking carried out at CEFAS Weymouth. He suggests himself that that is what was taking place. When we look at page 42 of the Macauley report, they hypothesise the same thing. When I first read this and put them together, I could not believe that scientists like this would not have realised what was happening. In fact, in only recent days it has occurred to me that actually the Macauley Institute at that time would not have had access to Professor Makin's report, so they would not have seen Professor Makin's report at Weymouth and dirty extract at Weymouth. Likewise, presumably Professor Makin would not have seen the Macauley Institute's hypothesis that the water and solvents were being carried over together. Once you have those two things together, it is really quite clear what is happening: they are producing an emulsion; once you have little spheres in emulsion—it is like vinaigrette dressing—no amount of distilled water will remove it.

Q26 Chairman: So, it is not in fact sensitivity, it is crudity.
Dr Askew: You are then injecting cockle juice into mice.

Q27 Mr Breed: So, it is nothing to do with sensitivity at all in terms of the methodology. So, what is the response when you say that the same methods are used in other shellfish without producing substantial numbers of atypical results? What is so special therefore about a cockle?
Dr Askew: We know that cockles are more stressed.

Q28 Mr Breed: And that is all?
Dr Askew: Yes and there may be something in cockles which makes them more liable to form emulsions. The Macauley Institute's recommendation on page 42 was that the extraction method is to be investigated in detail—that is what the Macauley Institute was advising them to do.

Q29 Mr Breed: And they have not done it as yet?
Dr Askew: No, not that.

Q30 Ms Atherton: We have talked about mice, we have talked about cockles and I want to talk about CIVITs, namely the Cockle Industry Initiative on Toxin Testing, and I think the acronym of CIVIT is much more helpful. Can you tell us how your proposal would actually improve matters?
Mr Rattley: With regard to CIVIT, it is an industry initiative for the testing for toxins within shellfish. It does not purely cover the cockle shellfish, it will cover the whole range of shellfish. We produced, along with our scientific advisers, our proposals back in October of last year. That was submitted to the Food Standards Agency on 13 November for them to peer review and place comments along with the local enforcement officers and, as of today, we have still not received any response from the Food Standards Agency and we are led to believe from the environmental health officers that they are not in a position to actually give us a response to CIVIT because they have to take advice from the Food Standards Agency. CIVIT will give a far greater consumer protection than is currently in place in the UK with the MBA. It has been designed to grow as science grows. LCMS can be incorporated along with the other biological assays

that are incorporated in it. It would be a quantitative test whereas the MBA is not quantitative. What we did suggest to the Food Standards Agency is that they should run both systems because where the MBA has been known to give false negatives as well as false positives throughout its history, Ireland and New Zealand have looked at using other methods which have given them a quantitative decision as to whether to close beds or not and run the mouse bioassay in background screening, which is what it was originally designed for, it was never designed for routine monitoring. The European Commission decision does allow for LCMS and other assays. The Food Standards Agency have taken it in their interpretation that the mouse bioassay is the only method to be used and, yes, it comes down to which way you read it and interpret it because, if you are in France, you interpret it in one way, in Italy another way and, certainly in the United Kingdom, the Food Standards Agency way. The CIVIT document does not give rise to full methodology. It gives rise to quantitative measures throughout and it is very difficult to actually go through the whole of our document without one of our scientists actually presenting it for you. Given the overall benefits, it would give a far greater consumer protection that the Food Standards Agency currently offer.

Q31 Ms Atherton: I can see where you are coming from but would you not agree that, if you had the two regimes running side by side, one the statutory one and then your voluntary one, it is even more of a recipe for argument and dispute?
Mr Rattley: That is debatable because, at the moment, Ireland use the MBA for background screening and the assays and the LCMS for the main monitoring. If they then have a problem, they will refer back to the mouse bioassay. That is what we have asked with the Food Standards Agency. If the CIVIT is proposed and used for normal routine monitoring and you then get a blip where it shows that you have quantitative okadaic acid or one of the other groups, the mouse bioassay can be run in conjunction and it would give a true picture whereas the mouse bioassay is a crude test that does not quantify what any of the toxins are.

Q32 Ms Atherton: Can they screen for unknown toxins? Are they as reliable? That is what the public are going to ask, is it not? That is the lynchpin question. Are the public going to buy this?
Dr Howard: Perhaps I can come in here. There is an onus on the industry to conduct what is called end product standard tests. The Food Standards Agency, through its various laboratories under the EU and national legislation, run the required statutory monitoring screen but there is also an onus on the producers of shellfish to do what is called an end product standard test. Now, this is extremely difficult for them at the moment with sole reliance on the mouse bioassay because there are relatively few laboratories in the country that are licensed to do that sort of test. So, a chemical assay would be much more advantageous to the industry. In answer to your question, yes, there are in the main now standards that would allow an LCMS or an HPLC analysis to be carried out on most known toxins. If there were an unknown toxin that came in, you would be likely to get an unidentifiable peak in the analysis trace from which, although you would not know what it was, you could hypothesise that there was a toxin there and then act on the precautionary principle.

Q33 Chairman: What range of tests are available? I take it that there is mouse testing, there is chemical testing and there is chromatography?
Dr Howard: There is a mouse bioassay and there are various different chemical tests. The main ones used in toxin analysis would be HPLC, high performance liquid chromatography, which is currently used as the required test for one shellfish toxin, ASP, amnesic shellfish poisoning. It can be used and so can LCMS, liquid chromatography mass spectrometry. They can both be used to identify the DSP toxin group, okadaic acid and the others. There is also what is called a missed kit, a missed alert kit, which is produced by an American company which can identify PSP, paralytic shellfish poison toxins. So, there are ways to certainly reduce the requirements on the mouse test.

Q34 Chairman: And these are all permitted under EU regulations?
Dr Howard: These would be permitted.
Mr Kershaw: The mouse test does not test for all unknown toxins and, if you wish to have further clarification from any scientific person, then we are more than willing to supply that information to you. The mouse test does not test for all unknown toxins.
Mr Rattley: You asked, would it give confusion? I think we have to look at it in two ways. The New Zealand food authorities only use the chemical methods now and we allow food imported into this country, particularly the mussels, from New Zealand without them going through a further mouse bioassay. Surely, if the Food Standards Agency had that much doubt that there was a risk to public health, they would not allow the product into this country.

Q35 Alan Simpson: Although food authorities are the third party in this relationship, it is quite clear that the major part of this relationship is between yourselves and the FSA. Just reading through some of your comments, they are pretty robust comments, that the precautionary principle has been misapplied, that the Agency now believes its own spin, it seeks to camouflage extremely poor science, it is paranoid about the release of information. I think if we were in a RELATE session, we might take the view that we have reached the stage where we were arguing about who had the fridge and who had the CD player. Is there any basis of a working relationship between yourselves and the FSA at the moment?

Dr Hunt: Of course there has to be and we wish there to be. We are seeking one single thing and that is security of our product. We have, it is relatively small, probably around a £20 million industry, principally export, and we are seeking only to protect that industry. Of course, we would welcome the opportunity to work with the Food Standards Agency. The attitudes that have been put to us have been quite insulting at times where we have had quite complex meetings and the minutes that come out sometimes do not reflect the discussions that we have had. The meeting that we had in January 2003, we thought we had moved a long way in getting towards a solution and then it all stopped and it just was not continued. Under the precautionary principle, there has to be some proportionality to risk. There has to be. Really, none has been identified at all. There is no chemical identification of any toxin, there is no clear policy of product recall, there has been no illness, there has been just no evidence. Also, any such precautionary approach has to be non-discriminatory. Certainly we are discriminating against UK producers versus other European producers because they have free access to our market. We are actually discriminating between England and Scottish producers. Scottish cockles are not subjected to this test and of course can place the product on the market and the English producers cannot. There is also an obligation to produce cost benefit analysis, which has to be continually applied. The cost of this has grown. There has to be some sort of cost benefit now to see where this risk or supposed risk is. What is the value of it? What is it doing? The decisions that have been taken have to be reviewed and they are not being reviewed. The industry has not been involved in those discussions. When we first started on this, if we had followed the empirical approach to identification of essentially whether it was a procedural, an artefactual, a response purely in mice or a human response, it would have taken, we estimate, six weeks for any reputable drug company to do that and it would have been finished in mid-February 2003. I am not of the school of which some of my side are where some people in the industry believe that it is right to withdraw a product immediately in June 2001. I believe that with such testing, when it is transferred from one laboratory to another and then suddenly all the results change, there is an obligation to check that the methodology being used is correct and that was never done. In fact, for the first six months, it was totally camouflaged; it was called a true DSP and, for six months, we believed it was proper DSP. The industry cannot afford to have true DSPs. We lose the business completely if we are going into real toxins. For six months it was declared as real DSP and then it was admitted that it was this very rapid CNS reaction. All along, right from July 2001, the Food Standards Agency and CEFAS were being advised that this was a solvent problem, because it has applied all around the world. Everyone has had the problem since the famous Torre Institute that was closed down in 1995 picked this up in 1990. If you read the protocol in Italy, it specifies exactly how you get round it. In June 2003, the New Zealand Government Authority sent to the Food Standards Agencies what they did, how they dried up the final extract to ensure that there was no solvent in the final product that was injected into the mice. It has all been on the table.

Q36 Alan Simpson: Have we learned anything out of this?
Dr Hunt: We have learned what it took Ireland a long time to learn. Exactly the same situation arose in Ireland some four years ago. In Ireland, their Food Standards Agency took a similar approach. It was a battle. As soon as industry got together with the Food Standards Agency here they established committees that worked closely together on the risk of each individual case of any positive result. They solved the problem. They have had no closures in Ireland since. It was forced upon the Irish Food Standards Agency by politicians and that is why we are hopeful that, by coming here, somebody can force them to work together with us to solve the problem.

Q37 Alan Simpson: Would you accept that the food authorities were the minor, third part of this relationship and they are perhaps the kids in the equation? Some of their submissions have been saying that the industry itself has also been pretty poor at sharing information. Would you accept that there is any validity in that?
Dr Hunt: Absolutely not, no. We called a meeting on 15 October, where we wished to present to everybody what our consultants had prepared for peer review. All the environmental health authorities came and the Food Standards Agency en bloc refused to come saying it was not possible because of other engagements, but there was more than a month's notice of that meeting.

Q38 Alan Simpson: Carmarthenshire County Council have said that the shellfish industry received information which would have benefited local authorities; yet it was not shared. They go on to be equally critical of the FSA, but it is very easy to 100% this and I was wondering whether the industry accepted that there were any down sides in its role in sharing information with food authorities?
Dr Hunt: I do not think there is, except that of course none of us is a great expert. All of us are feeling our way through what is a very difficult problem. We have had to invest an awful lot of money into trying to find out the answers. Even at the end of it, we cannot see how we have such a different view to other people.

Q39 Alan Simpson: In terms of the lessons to be learned, your view is that the whole industry, the sales and the FSA, has to be made by politicians to work together?
Dr Hunt: Yes.

Q40 Alan Simpson: That is the bottom line and why we are all sitting here?

Dr Hunt: We do feel that the science has to be properly investigated. We believe that in some areas it is so poor that it justifies an investigation by the Office of Science and Technology. We will be recommending that. We believe that industry has been treated very poorly and should be compensated fully.

Q41 Chairman: You want compensation?
Dr Hunt: We do indeed. We believe there is only one single body which thinks the way it does. This problem has been bandied around the world. Everyone is interested in it and we have not met any other government or anyone else who has had the same problem and not resolved it, certainly not the way we are going.

Q42 Chairman: Thank you. The evidence you have given us is very powerful and interesting. I end the session with you by saying that if there is anything else you want to add please drop us a note as quickly as possible because we hope for a fairly quick report. Alan said it was like Relate marriage guidance counselling. It would be fairly difficult if it were. Dr Hunt, could you sit at the front and if there is anything you want us to put or you think we are ignoring when we come to the Food Standards Agency wave a note and my colleague will fetch it over. That is a fairly unusual situation but it is frustrating for a Committee like this where we hear one set of evidence and another set and there might be grounds for bringing people together in a Relate fashion or for putting issues that we are dealing with inadequately from the Committee point of view.
Mr Kershaw: After this session, if there are any further details you require, will you be calling us back, writing to us or what?
Chairman: I will ask the clerk to have a word after the meeting. Thank you very much.

Supplementary memorandum submitted by the Shellfish Association of Great Britain (M5a)

Thank you for the opportunity to submit additional comments following the verbal hearing on Monday. There were certain parts of Dr Bell's statement with which we disagree and other matters in the discussion which need clarification.

1. The FSA Board and Management has repeatedly declared that "there is a toxin which could be harmful to people and that may not be apparent for many years" and that "the FSA has no doubts about the methodology used by their laboratories". These statements had never been retracted prior to the EFRAC verbal hearing when we understood Dr Bell to say that there was no evidence of a toxin and that he has never been convinced that there was one. This now needs to be formally rectified in public statements.

2. Dr Bell stated, and paragraph 26 of the FSA written submission reported, that Professor Makin's report provides evidence that atypical response was not caused by solvent carryover. Professor Makin agreed on 13 November 2003 that on the evidence, he could equally have made the opposite statement that " there was no evidence that the atypical response was not caused by solvent and there was no evidence that it was caused by a novel toxin". The point is that following the admission by Professor Makin, it is now knowingly misleading for the FSA to continue to use his original statement "No evidence emerged from this audit to support the view that the atypical response is due to the presence of ether in the Tween extract . . .". This is referred to in paragraphs 26 and 37 of the FSA written submission. However, page 42 of the Macauley Report shows the association of solvents with water carryover. The evidence to date does not eliminate either direct or indirect association with solvents and to infer that it does is misleading. Continued use of such unfounded claims by the FSA will initiate a formal complaint of misconduct by the Association to the Office of Science and Technology.

3. The implication by FSA of minimal impact on industry was misleading. Most cockle products are exported with remaining domestic sales supplied to retail, both on contracts to continually supply. These contracts could not be honoured and the business was lost. Size restrictions were relaxed to facilitate some continuity but juvenile cockles achieve 25 to 50% of mature cockle prices, dependent on quality, and there are also significant implications to future quotas and catches. I understand that the details of the impact were supplied to DEFRA and the FSA but have been selectively quoted.

4. There was reference to the Irish situation and I attach a communication from the Irish Shellfish Association (Appendix I) [Not Printed] which describes what actually happened. It illustrates that despite acrimonious beginnings, close, risk based, industry/regulatory cooperation can achieve sensible consumer protection with minimal disruption to industry. A similar approach applies in New Zealand, Canada and most other EU Member States.

5. The restrictions placed by the Home Office on the FSA and its contracted laboratories were only briefly mentioned. It is understood that the Home Office was not advised of the flawed methodology and multiple solvent/cockle matrix carryover until October 2003 after which the attached letter (Appendix II) [Not Printed] was sent to the respective parties.

6. Dr Bell stated that the results of the LGC project to detect and possibly identify unknown toxin/s in the cockle extracts was ongoing. The project was completed at the end of October 2003 and report received by the FSA on 6 November 2003, since when industry has been trying to secure a copy. The FSA website confirms that the project has not been able to identify the compound causing the atypical response but FSA editorial changes were being sought.

7. Most cockles are cooked immediately on landing and insufficient reference in the EFRAC Inquiry has been made to end product testing which Industry supports in order to demonstrate the integrity of its products. Such end product testing is required under Directive 91/492 but at the meeting with Industry on 1 October 2003, the FSA stated that end product testing does not have a role in ensuring safety.

8. Finally, with reference to the comments made by Alan Simpson, MP on the robustness of comments made in my written submission, many things are easier left unsaid, but need to be said, and I confirm my belief that the modus operandi of the FSA needs urgent investigation. Industry has very actively sought compromise and offered willingness to work with the FSA but this has been repeatedly rejected outright with contempt. The FSA publicity machine professes to science-based integrity, transparency, open consultation and participative investigation, all honourable and very desirable, but apparently not applied in reality. Environmental Health Authorities, contracted laboratories and Consultants and even related "subsidiaries" such as the FSA Scotland appear in fear of the Agency "power" and control on available funds; scientific challenge is ignored or worse. The final paragraph of my written submission was not said lightly, such control has enabled the paymaster to undermine the integrity of the science with impunity. The acceptance of flawed methodology threatens wider animal testing programmes. Industry and Enforcement Authorities have all noted repeated major deviations and omissions in Minutes of meetings prepared by FSA Officers. I fear the issue is much deeper than the EFRAC Chairman's concluding remarks on the need for counselling between warring partners.

22 January 2004

Supplementary memorandum submitted by Kershaws Frozen Food Ltd (M10a)

1. We would like to thank the members of the Efra Committee for giving us the opportunity to present our evidence to you on Monday 19 January. In addition, we appreciate your kind offer to allow us to submit supplementary comments and responses on the evidence presented by the FSA.

2. We are writing to deal with various points arising from the FSA's written submissions and the oral evidence given by Dr Bell on behalf of the FSA at the EFRAC oral evidence session on Monday 19 January.

3. We attach to this submission an appendix of documents marked "AR". Numbers in brackets in this letter refer to the page numbers marked in the bottom right corner of the documents in that appendix.

THE FSA WRITTEN SUBMISSIONS

4. Having seen the written evidence of the FSA we would like to focus on some specific points where we believe that there is a possibility that the Committee was being misled. We would welcome the opportunity to respond in detail to the FSA's written submissions but at this stage and in the time available, there are a number of points, which require comment immediately.

5. The most obvious omission from the FSA submissions is that they do not acknowledge that there have been no atypical results since the SOP was changed. This clearly shows that the atypical results are caused by methodology. The presence of solvents in the old SOP's and the subsequent removal in the new SOP strongly suggest that solvents are the root cause of the atypical response, working in conjunction with an unknown "cockle" factor.

6. The FSA attempt to justify their action with regard to the EU directive, however, the test results are meaningless unless the assay is being carried out properly. It is now obvious that the test was not being conducted properly at CEFAS and the atypical results were the result of the negligent application of the assay. This is evidenced again by the fact that the SOP has had to be changed significantly to reduce solvent carryover. Subsequent to this the atypical results have disappeared.

7. In general terms, we consider that the FSA's report to you is very selective and is written from the point of view of an organization justifying their position rather than attempting to inform you as to what has been going on. We strongly recommend that the Committee reconsider our previous written evidence and that submitted by Dr McKenzie of Integrin when evaluating the FSA's report. We cover the same ground but come to very different and rather more believable conclusions than the FSA have.

8. Reference is made in paragraph 25 to the extensive program of work that was commissioned to standardise the DSP testing procedures as if this was something, which the FSA planned all along. We contend that this work was commissioned because of growing pressure on the FSA by FRS and industry following the decision by FSAS and the NRL to commission the Macaulay report which proved that there was solvent carryover. This was not an FSA initiative. Indeed, having ruled out a methodological problem in December 2002 and having introduced the new standardised SOP in all laboratories in June 2003 prior

to the Macaulay report, the FSA had already ruled out solvent carryover at this stage and had ruled out a methodological problem; it was only the Macaulay report that forced them to revisit those two conclusions. In the meantime, the FSA blocked all attempts which were made by us to obtain a copy of the Macaulay report prior to the publication of the FSA's own evidence (pages 1 to 7). The FSA's own studies now conclusively show that there was solvent carryover, but the FSA had previously denied this was the case. They still refuse to accept this was an error. In their submissions the FSA do not mention that Professor Makin was highly critical of much of the quality assurance work undertaken by CEFAS.

9. Paragraph 26 of the FSA submission refers the Committee to the agency's action plan. It does not mention that solvents were detected in injections often at high levels, or that atypical results were always associated with the presence of solvent. Nor does it mention that the original FSA report on solvent carryover was compromised by errors at CEFAS. The original report is still on the FSA website but the addendum which the FSA released to industry has still not been publicised and the Committee have not been referred to it by the FSA.

10. This lack of openness with the Committee and with industry generally continues to this day. Dr Bell was asked what the current position was with regard to the report of the government chemist. Since attending the Committee on Monday, we have investigated this position further and the information is buried deep in the FSA website in their interim progress report dated 5 December 2003. This refers to the fact that the "experimental work has been completed and a draft report had been received on 6 November 2003. Also that "the LGC has identified some signals of interest using LC-MS, but the project has not been able to identify the compound causing the atypical response". Dr Bell gave the impression at the hearing on Monday that the report was not complete. It appears it is simply the case that the report has not been published. Why did Dr Bell not inform the committee of this important information?

Toxin or Methodological Problem

11. During the Committee hearing Dr Bell of the FSA made certain statements with which we disagree and which we contend are contrary to the documented evidence.

12. Dr Bell asserted in his evidence that the FSA kept an open mind as to all of these possibilities through the two and half years when the atypical results were encountered. In particular he said "we are not ruling out a whole range of possible explanations for this including the presence of a toxin" and "we don't know for certain that there is a toxin there, we are doing work to try to be clear about that". The documented evidence does not confirm this statement. During 2001 and 2002 the FSA referred to the results as being "positive" and "atypical positive". They refused to accept there was anything other than a toxin present in the cockles:

(a) As previously mentioned, Jonathan Back, head of Food and Microbiology at the FSA told the Shellfish Association's annual conference in 2002 that "We know there is a toxin in these shellfish which is killing mice within five minutes" (page 3A of the annex to my previous submission).

(b) On "Country File" (national television) Joy Whinney, the then director of FSA Wales, stated that "there was a toxin in the cockles which killed mice". No caveat was applied. The statement has never been qualified or retracted. Clearly, from the outset the FSA committed themselves to the "novel toxin" hypothesis.

(c) As previously mentioned, on 12 December 2002 Ann Hemingway stated publicly "This toxin could be harmful to people and that it may not be apparent for many years" (page 4 of the annex to our previous submission). No caveats were applied and no mention was made of a possible procedural or artefactual cause and the statement has not been subsequently retracted or qualified. The executive summary of the FSA 2002 report is now attached for your reference (pages 8 to 11).

(d) Joy Whinney in her letter to the local authorities (pages 15 and 16 of our previous annex) following the inter laboratory comparison in October 2002 stated that "the method used at Aberdeen does not detect the atypical DSP toxin" and "the clear indication is that the testing undertaken by CEFAS Weymouth is detecting a toxic substance in the cockles".

(e) Joy Whinney again in her letter to Rory Parsons (pages 18 and 19 of our previous annex) states that "the methods used at CEFAS and DARD may just be better at extracting the toxic substance".

(f) Again in her letter to Rory Parsons of 23 December 2002 Joy Whinney stated that "the agency is endeavoring to identify the toxin by analytical methods" (pages 12 and 13).

(g) Sir John Krebs, in a letter to Austin Mitchell dated 20 May 2003 (pages 14 to 16) cited the verbal comment of Professor Yasumoto and stated "the results being obtained were due to the presence of a toxin and were not an artefact of the analytical procedures being used".

13. This bias continued even with the publication of Professor Makin's report when the FSA's conclusion was that there was no evidence that the atypical response was due to solvent carryover. Yet at the October meeting at Aviation House, Professor Makin himself agreed that an equally valid statement would be that "there is no evidence that the atypical response is not caused by solvent carryover or that the response is caused by a toxin".

14. During the FSA oral evidence Dr Bell also informed you that while the FSA had kept an "open mind" as to the causative agent of the atypical response, industry had discounted the toxin theory. This is absolutely not the case. The SAGB gave a detailed presentation defining and accepting four hypotheses for the causative agent of the atypical response In January 2003 and March 2003. These being as follows:

(a) A toxin in the cockles of concern to human health;

(b) A material of cockle origin, which has no concern to human health;

(c) An artefactual effect in the test;

(d) A procedural effect associated with the test methodologies.

15. We have consistently acknowledged the possibility of a novel toxin, however, having spent over £100,000 in the research and have given our scientists findings to the FSA we have proven that the toxin hypothesis is not tenable. Of course, had the tests for solvent carryover been carried out in June 2001 when the atypical results first appeared it is highly unlikely that there would have been any debate as to the reason for the atypical results since, had changes in the methodology been made then, it is more than likely that those atypical results would have disappeared.

16. Dr Bell also responded to the Committee's questioning as to the current status of testing results by stating that although there had been no atypical results over the last two months this had been preceded by a decline in such responses thereby inferring that it was unrelated to the methodological changes in the test. This is a total misrepresentation of the facts. Firstly, the methodological improvements were not all uniformly implemented until mid November. If you take the figures prior to the method changes and those after the full implementation the case is clear: atypicals were recorded at a level equivalent to those previously encountered and on full implementation reduced to nil.

Insufficient Samples Since 17 November 2003

17. A major contention of the industry has been that the FSA has consistently failed to set standard testing method standards, monitor the laboratory performance or objectively evaluate the results. We appreciate the Committee's attention to this aspect of the FSA's role. It was therefore astonishing to note that in response to the Committee's questioning regarding reported "insufficient sample" and "operator error" citations in the results obtained after the method changes of November 2003, Dr Bell expressed no knowledge of these reports. How can Dr Bell give an opinion on change in the results after November 2003 when he is unaware of the emergence of this new factor?

18. We attach a copy of emails we have sent to Mercy Adebisi of the FSA and to Claire Boville of the FSA (pages 17 to 20). Mercy Adebisi explains that the reason for the "insufficient sample" was due to operator error but Claire Boville explains that her position was that the EHO did not provide sufficient cockle samples. The FSA indicated that they would deal with this point in their further submissions to the Committee and we have requested that Claire Boville copy us in on that reply, as this is an important issue. We suspect that due to the stringent methods now being employed by the laboratories to ensure that there is no solvent carryover contained in the extracts prior to the injection into the mouse, this results in a large number of extractions of cockle meat being rejected until such point that there is none left to inject into the mouse. Dr Bell indicated that the new SOP which was introduced into the three laboratories on 17 November 2003 was the DARD SOP with a "few tweaks". It is clear that these "tweaks" are quite significant and that elimination of solvent carryover is now a priority due to pressure from the Home Office. In part 5 of the Interim Progress Report dated 5 December the FSA stated that the extract safeguards included in the SOP had been effective in minimising solvent carryover levels which were acceptable to the Home Office, i.e., below levels causing clinical signs in the MBA. We would welcome clarification as to what this term means and an explanation from the FSA as to why steps to reduce solvent carryover levels were only taken in November 2003.

Professor Yasumoto

19. Reference was made on numerous occasions to the evidence of Professor Yasumoto as being critical. Professor Yasumoto analysed cockle extracts, which were sent to him having been produced by the flawed methodology. He commented on that extract but has not produced any formal report. He was not aware of the methodological problems at CEFAS when he analysed the cockle extract. In addition, when he visited CEFAS in May 2001, he did not discover any problems with the CEFAS methodology, yet we now know that such problems existed. The FSA has not, as far as we are aware, written to Professor Yasumoto bringing him up to date with the current position regarding changes in the methodology and has asked him if that would have any impact on his previous conclusions, however they continue to rely on them.

DARD Atypical Results

20. The committee asked Dr Bell why the atypical results only started after the testing had been transferred to CEFAS. Dr Bell informed the committee that DARD also began to experience atypical results at the same time. Dr Bell failed to point out to the committee that DARD had only started using the MBA after the forming of the FSA in 2000. They wished DARD to change to the MBA from the rat oral study in order that all three laboratories were operating a version of the MBA. The use of the MBA on cockles in Northern Ireland is still very limited.

21. We wish to point out that we have received no evidence from the FSA that it is actually the case that the atypical results began at DARD at the same time. Our lawyer has requested details of the DARD atypical results from DARD but this information has not been provided (page 21). We suspect that there may have been a downward trend in the DARD atypical results as they took steps independently to eliminate solvent carryover. In October 2002, they obtained a number of atypical results during the inter laboratories comparison. In October 2003 they obtained no atypical results during the FSA research studies. The committee may find it helpful to seek clarification of the DARD results prior to finalising their report and we would be grateful to receive this information as well. DARD have obtained no atypical results since the revised methodology was introduced.

Godfrey Howard

22. A question was raised by Alan Simpson concerning the "gagging" of scientists employed by the FRS. I have now been informed that Claire Boville telephoned Dr Colin Moffatt of the FRS before Godfrey Howard retired and asked if there was any legal way in which he could be stopped from giving advice to the SAGB and industry on his retirement. This can be confirmed to the committee if they wish to write directly to Godfrey Howard.

The New Toxicology Study

23 We believe that the FSA's toxicology study is flawed because the samples for testing have been previously prepared by CEFAS Weymouth prior to the changes. This means that the cockle extract that they are using may be contaminated with solvent. Any new studies should now be done on fresh atypical samples, however since these are no longer occurring that poses obvious difficulties for the FSA. We know that the extracts producing results are toxic. The FSA's statements appear to show that they are intending to use the results of this study, based on the samples from the discredited CEFAS SOP in an attempt to justify their position.

Additional Information Awaited From the FSA

24. For the Committee's information I attach a copy of an email I sent to Claire Boville of the FSA on Friday 16 January (pages 22 to 24) which sets out the additional information which we are still waiting to receive from the FSA at this time.

Unanswered questions which relate to the way in which the atypical results have been interpreted and acted upon by the FSA.

25. Following our review of the FSA's submissions and the evidence provided by Dr Bell on Monday, there remain numerous unanswered questions with regard to the FSA's conduct:

(a) Why did CEFAS use a different testing methodology from FRS when they began testing for cockle toxins in June 2001? Was the National Reference Laboratory consulted when the methodology was introduced? Was the National Reference Laboratory consulted when the atypical results first appeared? As the mouse bioassay test has always been associated with false positives, why was the possibility of solvent carryover not immediately investigated by the FSA in June 2001 when the atypical results first appeared? Solvent carryover being taken to mean that high levels of DEE, acetone and other particulate matter were carried over into the extract injected into the mouse.

(b) Was the FSA aware that different methodologies were being carried out by the three statutory laboratories prior to the studies carried out in October 2002.

(c) The National Reference Laboratory suggested further investigations into solvent carryover be carried out in October 2002. Why were these not commissioned immediately by the FSA?

(d) The FSA stated in December 2002 both in their updating report and to the media that (i) there is *no evidence* to suggest that the tests giving the positive results are in any way flawed (ii) the possibility that the positive results are due to chemicals used in the extraction process has been *ruled out* and (iii) that the investigations have eliminated a number of possible causes of the atypical DSP positives observed from cockles. Further, (iv) that the FSA had carefully considered the tests and have no *doubts about the methodology* used by their laboratories? Do the FSA stand by these statements now that the findings in their October 2003 report stated that there were high levels of solvent carryover found at CEFAS.

(e) Why was the CEFAS June 2003 SOP introduced at the three laboratories without the FSA conducting a formal audit of the SOP or seeking the advice of the UK NRL. The implementation of this SOP caused the FRS and Home Office Inspectorate to report to the FSA Scotland that the death of the mice was conclusive with solvent carryover, FSA Scotland stopped the use of the June 03 SOP immediately. The FSA London were informed of this and did not comment or object.

(f) Were the FSA surprised at the high levels of solvent carryover at CEFAS when they received the first results of the studies commissioned in October 2003?

(g) If the FSA were not surprised would they now accept that the CEFAS methodology should have been checked in June 2001 as soon as the atypical results appeared? Do they accept that if the methodology had been corrected in June 2001 there may have been no atypical results at all during 2002 and 2003?

(h) If the FSA were aware of the high levels of solvent carryover, why did they keep this information from the Home Office and on what basis did they continue to rely on the results from CEFAS after June 2001 when it was clear that the solvent carryover may be affecting the results.

(i) How do the FSA explain the fact that there have been no atypical results since the CEFAS methodology was changed and steps taken to minimise solvent carryover since 17 November 2003.

(j) On the basis that atypical results have ceased since attempts have been made to eliminate solvent carryover, why are the FSA continuing to investigate the toxicity of the old samples which produced atypical results, knowing that these samples have been prepared using a flawed methodology and contain high levels of solvent and other particulate matter.

Recommendations

26. The industry's recommendations are as follows:

(a) In order to build bridges with industry and to develop trust for the future, the FSA must acknowledge that the mouse bioassay test has always been associated with false positives. We look to the FSA to confirm that some 30 months after the atypical results first appeared there has been no evidence of human illness and they have not identified the cause of the atypical results. The FSA must admit that they have found no "novel toxin". The FSA must acknowledge that due to poor science and flaws in the methodology used by CEFAS no proper conclusions can be drawn from the results obtained from CEFAS prior to 17 November 2003. They must acknowledge that solvent carryover or some other methodological problem as described by Doug McKenzie in his submission to EFRAC was the most likely cause of the atypical response prior to 17 November 2003. Since the methodology has been changed there have been no further atypical results.

(b) The FSA must agree with immediate effect that they will no longer advise local authorities to close cockle beds solely on the basis of atypical results produced by the mouse bioassay test.

(c) The FSA and local authorities will agree to work together with industry to ensure that the CIVIT scheme or LC-MS chemical testing is in place by 31 March 2004 with the MBA being used to confirm the results of the alternative testing methods if necessary.

(d) The FSA will consider the losses suffered by all parties involved in the cockle industry resulting from the closure of the cockle beds since June 2001. The FSA will consider the costs incurred in bringing industry's case to the attention of the FSA and in working with experts to devise the alternative methods of testing and work together with industry's advisers to agree and subsequently provide a suitable compensation package before the commencement of the main cockle season on 1 May 2004.

(e) In order to comply with the agreed timetable and in accordance with the FSA's policy of openness and so that matters can proceed swiftly, meetings will take place on an ongoing basis and at least once every two weeks between industry, their advisers, the FSA and local authorities in order to implement the above provisions. The FSA and industry will work together and agree to issue a joint press release with regard to these provisions.

(f) An independent enquiry team led by the Government Chief Scientist, Sir David King and consisting of relevant scientific experts from industry and the FSA should be brought together to examine the atypical episode with a remit to identify areas of the FSA's approach that are inconsistent with good scientific practice and to recommend codes of practice and procedure for the future.

(g) Industry would also welcome the appointment of an FSA ombudsman to independently deal with industry complaints.

January 2004

Memorandum submitted by the Food Standards Agency (M15)

Executive Summary

1. Marine biotoxins accumulate in the tissues of filter feeding shellfish and can cause symptoms in humans, ranging from diarrhoea to serious, and sometimes fatal, neurological illness. Measures for the monitoring and control of marine biotoxins are laid down in EU legislation, for which the Food Standards Agency is the competent authority. The mouse bioassay (MBA) is the reference test method for the toxins that cause both paralytic and diarrhetic shellfish poisoning (PSP and DSP).

2. Since summer 2001, unexplained (atypical) responses have been observed in the MBA when some shellfish, principally cockles, were tested for DSP. These are positive DSP results within the terms of EU law. Reasons for the atypical response have been investigated but it has not so far been possible to identify the cause. Over recent years, a number of new biotoxins have been described, so the presence of a new biotoxin is not an unreasonable proposition and can not be ruled out at this time. A study is currently being carried out to investigate more comprehensively the potential toxicity of the shellfish. Until results from that study are available for consideration by scientific experts, the Agency will continue, as precautionary measure to protect public health, to recommend the temporary closure of beds when shellfish produce the atypical response in the MBA. The Agency has sought to mitigate the impact on the shellfish industry and allow as much fishing as possible, consistent with its role of protecting public health, by the zoning of harvesting areas.

FSA Role and Remit

3. The Food Standards Agency (FSA) was set up in April 2000 to protect public health and restore public confidence in the way that food safety decisions are made. The FSA is a non-ministerial government department governed by a Board appointed to act in the public interest. It is a UK body, accountable to the Westminster Parliament and to the devolved administrations through the relevant Health Ministers.

4. The Agency's core values are to:

- Put the consumer first;
- Be open and accessible; and
- Act as an independent voice.

5. Our sphere of interest spans the entire food chain. We aim to provide clear advice based on the best possible information, including surveillance data and evidence-based research. We consult widely, including international expertise, commission independent research and, wherever possible, seek views from stakeholders before reaching conclusions. We publish the evidence supporting our actions, and this is generally accessible via our website http://www.food.gov.uk/

Shellfish Biotoxins and EU Law

6. Marine biotoxins are usually produced by microscopic organisms known as algae or phytoplankton. They can accumulate in the tissues of filter feeding shellfish and, if consumed by humans, can cause symptoms, ranging from diarrhoea to serious, and potentially fatal, neurological illness. There are three main groups of toxins; those causing:

- Paralytic Shellfish Poisoning (PSP);
- Diarrhetic Shellfish Poisoning (DSP); and
- Amnesic Shellfish Poisoning (ASP).

7. The symptoms from shellfish biotoxins are often acute, but chronic (long term) effects cannot be discounted. For example, an outbreak in Canada 1987 which led to the discovery of ASP was associated with the death of 3/107 patients, whilst evidence of neurological dysfunction was still present in some survivors two years after the incident.

8. In recent years, a number of new shellfish toxins have been described from many areas of the World. For example, in 1995, toxins in Irish shellfish exported to other countries caused human illness. It took four years of investigations before the Irish authorities identified azaspiracid as the cause, and a further two years to complete the assessment of risks to public health. This shellfish toxin is now controlled under EU legislation.

9. EU Directive 91/492 requires Member States (MS) to operate a shellfish monitoring programme to protect public health in relation to marine biotoxins, including PSP, DSP and ASP. Chapter VI, section 2(c) requires Member States to close production areas where monitoring test results show that placing the product on the market may constitute a hazard to human health. In addition, EU Decision 2002/225 (Annex) establishes death of 2 of 3 mice within 24 hours of inoculation as the determining factor of a positive result in the DSP MBA. The atypical responses do lead to mouse deaths within that period, and thus are positive results under EU law.

The UK Monitoring Programme

10. The programme involves the monitoring of:

— harvesting waters to detect algal species known to produce shellfish biotoxins; and

— shellfish flesh for biotoxins.

11. EU legislation establishes the mouse bioassay (MBA), as developed by Professor Yasumoto of Japan, a leading international expert in shellfish toxins, as the EU reference method for DSP, and it is this method that is in use routinely in the UK monitoring programme. The method involves the extraction of toxins from shellfish flesh and injection of the extract into mice.

12. The laboratories that carry out statutory biotoxin monitoring on behalf of the Agency are:

— Centre for Environmental, Fisheries and Aquaculture Science (CEFAS), for England and Wales;

— Department for Agriculture and Rural Development (DARD), for Northern Ireland; and

— Fisheries Research Services (FRS), for Scotland

13. 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. Although it is based at FRS, it is managed, and operates separately from the shellfish monitoring functions carried out there.

14. Temporary Prohibition Orders (TPOs) are used to close shellfish harvesting areas. TPOs are imposed by local (food) authorities on the recommendation of the Food Standards Agency based on the results from the monitoring programme. Areas remain closed until subsequent sampling has provided satisfactory toxin testing results. Affected areas remain closed until two consecutive negative test results, taken a week apart, are observed. This is considered to be the minimum time necessary for toxin levels in shellfish to be diluted to within regulatory limits. Testing at shorter intervals would be unproductive and impracticable, and would incur disproportionate costs associated with additional sampling and testing. The costs associated with this work are paid by the FSA.

DSP Test Method and Animal Welfare Considerations

15. Commission Decision 2002/225/EEC specifies the use of biological methods, such as the MBA, to test for the regulated toxins. It also makes provision for the use of alternative methods, provided they can detect the required toxins, are no less effective than the biological methods, and their implementation provides at least equivalent public health protection. Article 5 stipulates that when the results of the analyses performed demonstrate discrepancies between different methods, the MBA should be considered the reference method.

16. The MBA also provides early warning of new toxins which may have implications for human health. These would go undetected by chemical methods, which by definition can only detect known toxins. In correspondence with the FSA, the European Commission (the Commission) confirmed that it continues to regard the mouse bioassay as the best method available because it detects all known toxins. However, it should be noted that there is no agreed Standard Operating Procedure (SOP) for the test at the EU level. The Agency has pressed the Commission and the Community Reference Laboratory for biotoxins (CRL) for urgent action at the EU level to address this issue. In recognition of the need for a harmonised DSP MBA method, a CRL Working Group (which will involve the UK) has been set up to develop a robust and scientifically validated EU MBA method. This working group is scheduled to meet several times during 2004.

17. Animal testing in Great Britain has to be licensed by the Home Office under the Animals (Scientific Procedures) Act 1986, which implements European Directive 86/609/EEC (in Northern Ireland the licensing authority is the Department of Health, Social Services and Public Safety). Under this legislation such testing can only be licensed when there is no non-animal alternative, and then only if the number of animals used and their suffering is minimised, consistent with satisfactorily achieving the scientific purpose—this is known as application of the 3Rs (replacement, reduction and refinement). The Home Office and their Northern Ireland counterparts regularly discuss with the FSA and the test laboratories ways of improving implementation of the 3Rs in the UK shellfish testing programme. The shared aim is to move towards non-animal means of testing as soon as practicable—and to refine animal tests as far as possible in the interim—without jeopardising continued protection of public health.

Alternative Methods

18. The Agency has commissioned work to develop alternative chemical tests for specific toxins that could be used routinely in the monitoring programme, backed up with a lower level of testing using the MBA to check for new or emerging toxins. In order for such methods to be suitable for use in this way, they must be able to detect the full range of known toxins. This requires preparations of all the regulated toxins to be available to use as reference standards in the tests, which is not currently the case. Additionally, the use of such methods needs to be considered at EU level and the necessary approval procedures have to be followed. At the present time no chemical alternative methods for detecting DSP toxins have been approved at EU level.

19. Partly as a result of Agency pressure, a CRL Working Group is scheduled to undertake work during 2004 to develop a validated EU wide method based on a physico-chemical analytical technique known as Liquid Chromatography—Mass Spectrometry (LC-MS), which appears to be the most promising alternative method for shellfish toxins. The UK is represented on this working group and will contribute to this important work.

20. The Commission and the CRL have also recently agreed to progress the development of reference standards for the full range of toxins covered by EU law with the EU Joint Research Centre.

Atypical DSP Test Results

21. Since the summer of 2001, atypical responses have been observed in the DSP MBA for some shellfish samples from England, Wales and Northern Ireland tested under the statutory programme. The atypical response involves mice dying more quickly than they do as a result of known DSP toxins. The species mainly affected has been cockles, although some atypical responses have been seen from mussel extracts.

22. Scientific advisers to the industry have suggested that the response may be an artefact of the way in which the test is carried out, on the basis that it was only observed after the transfer of the monitoring programme for England and Wales to CEFAS. The Agency has carefully considered this suggestion and, in the course of the programme of work to investigate the phenomenon, has included studies to address this issue. Nevertheless, it should be noted that the atypical response has been observed by DARD as well as CEFAS.

Agency Funded Work

23. The Agency has 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. It has sought advice on the most appropriate lines of enquiry to pursue from a wide range of independent and Government experts, both at home and abroad. Consultants appointed by the Shellfish Association of Great Britain also forwarded proposals on how the matter could be tackled. All suggestions were considered and, where appropriate, built into the Agency's work programme or reflected in the reports of work carried out.

24. In October 2001, CEFAS notified the Agency that atypical results were being observed in the DSP MBA and identified some work to investigate the issue. Formal proposals were sought and studies were commissioned in 2002. At the Agency's request, the UK NRL organised a UK Inter laboratory ring trial of the DSP method. The Agency subsequently commissioned the UK NRL to review the testing methods used at the three UK monitoring laboratories, recognising that there was no agreed Standard Operating Procedure (SOP) for the test, either in the UK or the EU. Differences in the ratio of solvent to flesh used in the extraction, as well as the particle and solvent removal stages of the tests were identified. Work was carried out to see if any of these differences or environmental contaminants might account for the atypical response. These studies eliminated a number of suggested causes of the atypical response. Further details can be found in a report to the FSA Board in December 2002 (http://www.food.gov.uk/aboutus/ourboard/boardmeetings/boardmeet2002/boardmeeting120202/boardmeet121202) and are referred to in the Agency's October 2003 report on solvent investigations.

25. During 2003, an extensive programme of work was commissioned to standardise the DSP testing procedures. Hugh Makin, Professor of Analytical Biochemistry at St. Bartholomew's & the Royal London School of Medicine & Dentistry, was appointed to assist with this work and independently audit the DSP testing procedures at the monitoring laboratories. This involved observing the way in which the test was carried out in practice at CEFAS, FRS and DARD against the documented interim SOP held at each of these laboratories and recording any deviations. He was also asked to report any issues which may otherwise have been overlooked and which in his opinion could be considered to affect the test results.

26. A series of studies was also undertaken to assess whether solvent carried over following extraction may have been implicated in the atypical response. These studies do not suggest that there is a direct causal relationship between ether and/or acetone levels in the extract injected into the mouse and the atypical responses recorded. The reports of this work, the Agency's action plan in response to this work and progress to-date have been published, and can be downloaded from the Agency's website.

http://www.food.gov.uk/multimedia/pdfs/shellaudittable.pdf

http://www.food.gov.uk/multimedia/pdfs/shellmakinreport.pdf

http://www.food.gov.uk/multimedia/pdfs/shelletherpaper.pdf

http://www.food.gov.uk/science/researh/microsafety/b16programme/shellfish—toxins

27. In addition, the Laboratory of the Government Chemist (LGC) was funded to carry out a study to assess whether LC-MS could be used to detect, and possibly identify, the unknown substance(s) responsible for the atypical responses. The report of this work is expected to be published on our website by the end of January 2004.

28. In November 2003 the Home Office approved proposals for a toxicology study to further investigate the atypical response. This study will inform the Agency's consideration of the associated public health implications. So far the study has confirmed that stored cockle extract is still potent, and is suitable for use in the investigations. Extracts will be administered to mice by intraperitoneal injection (ip) and by mouth. The clinical signs and post mortem findings will be compared. This work is expected to take place in January, with initial results available for consideration by the Committee on Toxicity (COT) in early February. The Committee will be asked to advise on what further work should be undertaken. The findings from this programme of work will be used by the Agency to review policy on the closure of shellfish production areas that generate atypical results in the MBA.

29. In line with its policy on openness, Agency activities to resolve the matter, as well as the data generated by them, have been made publicly available on the website. The Agency's Board and the public have been informed of developments through regular reports at open Board meetings.

The Precautionary Approach

30. On the basis that something is being detected in the MBA which is killing mice more quickly than DSP, the Agency recommends closure of affected shellfish beds, as a precautionary measure to protect consumer health. To do otherwise would be to ignore the conclusions of the Phillips Inquiry into BSE on the handling of potential threats to health arising from the food chain. The Phillips report lays great stress on the need to take precautionary action when the risk is uncertain; to openly and honestly communicate policy decisions and the basis for them to the general public, and to ensure that action is implemented and enforced effectively. This has always been our policy and we shall continue to apply it.

31. As discussed above, the Agency has yet to identify the cause of the atypical responses and assess the human health implications. Until the results of the current work programme are known later this year, the Agency will continue to recommend that Temporary Prohibition Orders be placed on beds where samples generate atypical results.

32. At a meeting hosted by the Agency in May 2003, Professor Yasumoto indicated that the atypical responses he observed when he visited CEFAS in May 2003 were likely to be due to a novel toxin, and he pointed out that the effects of ingested shellfish toxins on humans are simply not known. He underscored the need for caution, particularly in respect of vulnerable consumers (the elderly, the young, those with other illnesses), and reported that he had seen mice, apparently healthy when alive, exhibit internal muscle, liver and heart damage on post mortem examination following oral administration of shellfish toxins. This indicated that toxic effects might be chronic and insidious, rather than acute.

33. In view of the potential risks identified and the associated uncertainty surrounding the issue, the action taken is considered by the Agency to be proportionate.

Industry Considerations

34. The FSA has endeavoured to ensure that any effects of temporary shellfish harvesting restrictions on industry are kept to a minimum, consistent with the protection of public health.

35. Following discussions with stakeholders, the Agency introduced zoning arrangements for the shellfish harvesting areas most affected by the atypical response problem. The purpose was to minimise disruption for, and impact on, fishermen, and allow them to continue fishing wherever practicable.

36. Data from the Local Authorities and Sea Fisheries Committees for the main fishing areas indicate that, despite the closures, quota uptake in the Thames Estuary and Wash fisheries was at least 91% in all areas in 2001 and 2002, and approaching 100% in most. Comparable data on fishing against quota for the Burry Inlet, which has been the area most affected by closures caused by the atypical response, are not readily available. However, in August 2002 zoning arrangements were put in place, and since then the whole of the Burry Inlet has only been closed for 2 weeks in 2002, and 3 weeks in 2003.

Taking Forward Findings from Investigations

37. Work carried out so far does not suggest that the atypical response is caused by solvent carry over following the extraction procedure.

38. Nevertheless, since 17 November 2003 the monitoring laboratories have operated the UK NRL SOP, which includes steps to ensure no detectable solvent is present in the extracts injected into mice. Laboratory technicians undertook training beforehand, so the SOP would be applied consistently.

39. This SOP has been the subject of a further study to check that it is operating effectively and being applied consistently. This includes measurement of residual solvent levels. Results thus far indicate that solvent carry-over at all three monitoring laboratories is very low, and the method is detecting recognised DSP toxins. The report of this study is also expected to be published in January. The Commission and CRL are being kept informed of developments and are following progress closely.

CONCLUSIONS

The shellfish biotoxin monitoring programme exists to protect public health. The Agency's role is to ensure that it is carried out effectively and proportionately. On occasions it is necessary to restrict harvesting on the basis of test results, as required by EU legislation. The Agency has taken action to minimise the impact of the closures resulting from the atypical response on the industry, where this is consistent with public health protection, and is committed to resolving the atypical issue. The FSA is actively pursing improved testing arrangements and a move away from reliance on the MBA at the EU level.

9 January 2004

Witnesses: **Dr Jon Bell,** Chief Executive, and **Dr Andrew Wadge,** Director of Food Safety Policy, Food Standards Agency, examined.

Chairman: Welcome to the Committee. You have heard the industry side of the story. We want now to explore the Food Standards Agency's side of this argument, which I must say is fascinating for us to hear about.

Q43 Mr Drew: Can we start with the science because obviously where the breakdown in relationship comes from is on a scientific rationale. I think it would be useful if someone could say when you first suspected there was a problem, why you acted in the way you did and how the science that you believe is in place backs up the actions that you have taken.
Dr Bell: The problem first came to our attention as the laboratories in Northern Ireland and CEFAS began to see these unusual reactions in the mice that they were using for their standard DSP test. The mice tended to get into distress and die in a number of cases very much quicker than had been traditionally observed when using that type of test. This seemed to point to some possible new phenomenon which had to be taken seriously as it might point to the emergence of a new toxin.

Q44 Mr Drew: What is the hypothesis which you believe to be the case which is showing that there are these atypical reactions?
Dr Bell: The difficulty is that we have no firm hypothesis on what is causing this. Using the mouse test, which is the definitive test that is laid down in EU law, where there is any doubt between results from the various tests that are available, we are seeing reactions which suggest the possibility of a toxin. There can be other possible explanations as well but the difficulty at this stage is that we cannot rule out anything, including the fact that it may be a toxin.

Q45 Alan Simpson: It sounds a bit like bovine TB to me but we will not go along that path. This Committee spent long enough on that. Are you absolutely convinced that there is a novel toxin in existence?
Dr Bell: No. We do not know.

Q46 Chairman: Were you then convinced there was a novel toxin?
Dr Bell: No. We have never been convinced it is a novel toxin because we have never had the definitive evidence that one would need to say that it was.

Q47 Chairman: Did you think it was a new toxin at the time?
Dr Bell: We thought it was a possibility. We took advice from Professor Yasumoto and from Canadian experts. They had seen a range of various toxins over the years. We described the position to Professor Yasumoto and we sent him an extract. He reproduced, in his own laboratory, the same reaction with mice. We sent a video of the test mice to the Canadian experts. They both said, "This looks like a neurotoxin."

Q48 Mr Drew: Can I be clear about what determined the sequence of actions? You persuaded the industry that it needed to shut down its beds?
Dr Bell: No.

Q49 Mr Drew: Can you take me through it? I am very unclear what actions you took.
Dr Bell: We are required to take certain actions under EU law if we believe that there is a potential threat to human health arising from shellfish. The mouse test gives you certain results and you are required to interpret those as positive or negative. Once one gets what are classed as positive results—and this looked like a very firm positive, but in unusual circumstances; it certainly fitted the requirements for positive in the interpretation criteria laid down—we communicate that with the local authorities whose job it is to take action locally to protect human health. That is the sequence. Any subsequent action to be taken is their decision but obviously it would be difficult to make any other decision than the one that they have customarily made to close the beds until such times as negatives start coming through on repeat tests.

Q50 Mr Drew: What is the overall picture in terms of people being poisoned by eating shellfish? Is this a common problem?
Dr Bell: No. Thankfully, it is a very uncommon problem. We have had very little of it in this country over the years but there have been some very marked outbreaks in some other countries. As a result of the toxin that the Irish discovered in recent times, there was a number of people made quite ill and the Canadians had a very severe outbreak a few years ago. It is certainly a possibility. You could argue that the reason we have not had it in this country is because we have been very careful about how we have operated the protection regime that we have,

but I cannot be certain of that one way or another. We certainly have not experienced thankfully what others have experienced in this area.

Q51 Mr Drew: In terms of the evidence of the previous people, we could be importing this material from the Netherlands. If there was an incident of poisoning, we could act but we could not take a precautionary principle stand against those importing.
Dr Bell: Unfortunately, the position is difficult in that regard because we are working within the Community on this, as you know, and the rules supposedly apply across the whole Community in an even handed way. The position we have taken on this is that we want to protect human health of course. That has to be our primary role but we also want to be proportionate in the way that we are doing this, as far as we are able. We have taken the view that these sorts of issues can have chronic effects as well as acute effects and small amounts over a short period of time are not likely to be the issue here. It is likely to be longer term effects over an extended period of time. Provided one acts reasonably swiftly on closing beds and provided we are not talking about similar problems elsewhere that would involve consumption of large quantities, we think we have application of the precautionary principle about right. It is a matter of judgment.

Q52 Mr Drew: What is the minimum period of time that you think you have to enact the precautionary principle?
Dr Bell: Usually, we try to do all the testing from the collection through to the testing within one week, with the collection and the despatch of samples occurring in the early part of the week from Monday onwards, arriving at the laboratories by Wednesday and results by Friday, temporary prohibition orders being put on at that time if necessary.

Q53 Mr Drew: How do you respond to the view that the industry has advanced that may result in legal action—we hope not—that you do not have the powers to impose closure, notwithstanding you do not do that, but you are making a strong recommendation? Do you feel confident you have the powers?
Dr Bell: The legal powers are most certainly there. Further than that, we are required to act in a certain way as laid down by EU law. You do the test. If you get what is classed as a positive and therefore there is a concern that there may be an effect on human health, you are required to take the necessary steps to ensure that you control that risk and that means closure of beds.

Q54 Chairman: There was a change in the laboratory doing it from Aberdeen to CEFAS. Why was that? Was it as a result of a competitive bid?
Dr Bell: Yes. It was two fold. Firstly, we had a visit from the Food and Veterinary Office in 1999 to look at the way we were applying the EU regulations and they made a number of criticisms, the principal one of which was that we were not doing enough sampling, by a long way in their view. The levels needed to be stepped up considerably.

Q55 Chairman: Who visited you?
Dr Bell: The Food and Veterinary Office is the European policeman, if you like. They are the European local authority. They check that you are applying the law in the correct way and they report their findings back to the Commission and the Commission could at the extreme take you to the European Court.

Q56 Chairman: They put the fear of God into you?
Dr Bell: They are obviously a very powerful body and one takes careful note of what they say. We do not always accept everything they say but in this case they said that they thought that the extent and the timing of the collection and testing of samples were not adequate to cover the risk.

Q57 Chairman: That is not an argument about the methodology, is it?
Dr Bell: This was nothing to do with the methodology. This was to do with how frequently and how much sampling and testing were being carried out. We took the view that we should increase the amount of testing as it was not at a very high level at that time. It became appropriate also, since there had never been any competitive tendering and these are fairly large contracts, to put the work out generally for tendering.

Q58 Chairman: This was a cheaper bid?
Dr Bell: No, not necessarily. It was judged against a whole range of criteria by an independent group.

Q59 Chairman: Was it cheaper?
Dr Bell: I cannot say. That certainly was not the deciding factor. It was to do with their ability to deliver and its timeliness.

Q60 Chairman: In asking people to frame bids, did you set out a standard operating procedure for what they should do?
Dr Bell: Not in the way that we now talk about the standard operating procedure. Certainly it was made clear what was required. It had to be done in line with EU legislation and that meant effectively following the Yasumoto approach. That was understood.

Q61 Chairman: You had a competitive bid. In comes this bid from CEFAS. They start doing the tests. It is argued in a different way to the way it had been done in Aberdeen and all of a sudden you find yourself massacring mice. Did a bell not ring that it could have been due to a change in the lab, a change in the methodology or the climate?
Dr Bell: The story is not quite as straightforward as that. We might well have drawn that sort of conclusion, quite rightly, if it had been straightforward. Although there was a change in England and Wales as to who was doing the testing, there was not a change in Northern Ireland. The

Northern Ireland testing had always been done for very many years by the Department of Agriculture's laboratory there and they carried on doing it. They started to get exactly the same results at about the same time.

Q62 Chairman: Did they change their methods?
Dr Bell: They did not. They had been operating at that time for a while, certainly some time, using the mouse test and they began to see quite independently much the same sort of results.

Q63 Chairman: There was no change in Scotland.
Dr Bell: No. They were using a rather different approach in Scotland. You have heard some of the detail of that in terms of the amount of extractions they were doing, over what period and whether they stood their extractions overnight. There were some differences in the way that they were doing the work. There is no real evidence for this one way or another but you could argue they might not have been as vigorous in the extraction of material. That is a possible interpretation. I am not saying it is the only one. We were not clear why these differences should appear.

Q64 Chairman: At what stage did you begin to think, "This is not a new toxin", a killer toxin or whatever; "This is a change in the way it is done"?
Dr Bell: We never thought that. We never have thought that. We took the view that we did not know what was causing this effect. We still do not know clearly what is causing this effect. What we had to ask ourselves was: "Are we certain this is not a new toxin?" If we are certain of that, we can proceed as normal but if we think that one possible explanation here is a new toxin, and we cannot rule it out, what position should we take in terms of protecting human health? We were very mindful of the lessons that have been learned since the days of BSE about what one does in the face of uncertainty in such a situation and that is that you take reasonable precautionary action to ensure that you do not learn after the event that it might have been a toxin.

Q65 Alan Simpson: When you talk about not knowing what caused the effect, is it correct that when you changed the procedures, since doing that, there has not been an effect?
Dr Bell: There have been no atypical results in the last two or three months. When we plotted out what had been happening previously, it is clear that there had been a drop in the number found before the changes were made. One could not necessarily draw the conclusion that it was as a result of making further changes to the methodology that it has now dropped down effectively to zero. Two positives were found immediately after CEFAS made the changes and then it dropped away after that. Positives were being found in Northern Ireland consistently because it was effectively their methodology that was transferred across to CEFAS and the Aberdeen laboratory with some changes.

Q66 Chairman: You were taking reassurance from Northern Ireland but Northern Ireland changed from feeding it to rats in 2000 to using the mouse tests. They did not have the experience that the Aberdeen laboratory had in using mice, so you were both going down the same track.
Dr Bell: That is true, but they had been doing the mouse test for some while before these atypical results started to turn up. You would think, if it was their inexperience with the methodology, you would see it almost immediately that they moved away from the rat and that was not the case. The other factor we have to take account of here is that not every cockle result turns up positive. Far from it. A good 60% over the three years we are talking about have turned out negative.

Q67 Chairman: You have just said to us you did not think and you do not think now it is the methodology.
Dr Bell: We do not say that at all. We are not clear what it is.

Q68 Chairman: You must have been suspicious because you then commissioned studies of the methodology.
Dr Bell: We have been looking at all the facets of it, which is what you would expect us to do. If we had been clear it was a toxin and we had good evidence for that, it would not have been necessary to have done anything else on that, except perhaps to try to characterise what that toxin was. Because we were not clear and there was a range of possible explanations, we thought it necessary to do work right across the spectrum. We have done quite a lot of work looking at the methodology and we are doing some toxicological work to look at the possible threat to human health as well. We are under way with that now.

Q69 Chairman: Somebody said tests are done on Monday and Tuesday and you have the results by Thursday or Friday. By that stage a lot of the stuff can have been eaten, can it not?
Dr Bell: Yes. We are trying to work in the most realistic way we can. We are trying to be as proportionate as we can. Our main concern here with toxins of this type is about consistent consumption over a period. We took the view—you may say it was a wrong view to take—that consumption over a period of a few days would not be an issue in itself and we should act as soon as we definitely had positive results that we felt we could act on.

Q70 Chairman: You had positive results and people did not die or fall ill.
Dr Bell: No, they have not, so perhaps we are not looking at an acute effect here. The difficulty with all this is that these toxins do not only manifest themselves in that way. We have had discussions with Professor Yasumoto and he has been able to produce evidence that shows that some animals on which he has done toxicological studies appear healthy until he opens them up.

Q71 Mr Breed: Can we look at the way in which differing laboratories came up with differing results, differently interpreted by different people? Why was there no standard operating procedure put in place right at the beginning so that at least there was some comparability between the laboratories involved?
Dr Bell: I take the point. With hindsight, we should have taken steps to do that. This general shellfish testing has a long history and it had never been considered necessary to do it up to then. As long as you followed the Yasumoto approach—and there were variations that scientists made around the general core of that approach—nobody thought it necessary to have an absolutely standardised method in every regard. That had never been negotiated and agreed in Brussels. As far as I know, no Member State had taken any action to do that. Once we got into this position, it became very clear very quickly that we needed to do some standardisation because obviously laboratories testing within the UK around the same waters should, one would presume, have been obtaining the same type of results, had variation.

Q72 Mr Breed: In the bid process, there was no laid down procedure that you required of them in order to fulfil the contract for the testing? They could do what they liked?
Dr Bell: No, not to that extent, not fine detail laid down, as every step would be laid down as in a standard operating procedure, but making it quite clear that the procedure had to follow the EU requirements which are the Yasumoto method.

Q73 Mr Breed: That is then; this is now. Do all laboratories now operate under an SOP?
Dr Bell: Yes.

Q74 Mr Breed: Which was laid down by?
Dr Bell: We drew the laboratories together following Hugh Makin's report where he had found discrepancies between the various laboratories we thought ought to be addressed. He did not consider these materially affected the results but nevertheless he thought it sensible that we should take action to tighten these up so that is what we did. We called a meeting of the laboratories and everyone agreed that the methodology which should be followed would be the Northern Ireland methodology with some small tweaks.

Q75 Mr Breed: The Northern Ireland one is now being carried out in the other two laboratories?
Dr Bell: Yes.

Q76 Mr Breed: What effect has that had on the test results?
Dr Bell: At the moment we are in this period—long may it last—where we are not getting positives.

Q77 Mr Breed: From anyone?
Dr Bell: From anyone. Whether that is as a result of the change to the standard operating procedure or whether it just happens that we have fallen into a period when the problem has gone away for the time being, it is not possible to say. We have looked at what was happening immediately before this and sure enough the number of positives was falling away anyway before we made this change. We do not feel confident that we can make the decision, at this stage anyway, on only a few months of negatives. Either the toxin has gone away or the change in the methodology resulted in the change.

Q78 Mr Breed: If everything carries on as it is at the moment, when would you expect to be able to say that everything is okay?
Dr Bell: The principal thing we have to do is to complete the toxicology. If this toxicology comes out negative, I think we will be pretty confident that we do not have a threat to human health here and that is assuming that the toxicological experts on the independent committees agree with that. Then we will be fairly confident that whatever the background to this was there was not a threat to human health and we can take action accordingly.

Q79 Ms Atherton: You appointed Professor Hugh Makin to come in and independently audit the testing. What was your response to Dr Askew's assertion from the Shellfish Association that Professor Makin could not say that ether did not cause the atypical results?
Dr Bell: Professor Makin did say quite clearly in his report he did not consider the carry over of solvent was giving rise to the observed results. That was his professional view. Obviously, one combines that with other information but we did not take that as an absolute, definitive answer to the question of solvent carryover and we have done quite a lot of work since to make sure that solvent levels are kept absolutely as low as possible.

Q80 Ms Atherton: Earlier we heard a suggestion that the transportation issues in this country are very different perhaps to New Zealand. What is your reaction to that? Do you think that might have been a contributory factor and have you taken that into account?
Dr Bell: I do not know whether that is a contributory factor. I am not sure that we have done any particular work on that. The National Reference Laboratory lays down the requirements for transportation and the way that the samples should be treated on receipt. One would hope that they have taken account of that but I cannot answer that definitively at this time.

Q81 Ms Atherton: You talked a little bit about testing the methodology. Can you tell us a little more about how you reacted and what your response was to the Shellfish Association's suggestion that poor scientific methodology at CEFAS is responsible for the atypical results?
Dr Bell: We considered it very carefully. We could not see any immediate grounds for that. Although the shellfish interests said that they considered that solvent carry over was a serious problem, working on what Professor Yasumoto had told us when he reproduced the results himself in his own laboratory,

the fact that he came over and witnessed the work being done over here and took a similar view that a novel toxin could not be ruled out, taking into account that Professor Makin did not think the solvent was the issue, we saw no immediate reason to suppose that was the answer and to alter policy on the basis of it. Having said that, obviously we recognise that this could be an issue. We have done quite a lot of work on it. We have published quite a lot of work on trying to get to the bottom of whether solvent carry over or other factors of this nature might have been the reason for this, but that is as much as one could say. We certainly did not immediately draw firm conclusions.

Q82 Ms Atherton: Since the current assay was introduced, I gather there have been numerous insufficient sample and operator error reports in the results. Is that true? How could you explain that?
Dr Bell: I do not think any of us are aware of that.

Q83 Ms Atherton: Perhaps you would be kind enough to come back to us with the extra information if that is the case?
Dr Bell: Yes, certainly.

Q84 Ms Atherton: What is your response to the Shellfish Association's assertion that other laboratories have been unable to replicate the CEFAS results?
Dr Bell: I am not aware that other laboratories have been asked to do that sort of thing.

Q85 Ms Atherton: Would it not have been a sensible thing to do?
Dr Bell: Yes, but it is difficult. You have to recognise that you have to use the same material. You are dealing with very small amounts of material in most cases in this sort of issue, so trying to reproduce across laboratories is quite a difficult process in these cases. We have seen a lot of similarity in the way that at least two laboratories have turned up these results and it is fairly clear that the third laboratory would not necessarily turn up the same results with the methodology they were using. There may be a variety of reasons associated with that, including the method of extraction.

Q86 Ms Atherton: I understand some other countries such as Holland have tried to replicate the results and have been unable to do so.
Dr Bell: I do not have the information at my finger tips. We will look into that and write to you if that is the case.

Q87 Chairman: We are quoting Professor Makin who said that there was no evidence that the atypical result was due to the presence of ether, but Dr Askew tells us in his evidence that he also agreed that he could have said there was no evidence that it was not caused by ether. In relying on his endorsement either way, we are going to fall down because that is not really saying one thing or the other.
Dr Bell: I do not think we did rely on his opinion in that regard. We took note of it and that was his considered, professional view. That is what he said, but we did not rule out the possibility that—

Q88 Chairman: He also said it is not caused by ether; there was no evidence that it was not.
Dr Bell: His considered view was that he did not think that solvent carry over was the reason for the effects. Nor, come to that, did a number of other experts including Professor Yasumoto. We did not however rule out that possibility. We have done work to see what we are dealing with in the way of solvent carry over and the amounts that have been found are far below those that are known to cause toxic effects in laboratory animals. It is very difficult to prove negatives with these things.

Q89 Chairman: Surely the cases Professor Yasumoto dealt with when he came over would be based on samples which were produced by the methodology which the Shellfish Association is saying was flawed and you are saying was not, so he was working on the same material?
Dr Bell: Yes. He witnessed this methodology when he came over. He did not think it was seriously flawed, but he did not do it himself at the bench. He witnessed it being done. He did however do some work on some extracts. I do not have the detail at my finger tips but I would imagine, since he is somebody who has been immersed in this area of work for very many decades, that he would not just have taken a sample and tested it in animals without having a look at things like whether it had a large amount of solvent in it.

Q90 Alan Simpson: A number of the people who have made submissions to the Committee have made their own references to the difficulties about having an independent laboratory assessment of the evidence and the conclusions that you are drawing. Would you accept that there is a perception of the non-independence of the National Reference Laboratory?
Dr Bell: The difficulty is that the National Reference Laboratory is embedded within the laboratory in Aberdeen. We are assured by Aberdeen that they work independently of each other and we have no reason to suppose that is not the case, but from a perception point of view I agree it is difficult to be able to demonstrate that conclusively when they are part of the same organisation. That is something we need to look at for the future, but we certainly would not take the view that we consider they operate other than in an independent fashion in this matter.

Q91 Alan Simpson: Would you accept there is a case to be made for something that was genuinely independent and seen to be independent?
Dr Bell: Yes, I think there is a case to be made for that simply because of where they are housed and which organisation they are part of. It has inevitably to be a case of Chinese walls in that situation. It depends what faith one puts in that arrangement but I agree that to be absolutely certain one would want

to have it perhaps based somewhere else or clearly divided away from the rest of the organisation. I would add that we have no reason to believe that they have not acted independently in this matter. We have seen no evidence that they have not, as I said before.

Q92 Alan Simpson: Without going down the path of saying that, if that was the case, who should it be, if I could focus on the principles of this, would you accept that if we are to address the communications issue—and clearly there is a problem to be addressed—there would have to be a commitment that the science that underpins that reference laboratory would be rigorous and open?
Dr Bell: Yes, absolutely.

Q93 Alan Simpson: One of the points that really rankled with me was in this reference to the suggestion that the FSA has banned communication, going so far as to threaten officers under the Official Secrets Act. How do you justify that?
Dr Bell: I have no idea what that refers to at all. Certainly we do not operate in that way. As you know, we have prided ourselves since our establishment in 2000 on being an open organisation and hopefully a constructive organisation with those we deal with.

Q94 Alan Simpson: Are you saying that the FSA would refute that allegation?
Dr Bell: Yes, absolutely.

Q95 Alan Simpson: If we were to turn that back to the industry and say that that is a pretty robust accusation to make—
Dr Bell: If there is evidence of it, I will look into it.

Q96 Alan Simpson: We can ask the industry to come back on that?
Dr Bell: If they have firm evidence on that, I will look into it.

Q97 Alan Simpson: Whether the FSA come out of this well or the industry comes out of it well, it is quite clear that the mouse comes out of it pretty badly. I want to raise questions about the validity of the mouse bioassay and whether you regard this as an adequate, acceptable form of testing, because we have had disputes about the methodology and the consistency of application of that methodology. I just wanted to get your thoughts on the adequacy of the test itself.
Dr Bell: I think the test inevitably has a number of drawbacks. There is no doubt that we would ideally like to move, where we could, to a more precise chemical test, but there are a number of difficulties associated with this. One is that you have to have good standards on which you can base your chemical test. They do exist for some of the toxins. We are talking now about ones we know about. They do not exist for all of them. You have to have a chemical test validated. We are pressing within the Community to move in this direction as fast as possible and we are pressing for the European Reference Laboratory to take a lead on this. I am glad to say they are now getting a grip on the matter. You can only really use chemical tests where you know what the toxin is; it has been characterised, you know how to recognise it and you know where the peaks are in the chromatogram. Where the difficulty comes is that it is very hard to see how you can avoid using a biological test at all because the only way you can pick up new toxins is by using a biological system by definition. It is very difficult to see how else you can do it. What we would like to see is the mouse test used, if you like, to support the rest of the tests and not be the definitive test. We would like chemical tests to be the definitive tests wherever possible but with the mouse test as the back-up to pick up anything that may suddenly appear, as with this Irish toxin that they found a few years ago which had not been known before and which you would miss with a chemical test because you simply would not see something you were not expecting.

Q98 Alan Simpson: Can I ask whether you have taken a view on the appropriateness of the New Zealand regime, the fully validated chemical testing regime?
Dr Bell: I think that is certainly a step in the right direction. I do not think that brings all the answers for the reasons I have described, but there is a lot of work going on round the world now to develop good, robust chemical tests for the known toxins. What we would like to see is this being brought forward into Community law so that we get definitive tests for the toxins we know about.

Q99 Alan Simpson: Have you made formal submissions to the EU about your preferred chemical testing regime to replace the MBA?
Dr Bell: We have written on a number of occasions and made formal representations on the need to move to a chemical based system where at all possible.

Q100 Alan Simpson: Have you done the work that made the submissions? The Committee receives evidence in all sorts of circumstances where people are saying to us that someone else should do the work. Have you done the work? Have you put any proposition up at a European level that would allow that moving on process to be driven by us?
Dr Bell: Yes. We think this has to be something that we work across the Community on but we are doing work at the Laboratory of the Government Chemist, developing these methods. We have asked them and they have been looking to see if they can find a chemical profile for what might be in the samples that are giving the atypical results. They are seeing a lot of material there but they cannot be certain which of that might be giving rise to these results, if at all, so there is work to be done there, but we are doing work in this area and we are urging the European reference laboratory to coordinate action across Europe. We are now beginning to get some action on

this and there is a working party coming up very shortly that we shall certainly be taking a strong lead in.

Q101 Alan Simpson: We have not got to a point of putting any counter or replacement proposals on the table for consideration about this different European approach that you say we need?
Dr Bell: We have not put down definitive methods on the table and said, "That is what we should go with." Such methods do exist in some cases and we would certainly support those but we have not got that far because we have been trying to raise enough interest to get the matter properly discussed so that we can move in that direction as swiftly as possible. I think it is a matter of degree. It is certainly not a lack of intent.

Q102 Alan Simpson: If we were trying to wrap all of this up, it seems to me that from the industry perspective and from an ethical perspective we have serious doubts raised both about the validity of this form of testing and the consistency and rigour of the testing process. The biggest criticism, I suppose, that has been levelled at the door of the FSA is that you have used the precautionary principle not to protect the public but to protect your own perineum. I wonder whether you can justify the size of the outcomes of the tests that you are now conducting to say, "We have a case for a ban."
Dr Bell: That really is the nub of the matter. The principal difference between the position we have taken and the one that the industry has taken, as we have heard today, is that we are not ruling out a whole range of possible explanations for this, including the presence of a possible toxin. If that was to be the case, it would obviously be our responsibility to try and protect public health as much as we can from the presence of that toxin. We do not know for certain there is a toxin there. We are doing work to try and be clear about that, but while we do not know we are very much minded to take the advice that was presented by Lord Phillips in his report that one should take precautionary action to protect public health in areas of uncertainty of this type. We think there is a range of possible explanations. That is one of them. The way I see it from the industry point of view is that they seem to have firmly ruled that out and I cannot see the evidence for firmly ruling that out.

Q103 Chairman: Why was the Scottish Food Standards Agency more accommodating than you? When the Aberdeen laboratory began to test in the same way as CEFAS was testing, they too started killing mice and then they reverted back to their former procedure, with the consent of the Scottish Food Standards Agency.
Dr Bell: They certainly were. They are part of us as a whole because we are a UK body and the director of Scotland reports to me. The position there was that, in the hands of the people in the Aberdeen laboratory, using the standardised method that was brought in in June—this was before we resolved all the issues and brought in a better one later in the year—it was felt that there was likely to be more solvent in there than they thought was appropriate. They felt they could smell it in the final extract. Clearly, to use that on animals was contrary to their Home Office licence. If they felt there was a risk they might be killing the animals through having too much solvent present, they should not do it, so they paused at that point, consulted FSA Scotland and said, "Should we carry on or not?" and clearly the advice was, "No, you should not carry on until you have satisfied yourself that you are preparing the samples as rigorously as possible with minimisation of solvent." Further work has been done to ensure that we have reached that stage now, where everybody is content they can operate the method effectively in their own laboratories to achieve that.

Q104 Chairman: Has there been a report by the government chemist on the procedures? It is my understanding that there has been. Can we have that report?
Dr Bell: The work that has been carried out at the government chemist, which we commissioned, has been looking to see whether we could chemically identify a new toxin in the extracts. They have done quite a lot of work looking at the chromatographic profiles that they are finding, comparing those with other profiles they have had, to see whether they can find something new in there that may then warrant further investigation.

Q105 Chairman: Have they?
Dr Bell: They have found a whole range of unexplained peaks and they need to do further work now to see whether any one of those may be the reason for the atypical effect and then whether this amounts to a new toxin. They have done quite a lot of work but they need to do more. That is the work they have been concentrating on doing. Clearly, if they were to identify a peak as being the cause and it was a toxin, they would not only demonstrate a new toxin but simultaneously they would provide a chemical method for it, so it would be a very powerful outcome if it could be achieved. We are too early on in the process to be able to draw any conclusions, I think.

Q106 Chairman: Alan mentioned people being silenced. This is a scientific argument, is it not? You need the exchange of information between scientists and specialists so that you can get a common ground of understanding. I have had passed to me a letter which was from Dr Wadge which says, "Godfrey Howard", who has given evidence, "has been involved with the Scottish monitoring programme for shellfish toxins." If, as you suggest, he has been keeping you informed of progress on FSA funded contracts, he has been breaching the confidentiality clause of the FRS contract with the FSA in releasing early preliminary results to third parties. That seems to me totally undesirable. This is an argument between scientists in which you need the exchange of information.

Dr Bell: The position is always the same. It depends what work is being done. If the work is just being overseen to see that it is being done correctly, that seems perfectly in order and is a matter between the contractor and the laboratory doing the work. Once results start to appear and they are properly checked and they are robust, I think it is absolutely right that everybody should have access to them and discuss them. It is a matter of argument as to what stage of the process that is. If you release results literally as they come off the bench, you are prone to finding that you have errors in there and starting all manner of hares running unnecessarily. It is the way that scientists normally work. They like to have their results looked at within their laboratory. They like to go over them themselves and they like to be reasonably satisfied with them before they expose them to the gaze of their peers. I think that is perfectly in order. My argument is that you do not release them absolutely at day one but you release them as quickly as you can, the necessary people having satisfied themselves that they do not contain errors.

Q107 Alan Simpson: Is not that one of the big criticisms that runs through the allegations made against the FSA that, by and large, you had to be dragged into openness in terms of inconsistencies in the methodology? Whether it is backed up with the formal threat that it is a breach of the confidentiality clause or not, both the timescale and the processes that you work to have been much more focused around defending that original decision that you made than checking the rigours of the scientific method.

Dr Bell: No. It has been very much focused on protecting public health. That is where we have come from all along and that obviously has been our driver. I make no apology for that. To that extent, we had to take note of what was coming out of here, even if other people quite rightly had doubts about various aspects of it. We had to say, "We will look at what the other aspects are but in the meantime we have to continue to go down the precautionary path because we cannot just pause and put the whole thing on ice while we investigate methodologies and all the rest of it." We are being faced with positive results in accordance with the tests that the EU require and we have to decide what to do with those positive results. We decided we had to take precautionary action on the basis of them, but we have always acknowledged that the methodologies are not ideal. We know the biological test is not ideal in itself. We know that standard operating procedures did not exist, so there have always been areas that needed further investigation and we have tried to run all these investigations in parallel. It takes time as the Irish demonstrated when they did it. It took them a number of years and I know we have heard that to some extent there might have been some foot dragging there but from what we found out, in discussing it with the scientists, these really are difficult problems to crack and they do take time to get to the bottom of.

Q108 Chairman: You have been accused by the Shellfish Association of being heavy handed, grudging with information, secretive and of a persistent reluctance to admit that you might have been wrong. What is your assessment of the way the Food Standards Agency has handled this issue?

Dr Bell: I am bound to say that we have handled it in what I would consider to be the correct manner, but I can understand the sensitivities attached to this. I think we have a lot of sympathy for the position the shellfish industry has found itself in. We have zoned the beds as far as we were able to, to enable as much fishing as possible to continue. Despite what you have heard today, I would argue that we have had frequent and repeated conversations with all sides. We have had many letters. We have written many explanatory letters back. We have exposed all the work we have done. We have published the results and we shall carry on doing that. Naturally, people see it from different points of view. We see it very much from the point of view that we do not feel we can ignore what could be pointing to a new toxin. We do not know whether that is the case yet. Others whose livelihoods are at stake here I quite understand might think that that was being too precautionary and there will be a difference of opinion on that but that does not mean to say we cannot continue to talk together and try and work to a common solution, I hope.

Q109 Chairman: Is not there an argument here for rebuilding working relations with the industry and with the local food authorities?

Dr Bell: Yes. I would certainly hope things have not got to the point where we do not have a working relationship. I have heard what is said today. I think we need to redouble our efforts, I might say on both sides, to ensure that we work together to get a solution as quickly as we can. I can understand the frustration at the time this takes and we are doing all we can to get things moving and make sure we get to an end as quickly as we can. No purpose is served by being at war. I hope that is not the position we are at. I do not recognise that position and we would want to continue to talk and work with all the parties that are involved in this.

Q110 Alan Simpson: Is not the logic of what you are saying that, if we are to believe that the risk element that you are concerned about justified the application of the precautionary principle, should we not be saying as a government that that has to apply to the importation of all mussels? If we are talking about a common European position and the protection of the public, when you buy stuff from the shops, you are not saying, "I am buying this because it has come from the UK", I suppose, or because it has come from Germany or the Netherlands. You are buying the product. You are making a judgment that says, "We do not believe it is safe to sell this product." If that is so, surely in terms of protecting the public it is not origin determined; it is determined on the basis of whether precisely the same tests that

you are insisting we go by as the measurement of risk to public health are applied to every part of that industry.

Dr Bell: Yes, that is absolutely right. We are looking for a level playing field and quite rightly so. A lot has been made of the fact that other European countries use other variants of the test, the rat or whatever. We have written to the Commission and we have had definitive advice from them. We have also spoken to the Dutch and we know it is the case. You can use other tests but you are required to demonstrate their equivalence, which is very difficult. However, in the case of doubt where you get a different answer with the mouse test to the rat test, the mouse test is the definitive test. That has clearly been laid down by the Commission to us in writing and in other ways. What we are looking for is to move as quickly as possible to more robust forms of test right across the Community. This is what we shall be talking about within a week now, round the table. We want to get chemical tests in where we can and we want to be much clearer about what the standard operating procedure ought to be across the whole of Europe, not just the one we might operate or the one the French or the Dutch might operate. I think that is the way we have to go. I do not think it is an ideal situation but we have to operate within the framework that we have and we have to move as quickly as possible to resolve these differences.

Q111 Alan Simpson: If we are going to apply that principle and say that we are concerned about something that we do not know, to a point at which we are prepared to ban it, that has to apply to the importation of the same products from different countries who do not use precisely the same testing methodology that you use, because it would fail at that first test. Do we know? The answer is no. I am pushing you on this because we either have to have a position that is tenable across the food sector or no position at all.

Dr Bell: I accept what you say. I think there is a case for what you do about imports. There is equally a case for what you do about your own production. We have heard most of it is exported and it is an important industry, which we accept. But we have to protect our own population. We have to decide what we are doing about the results we are getting from shellfish from our own waters. That is what we are doing, but I agree with you that we need to make sure that, across the Community, we are on a level playing field and that testing is being done in a similar way to protect public health. I have no evidence that the shellfish that are coming from outside the UK waters have this problem. You can say that is because people have not looked in the right way. You can make that argument certainly. The rat test may not pick this up. We are not clear about that. But it has the mouse test at the back of it. At the moment, I am trying to work with the problem we have but not ignoring the fact that we need to work in the Community to get everything properly set up so that everybody gets the same answers across the Community.

Q112 Chairman: I have a couple of other questions which relate to farm salmon, not part of our agenda, but since you are the chief executive of the FSA and since it is so topical I put them to you because I think they are important. We may need to look at this as a Committee at some other stage but since we can get some preliminary answers from you now I would like to put these questions. It relates to the material published in *Science* by researchers from Indiana. The FSA effectively pooh-poohed them, emphasising the known benefits of eating oily fish. I am a great advocate of everybody eating as much fish as possible, particularly fish that is caught by the Grimsby fleet which is not a very large quantity now. Should we continue to eat farm salmon?

Dr Wadge: The evidence produced on the levels of dioxins in salmon was nothing new. It matched the types of levels that we reported ourselves a few years ago. This was a much more extensive study and it looked at Pacific salmon and compared them with the farmed salmon from Scotland. It did not compare like with like. It did not compare farmed salmon with Atlantic salmon. The big difference in this particular study was the approach that the researchers used to assess the risks to health. They took a model developed in 1991 published in draft form, which incidentally has never been finalised by the United States Environmental Protection Agency, which assumes that whatever exposure of dioxins someone receives there will be some level of cancer risk. That is making an assumption that dioxins at whatever level carry with them a risk of cancer. An awful lot of work has been done on the toxicology of dioxins. It is probably one of the most well studied environmental contaminants since 1991. The World Health Organisation, the United States Food and Drug Administration, our own Committee on Toxicity and the Scientific Committee for Food which advises the European Commission have all looked at this subsequently and have said that dioxins do not operate in this manner. There is a threshold below which there is not thought to be any harmful effect over a lifetime of exposure. We have taken that more recent, what we consider to be more appropriate, risk assessment that is widely accepted internationally by the World Health Organisation and compared the sort of exposure that you would get if you consumed salmon as part of your healthy, balanced diet. We have said the levels are within those accepted guideline values. Set against what is really a theoretical risk are some very clear, known benefits of eating oily fish as part of a healthy, balanced diet, such as protecting people from cardiovascular disease, one of the biggest killers. That hopefully explains the difference of approach that has been taken.

Q113 Chairman: How are the safety limits for toxins and PCBs and dioxins determined for farm salmon? Who fixed them and how do you enforce them? What are they?

Dr Wadge: There are independent, expert committees that advise the World Health Organisation in this case, which will look at the

toxicity of a particular compound such as dioxins and work out, not in relation specifically to salmon, but how much a human being can ingest over a lifetime without any adverse effects. Having established that guideline value, you will then compare it with dietary intake information. We carry out surveys of what food people consume and you look at the total dietary intake, of which salmon will be one part, and you compare that with the guidelines established by the independent experts. That is the basis on which we are able to say that the UK diet and the salmon intake do not present a risk from dioxins. There are now quite tight controls on the levels of dioxins permitted within the fish feed. Those are controlled at a European level.

Q114 Chairman: Does it accumulate in salmon?
Dr Wadge: Dioxins do accumulate. Dioxins are essentially there as a legacy of past industrial activity, so they will accumulate in the environment, probably in the sediment, and gradually accumulate in the food chain. The good news that we have from our quite comprehensive dietary surveys shown that the levels of intake that people are exposed to have dropped by at least 50% in recent years. That reflects the controls on industrial emissions.

Q115 Chairman: The limits used by the FSA in determining the safety limits for toxins differ from those in this study because you are saying yours are more up to date?
Dr Wadge: We have taken advice from the World Health Organisation and our own Committee on Toxicity, who have looked at the recent evidence on the toxicity of dioxins. These researchers from the University of Illinois did not carry out, as I understand it, their own risk assessment. They used the USEPA model which assumed that, whatever exposure occurs, there is some risk of cancer. We think that the new scientific information on the toxicity of dioxins does not support that approach. We think it is inappropriate.

Q116 Chairman: You do not see a need for invoking the same precautionary principle that you invoked for shellfish?
Dr Wadge: We would always take a precautionary approach and we would look at the exposure against the risk assessment carried out by independent scientists. In this case, the big difference is we know what the toxin is. We know what the effects are. We know what the levels are in food and we know what the exposure is, so it is quite easy to make that comparison. The shellfish situation is very different because we simply do not know what is causing these atypical effects.

Q117 Mr Drew: I wonder how much resource you are putting into studying some of the issues to do with fish. Give us a feel for the sort of work comparison that it might be possible to draw compared to meat, where we are, dare I say, hopefully at the end of a lot of various scare stories and have done some invaluable work, if nothing else, to be able to tell the rest of the world how to try and avoid BSE and how not to do some of the things that we got wrong. Could you give us a feel for the research in this area? Are you under-powered in terms of being able to pull together? As Austin said, we go into salmon; we have looked at shellfish and some of the other problems which affect this industry pretty drastically.
Dr Bell: I cannot give you a figure off the top of my head that covers all the research spend on fish per se. On shellfish we have spent around £300,000 on research in the last couple of years, trying to get to the bottom of this issue. We spend nearly £1 million a year on paying for the testing and all the aspects that go with that. If you want to compare it with what has been spent in the meat area in the last few years, obviously there is little comparison there because, we you well know, the expenditure on BSE has been simply huge over that period of time. One might argue, I hope, that because of that huge expenditure and what we have learned in the process we can get a grip on things at rather less expense in the future. A lot of the response to BSE was done with hindsight and maybe more could have been done at the beginning. I do not know, but there is not really a comparison in that way to be made. The sums are quite different. If you are interested, I am certainly prepared to look out the figures we are spending on fish across the board and write you with some breakdowns on that.
Chairman: Can I thank both of you particularly for your patience in dealing with these last, extra questions and for your evidence. If you have anything which occurs to you which you think would be helpful to us, please do not hesitate to send it to us in writing as quickly as possible. I hope a bit of marriage guidance can come out of it and Relate can bring the parties in this dispute together, but we are dealing with the story of the divorce and the acrimonious dispute when we write the report. Thank you and thanks to the other parties for giving evidence today.

Supplementary memorandum submitted by the Food Standards Agency (M15a)

1. During the Food Standards Agency's oral evidence to the Committee on 19 January 2004 I undertook to provide the Committee with some further information on:

— Insufficient sample, and occasional operator error in DSP testing, at CEFAS (Qs 82 and 83)

— Replication of the results in the Netherlands (Q86)

— Spending on shellfish work (Q117)

2. I am also taking this opportunity, further to the Chairman's offer, to provide additional information which may assist the Committee in its Inquiry.

Insufficient Sample, and Occasional Operator Error in DSP Testing, at CEFAS

3. Guidance on the size of in-shell sample to be collected was provided to Local Authorities at the time CEFAS assumed responsibility for statutory testing. On occasions, insufficient shellfish flesh is received at CEFAS to allow them to undertake the biotoxin tests. This can be because not enough individual animals are sent, dead material is inadvertently included, or the sampled animals are too small to provide the necessary weight of meat. In such cases CEFAS requests a further sample, but if this is not provided, and bearing in mind testing is in the interests of protecting public health, tests for the regulated toxin groups are prioritised according to the status of the fishery. Thus, for example, where an area is closed for DSP, the DSP test would have priority.

4. As part of the CEFAS accredited system a log of departures from protocols (including operator error) and the associated corrective actions is maintained. Following the Committee's interest, CEFAS has reviewed the log, and for the 3,464 samples processed for the DSP test since June 2001 there were logged departures in respect of less than 1% of samples. Examples of logged departures include glass funnels shattering through wear and tear, difficulty in sample homogenisation and partial sample spillage because of equipment problems.

5. Since June 2001, only six logged departures have been recorded as operator error. Five of these were due to sample spillage. On 12 November 2003, however, a technician mistakenly used ether instead of acetone at the first stage of the procedure. The error was immediately picked up, appropriately logged, and the affected samples were not processed further. No result was given for those samples, and the Local Authority was asked to resample the area.

Replication of the Results in the Netherlands

6. The Agency is aware that some Food Authorities have been approached by the industry to collect extra samples for "duplicate testing", however, we are not in receipt of any data to back up the assertion that replication of the results has not been possible in the Netherlands.

7. Statutory testing is the responsibility of Member States, and the results are not interchangeable with those from the industry's own testing. Public health protection decisions are made on the basis of the statutory results. Any industry testing does not form part of the UK or Dutch statutory monitoring programmes, and will have been undertaken on a commercial basis, using non statutory samples.

8. In 2001 the EU Food and Veterinary Office (FVO) visited the Netherlands to inspect the official monitoring and testing arrangements for shellfish. It noted that the routine testing is carried out by a private laboratory (RIVO), using a rat bioassay, and that verification or confirmatory testing in cases of positive or unusual results is carried out by the Dutch National Reference Laboratory (RIVM) using the mouse bioassay as the reference method.

9. The FVO report criticised the biotoxin analytical methods used in the Netherlands for not complying with EU legislation. It also criticised the Dutch NRL for not adequately co-ordinating the analytical activities at the laboratory. The FVO indicated that the number of sampling points for routine biotoxin monitoring in the Netherlands should be increased. In responding to those criticisms, the Dutch Competent Authority pointed out that the rat bioassay cannot detect the full range of DSP toxin groups regulated by Commission Decision 2002/225/EC (ie it is unable to detect yessotoxins and pectenotoxins).

10. The Agency takes the view that, until we have assessed the human health implications, any test method used for comparative purposes must be capable of detecting the atypical response seen in the UK.

Spending on Shellfish Work

11. The Tables at Annex 1 outline Government expenditure on shellfish matters. A list of programme research projects on shellfish issues is provided. This includes the work undertaken to develop alternatives to the mouse bioassay: work in this area has been undertaken since the mid 1990s, and has been stepped up since the Agency took over responsibility for this area of work in 2000.

Interactions with Stakeholders on the Atypical Issue

12. The FSA has written to, and talked regularly with, industry, the enforcement authorities, laboratories, and other Government Departments in its endeavours to resolve the complex problem of the atypical MBA results. The list of the meetings held (Annex 2) indicates the extent of stakeholder engagement. This does not take account of extensive written, e-mail, and telephone contacts, as well as

responding to industry questions at FSA open Board meetings. In all these interactions the FSA has carefully considered the points made by industry, and has taken them into account wherever possible when planning research and other investigations, which so far have been undertaken at public expense.

The Biological System Used to Test for DSP at DARD

13. DARD has been testing for marine biotoxins in shellfish for a long time. They have been responsible for the statutory programme in NI since it was first required under EU law (1992). The rat bioassay was originally used to test for DSP in Northern Ireland, but since January 2001 the mouse bioassay has been used. The first atypical response was detected from cockle samples collected on 22 August 2001 from Dundrum Bay, and the laboratory has continued to detect atypical responses since then. In both 2001 and 2002, 45% of cockle samples tested at DARD gave atypical results; in 2003, the figure was 10%. The number of cockle samples tested in each of those years was 20, 83 and 59 respectively.

Independent Review of Agency Work by the Irish Marine Institute

14. Local Authorities in England and Wales recently commissioned an independent review by the IMI (the Irish National Reference Laboratory for biotoxins) of the Makin report, the Agency's solvent carry over report, and the industry critiques of those reports. A copy of the report is at Annex 3 [Not Printed]. Dr Terry McMahon, who carried out the review, concludes that "the fundamental issue of the unambiguous identification of the cause, or causes, of the atypical response still remains unresolved . . . Based on the documentation provided to me there is no clear and unambiguous evidence available which explains the atypical response seen."

15. Dr McMahon disagrees with the suggestion from Dr McKenzie, a consultant for the SAGB who reviewed the FSA report on solvent carry over, that the lack of a known toxin, or known toxic algae, is evidence against a toxin being the cause. Dr McMahon draws attention to the situation in Ireland in 1995 when atypical responses to the DSP test were detected. These subsequently led to the identification of azaspiracid, a novel toxin, which is now regulated by EU legislation. He also points out that the concentration of lipophilic toxins in shellfish can vary considerably over very small distances and states "it would be very surprising if every sample from a production area gave a positive response in a mouse bioassay".

Quota Figures

16. The quota uptake tonnages provided in the FSA's Written Evidence were provided by the Sea Fisheries Committees and Local Authorities. These figures do not seem to be in dispute. The FSA is not aware of any evidence that the overall quality of cockles harvested since the occurrence of the atypical problem has been different to that previously.

Condition of Samples Sent to the Laboratories for Testing

17. Protocols for sample collection, packaging and transportation have been in place in all parts of the UK since 2001. These protocols were developed by the laboratories (CEFAS, DARD and FRS) and are issued to Local Authorities which collect the statutory monitoring samples. The UK NRL has been commissioned by the Agency to produce best practice guidance, which can be used throughout the UK. This document is expected to become available in April 2004.

18. It would seem unlikely that sample collection and transportation has any significant bearing on the atypical results because practices in England and Wales and Scotland are similar, yet Scotland has not experienced the atypical DSP response. Additionally, cockle samples from the Burry Inlet have always been transported under chilled conditions but have shown no difference to other cockle areas in terms of the atypical DSP response. The most stringent sample collection and transportation arrangements apply in Northern Ireland, and the DARD laboratory has detected atypical responses throughout 2001, 2002 and 2003. The industry's assertion that the atypical findings might arise from "stressing" is therefore very questionable. Certainly no scientific evidence has so far been produced to support this.

Dr J R Bell, Chief Executive

29 January 2004

Annex 1

ESTIMATED GOVERNMENT EXPENDITURE FOR FINANCIAL YEAR 2003–04 (£K)

	England	*Scotland*	*Northern Ireland*	*Wales*	*Total*
Biotoxin Monitoring Programme	355 (EW)	500	173	—	1,028
Atypical Research	193	7	0	0	200
Staff costs on Biotoxins/Atypical	202	14	12	6	234
Staff costs on all shellfish matters	267	138	23	6	434
Research costs—Alternative methods and standards	159	0	0	0	159
Other Atypical costs—training visits, equipment etc	2	32	1	1	36
Phytoplankton Monitoring	60	100	20	0	180
Inspection and Approval of Depuration Plants	218	48	5	0	271
Shellfish Bacteria and Virology Research	281	0	0	0	281
Shellfish Classification	330	170	106	0	606
Other Shellfish Research	73	50	0	0	123
Other shellfish costs	27	70	10	0	107
Compensation	0	0	0	300*	300*
Total	2,147	1,129	350	313	3,959

* = 50% EU funded

Value of cockle market quoted by SAGB in evidence to EFRACOM—£20 million

Research: programme projects on shellfish biotoxins commissioned by MAFF and FSA since 1988

Title	*Cost £*
Further work on scombrotoxin (FC0707)	118,204
Development of improved sensory methods for detecting and measuring taints in seafoods (FC0708)	63,350
A preliminary study investigation of distribution of Dino-flagellate cysts in sediments in Ardtoe region of Western Isles. (FC0710)	2,000
A study of Alexandrium cysts off the East coast of Britain (FC0711)	111,499
The Isolation and Culture of Dinoflagellates potentially associated with Diarrhetic Shellfish Poisoning (DSP) (FC0712)	15,000
Detection of sodium channel blocking toxins in British coastal waters (FC0713)	54,786
Immunodetection of toxin dinoflagellates (FC0715)107,975Large volume culture of toxic dinoflagellates (FC0720)	50,000
Toxic algae and their effects on coastal zone fisheries (FC0722)	66,522
Cultivation of toxic dinoflagellates (FC0725)40,053Coastal zone colour zone scanner archive in relation to toxic phytoplankton blooms (FC0726)	23,365
Cultivation of toxic dinoflagellates (FC0730)31,882Reviews of current research into phycotoxins (FC0731)10,320PSP bioassay studies (FC0734)	10,325
The significance to human health of the chemical contamination of commercial shellfish (FC0735)	40,239
Development of reliable and specific analytical methods and rapid assay procedures for phycotoxins (FC0736)	26,250
Development of reliable and specific analytical methods and rapid assay procedures for phycotoxins-PSP (FC0737)	26,250
Development of in-vitro bioassays for detection of PSP and related toxins (FC0739)	87,095
Development of reliable and specific analytical methods and rapid assay procedures for phycotoxins (FC0741)	40,062
Development of reliable and specific analytical methods and rapid assay procedures for phycotoxins (FC0742)	33,993
Development and assessment of reliable specific assay procedures for detection of marine biotoxins in shellfish (FC0745) (B09012)	322,388
Development of methods for and Survey of Recently Discovered Toxins in UK Shellfish (B04004)	376,024
Assessment and Validation of a Commercial Rapid Qualitative Assay (MIST Alert) for the Detection of ASP and PSP in the UL Monitoring Programme and as an End Product Test (B04006)	231,779
Assessment, Development and Validation of Alternative Methods for the Determination of	385,047

Title	*Cost £*
PSP, DSP and ASP Toxins Using HPLC-MC-MC (B04007 and B04010)	
Development and Assessment of Reliable, Specific Assay Procedures for Detection of Marine Biotoxins in Shellfish	322,388
Validation of the Extraction Procedures Applied in the Yasumoto Method for the Detection of Toxins in Shellfish Associated with DSP (B16002)	31,567
A Study to identify the causal agent(s) responsible for the atypical DSP symptoms from cockles and mussels using LC-MS (B16001)	39,993
Evaluation of the acute toxicity of cockle extract following IP and oral administration in the mouse	19,600
Total	2,687,956

Research projects on shellfish bacteriology/virology commissioned by MAFF and FSA since 1990

Title	*Cost £*
Shellfish Microbiology (advice and inspection) (Replaced by FC0724 and FC0718) (FC0701)	74,909
Development of molecular biological methods for fisheries research (FC0702)	90,608
Studies of viruses in shellfish in relation to Public Health (FC0703)	1,133,792
Naturally occurring biological contaminants (FC0704)	186,517
Microbiological quality of shell fish waters (FC0705)	99,600
Investigation into use of coliphage to assess influence of re-laying and depuration on contamination of m. (FC0706)	33,600
Handling Live Molluscs (FC0709)	30,000
Depuration techniques for Oysters and Clams (FC0714)	31,400
A study to evaluate the feasibility of using coliphage as hygienic indicators in molluscan shellfish (FC0717)	52,789
Duties relating to EC directive 91/492 EEC on Shellfish Hygiene (FC0718)	1,086,135
Development of gene probe techniques for the detection of viral pathogens relevant to fisheries research (FC0719)	220,909
Monitoring for food quality assurance purposes (FC0712)	461,428
Shellfish Microbiology (advice) (FC0724)168,407	
Role and fate of micro-organisms in bivalve molluscs with reference to bacteria and viruses (FC0727)	159,700
Technological developments to improve the hygienic standards in the inshore shrimp fishery (FC0728)	32,600
Studies on application of enterovirus RT-PCR to environmentally contaminated shellfish (FC0729)	18,650
Re-appraisal of existing operating criteria for purification of bivalve molluscs in the UK (FC0732)	46,312
Studies on the removal of human pathogenic viruses from molluscan shellfish during depuration (FC0733)	113,583
Detection and removal of human viral pathogens in bivalve shellfish (FC0738)	974,933
Monitoring for food quality assurance purposes Phase II (FC0740)	67,100
An assessment of the impact of different types of sewage treatment on the contamination of shellfish (FC0748)	24,817
The development of improved, simplified and standardised PCR based techniques for the detection of Noroviruses and Hepatitis A Virus in Molluscan Shellfish (B04001)	319,906
Development of procedures for improved viral reduction in oysters during commercial depuration (B04002)	296,467
Developing methods for the isolation and detection of viruses in shellfish, particularly Noroviruses (B04003)	150,185
Application and validation of techniques for the detection of pathogens in shellfish (B04008)	211,682
Evaluation and validation of alternative indicators of viral contamination in bivalve molluscan shellfish (B04009)	232,209
Survival of small round structures viruses and potential viral indicators in sewage treatment processes and in marine environments (B05001)	354,930
Evaluation of methods for the assessment of sewage discharge consent applications with respect to shell fisheries (B05002)	163,268
Development of procedures to distinguish between human and animal faecal contamination in shellfisheries (B05005)	272,714
Evaluation of the impact on shellfisheries production of runoff from land receiving organic wastes (B05006 and B05007)	315,800
Total	7,424,950

Annex 2

MEETINGS WITH TRADE, INDUSTRY AND LOCAL AUTHORITIES

Date	*Meeting*
12 February 2002	FSA meet with Carmarthen and Swansea Council, local gatherers, processors, representatives from National Assembly of Wales, Environment Agency and Sea Fisheries to discuss the problem of DSP in Burry Inlet.
10 June 2002	Food Legislative Advisory Committee of Seafish attended in York by FSA, SAGB and other Members of the fish and shellfish Industry to discuss various issues including atypical update and discussion.
24 June 2002	FSA attend open forum meeting at Whitstable with local authorities, industry and other stakeholders to discuss atypical issue.
12 August 2002	Food Legislative Advisory Committee of Seafish attended in York by FSA, SAGB and other Members of the fish and shellfish Industry to discuss various issues including atypical update and discussion.
19 September 2002	Meeting in Swansea to discuss DSP issues. Open forum meeting attended by members of the industry, local authorities and other stakeholders to discuss the atypical issue and particularly the Burry Inlet.
14 October 2002	Food Legislative Advisory Committee of Seafish attended in York by FSA, SAGB and other Members of the fish and shellfish industry to discuss various issues including atypical update and discussion.
9 December 2002	Food Legislative Advisory Committee of Seafish attended in York by FSA, SAGB and other Members of the fish and shellfish industry to discuss various issues including atypical update and discussion.
14 January 2003	FSA attended SAGB Mollusc Committee meeting in London at Fishmonger's Hall to discuss various issues including an update and discussion on atypical issue.
15 January 2003	FSA meeting with Chairman, FSA officials and SAGB delegation to discuss atypical issue and way forward.
5 March 2003	FSA attend meeting with SAGB at Fishmonger Hall, London to discuss way forward on atypical issue.
14 April 2003	Food Legislative Advisory Committee of Seafish attended in York by the FSA, SAGB and other members of the fish and shellfish Industry to discuss various issues including atypical update and discussion.
2 May 2003	At Agency request Professor Yasumoto attends a meeting with stakeholders in London to give his view of UK atypical problem and report on his findings while at CEFAS.
7 May 2003	Meeting of Thames Shellfish Advisory Committee attended by Local Authorities, FSA, Thames and North Kent Coast shell fishermen to discuss various issues including atypical update and discussion.
9 June 2003	Food Legislative Advisory Committee of Seafish attended in York by the FSA, SAGB and other members of the fish and shellfish Industry to discuss various issues including atypical update and discussion.
23 July 2003	FSA meeting with stakeholders in Wales on atypical DSP matters.
1 October 2003	FSA meeting with industry, SAGB, Food Authorities and Prof. Makin to outline findings of independent audit, solvent carry-over investigations and agreed action plan.
13 October 2003	Food Legislative Advisory Committee of Seafish attended in York by the FSA, SAGB and other members of the fish and shellfish Industry to discuss various issues including atypical update and discussion.
13 November 2003	FSA meeting held with stakeholders, scientific advisors to the industry and representatives from the 3 statutory monitoring labs, CSL and Professor Makin to discuss detail of the audit and solvent carry over reports.
8 December 2003	Food Legislative Advisory Committee of Seafish attended in York by the FSA, SAGB and other members of the fish and shellfish Industry to discuss various issues including atypical update and discussion.

29 January 2004

Written evidence

Taken before the Environment, Food and Rural Affairs Committee

Memorandum submitted by Professor R D Combes (Scientific Director, FRAME, Nottingham) (M1)

EXECUTIVE SUMMARY

The UK shellfish industry has recently been affected by the statutory closure of several cockle beds, following the detection of samples causing rapid and severe reactions in the regulatory approved test for diarrhetic shellfish poisoning (DSP) toxins, the mouse bioassay (MBA). Several studies have failed to identify their cause. Following a detailed assessment of the MBA[1] it has been concluded that the test should never have been developed for the routine screening of shellfish samples, as it has a substantially severe endpoint and is not used in a tiered testing strategy with non-animal methods. Moreover, it has been used without an optimised and universal protocol, and apparently without due regard to the principles of basic scientific methodology, during the UK monitoring programme for DSP toxins. In view of this, the atypical results obtained for cockle samples cannot be relied on as being evidence of a human health hazard. It is recommended that the use of the MBA should be discontinued as soon as possible, in favour of other methods, especially those involving non-animal techniques. In the short-term, these methods should be based on analytical chemical detection systems and the essential availability of the relevant pure toxin standards. The lack of any known toxins in samples should be taken as evidence of lack of contamination. The suitability of the existing non-animal methods needs to be assessed as a matter of urgency. It is crucial that all new methods should be properly validated and their acceptability for their stated purposes endorsed by recognised criteria and validation centres, before being recommended to or required by regulatory agencies. In this way, the possibility that scientifically-unsuitable methods will once again used for monitoring for the contamination of shellfish with toxins can be avoided. This gross misuse of laboratory animals and ill-judged application of science should never be allowed to happen again.

Acronyms

CEFAS—Centre for Environment, Fisheries and Aquaculture Sciences; DARD—Department of Agriculture and Rural Development (Belfast); FRS—Fisheries Research Services (Aberdeen); FSA—Food Standards Agency.

The UK shellfish industry has suffered the statutory closure of several important cockle beds because samples from cockles caused so-called atypical results characterised by unusually rapid, severe and extreme reactions in the EU-stipulated test for diarrhetic shellfish poisoning (DSP).

1. The results of several investigations have raised important questions about the use of the MBA for the above purposes: (a) its suitability for the detection of DSP toxins in cockles; (b) the scientific rigour of the protocols being used; (c) interlaboratory variations in the conduct of the regulatory assay and in the interpretation of the data; and (d) the justification for the animal licences that were granted for the tests on mice, in view of the un-anticipated severity associated with the atypical nature of the effects observed later.

2. DSP is the mildest form of the four types of shellfish poisoning in humans, the main symptoms being diarrhoea, nausea, vomiting and abdominal pain with sufferers normally recovering within a few days.

3. Although there have been genuine cases of DSP contamination due to consumption of cockles, to the best of my knowledge there have never been any medically-endorsed instances of diarrehtic shellfish poisoning.

4. High molecular weight fat-soluble acidic polyether chemicals, namely okadaic acid (OA) and its derivatives, and dinophysis toxins (DTX-1 and DTX-2), are primarily responsible for DSP. Other potentially important toxins include neutral polyether lactone pectenotoxins (PTX) and yessotoxins (YTX; including homo-yessotoxin (45-OH YTX)). Several other toxins have been associated with DSP, including spiramino acid and the azaspiracids (AZAs).

5. OA and the DTX toxins are potent inhibitors of the PPP family of serine/threonine protein phosphatases that reversibly phosphorylate many proteins with the concomitant hyperphosphorylation of proteins in ion channels of the intestinal epithelia, disrupting mechanisms which maintain water balance thus leading to other degenerative changes in the absorptive capacity of the small intestine. PTX toxins also affect the cytoskeleton of cultured cells, and OA can disrupt mitotic spindle formation in cells by binding to phosphatases, and these effects could be related to the ability of the toxin to induce diarrhoea.

6. A 24-hour mouse bioassay (MBA) is the standard test for DSP toxins, and is stipulated in the current EU Directive. However, the test fails to detect all PTX toxins and is insensitive to AZAs.

[1] Combes, R.D. (2003). The Mouse Bioassay for diarrhetic shellfish poisoning: a gross misuse of laboratory animals and of scientific methodology. Alternatives to Laboratory Animals 31, (in press).

7. The MBA involves a series of solvent extraction steps of shellfish samples, before the final extract is dissolved in Tween 80 and injected intraperitoneally (ip) into mice. The death of 2 or 3 of the mice within 24 hours following exposure is recorded as a positive result.

8. Exposed mice can undergo a variety of abnormal responses, including prostration, hypothermia, and tachycardia, with death occurring between 2-5 hours following dosing.

9. The use of solvents is crucial, as it dictates the sensitivity and specificity of the test, by affecting which toxins are extracted and detected. Also, the assay can be affected by several problems, including the presence of zinc, incomplete separation of the water phase during aqueous washing of the diethyl ether and acetone, and carry-over of organic solvents, resulting in lipophobic chemicals or solvent, respectively, being in the extract for dosing.

10. Atypical MBA results were first detected during routine monitoring programmes conducted by CEFAS in June 2001, but for 6-9 months these results were reported as normal positives.

11. Atypical results are characterised by the mice dying very rapidly following dosing, from heart failure, preceded by shock and extensive trauma, accompanied by more violent and rapid leg and body movements, and agonal breathing after collapse.

12. Atypical results in the MBA have not been detected in any laboratory, other than CEFAS, in the UK, and samples that gave atypical results at CEFAS have proved negative when re-tested in other laboratories. Furthermore, there have been no cases of adverse effects occurring in individuals that have ingested cockles from beds yielding samples that have generated atypical results.

13. There is further evidence for interlaboratory variation in data obtain with the MBA, and also for results being dependent on body weight, sex and strain of mice.

14. The FSA contends that the atypical positive are attributable to a real effect caused by an unidentified substance in the cockles that elicits symptoms in mice that are similar to those produced by neurotoxins.

15. A recent independent audit of the three laboratories (CEFAS, FRS and DARD) involved in the monitoring of cockle beds for DSP in the UK found that: (a) each laboratory used a different protocol; (b) there were differences between the requirements for a positive and negative result; (c) there were no provisions for internal and independent quality assurance; (d) controls were lacking; and (e) there was a lack of precision in the methods detailed in the Standard Operating Procedures being used.

16. There is evidence in a report produced by the FSA that carry-over of both organic solvents used, and also of water, into the final extract did occur in some of the tests undertaken. The extent of this carry-over varied between replicate samples, laboratories and also between shellfish species.

17. The conclusion in the FSA report that diethyl ether is not the cause of the atypical response might be erroneous as the conditions of the confirmatory experiments that were undertaken to investigate this possibility were not the same as those that applied during the routine use of the MBA.

18. The MBA can result in severe welfare costs to the individual animals involved. Thus, mice can rapidly (within 30 mins following dosing) become subdued, unresponsive with bluish extremities, and cold to the touch. This is followed by prostration and extension of the rear legs. The animals can also display clear signs of disorientation, paralysis of the hind limbs, breathing difficulties, and a violent jumping reaction, just prior to death. The MBA is conducted without anaesthesia and the use of humane endpoints.

19. It is clear that experiments involving the MBA, particularly when atypical results for DSP have been obtained that could be due to a substance acting like a neurotoxin, fall into the substantial category of experiments, under the UK (Animal Procedures) 1986 Act, and this fact should be taken into account when consideration is being given to granting a licence for the test.

20. The MBA for DSP has been developed specifically as a test for the presence of the relevant shellfish toxins, and the endpoint detected in the assay (the death of mice) makes no attempt to model the non-lethal clinical signs (diarrhoea) observed in humans following their ingestion of such toxins via the consumption of infected shellfish.

21. There are many deficiencies in the experimental design of the MBA, as undertaken in laboratories in the UK. The most important of these is the lack of negative and positive controls, despite the fact that this was criticised in a report of a mission conducted by the Health & Consumer Protection Directorate-General of the EC (DG SANCO) made in July 2002. The inclusion of the controls is absolutely crucial for correct data interpretation, to ensure the absence of false-positives due to the generation of artefacts during extraction and of any false negatives due to the lack of extraction of toxic material that was actually present. False positives can also be due to the carry-over of either a toxic organic solvent, or possibly of lipophobic material in the aqueous phase into the final test extract.

22. Some controls should be undertaken concurrently with the test, and others should have been used when the test was first developed, or when any significant part of the protocol had been altered (eg when the extraction conditions (solvents used, their order and the times and temperatures of extraction) and/or the starting material (species of shellfish, or tissues extracted) were changed).

23. These controls should verify the scientific robustness of the test, and the fact that each laboratory undertaking the test can obtain positive results under appropriate conditions. Thus, each laboratory should establish historical positive and negative control databases. On a routine basis, only a solvent-negative control needs to be run concurrently with every test.

24. The MBA also involves ip exposure by injection (ip) even though humans ingest shellfish. Such dosing in the MBA has resulted in an over-estimate of toxicity.

25. The benefits to human health to be gained by MBA testing for DSP are dubious since at worst the condition is not life-threatening, and the test is likely to be scientifically unjustified producing meaningless data. On the other hand, the adverse welfare costs to the animals are substantial, and there are other in vivo and in vitro tests that might be more suitable for routine screening.

26. The MBA for DSP should never have been developed as: (a) it involves death as an endpoint, without the possibility of applying more-humane endpoints; (b) it often results in animals suffering severe shock and trauma within a very short time after dosing; (c) despite the extreme severity of the assay, anaesthesia is not used; (d) it lacks scientific justification concerning the relevance of the endpoint to human health; (e) there are important shortcomings in the experimental design of the assay; and (f) the test is not used on the basis of prior data from in vitro screening.

27. The atypical results obtained when using the MBA for detecting DSP toxins cannot be assumed to be indicative of actual hazard. The continued use of the MBA, especially to detect atypical results for DSP toxins, has been a gross misuse of laboratory animals and a lack of application of sound principles of scientific methodology. As a consequence, HO licences for the use of the MBA for DSP toxins should be revoked and no more should be issued, whether or not atypical results are expected.

28. Several in vitro methods can be used to detect DSP toxins, including: (a) a cytotoxicity assay; (b) immunological tests; (c) analytical methods, such as TLC, (HP)LC and MS; and (d) phosphatase inhibition assays. However, none of these has been formally validated, one problem being the lack of a complete set of pure toxin standards.

29. Existing non-animal test alternatives to the MBA should be assessed and improved urgently, taking account of the availability of all relevant toxin standards. Mechanistically-based assays, involving immunological and specific phosphatase binding systems, should be considered first, and then (Q)SAR modelling in the longer term.

30. In the immediate term and short term, the monitoring of cockle beds for DSP toxins should continue by using analytical chemistry methods. Where evidence for a DSP toxin or any other toxin cannot be found, cockle beds should be re-opened.

The references supporting the statements made in the above evidence can be found in this paper which is about to be published.

December 2003

Memorandum submitted by Integrin Advanced Biosystems (M2)

SUMMARY

— The "atypical" problem stemmed from CEFAS and DARD's inexperience in running the DSP Mouse Bioassay. This led to solvent-related deaths of mice most probably because of anaesthetic effects and heart failure.

— The lack of controls in the assay meant that this was not immediately recognised as an artefact and CEFAS and DARD did not conduct an appropriate investigation of possible matrix effects. Nor apparently did they seek and heed the advice of the more experienced FRS.

— The initial response of the FSA in closing cockle beds was correct. There was the threat of a genuine toxin being present and this merited further investigation even if it was a remote possibility.

— As the DSP MBA was uninformative as to the cause of the atypical response, the FSA should have suspended its use in cockles and banned both harvesting and imports of cockles into the UK until it was satisfied that there was not a risk to the public.

— The FSA did commission research to investigate possible reasons for the atypical response other than toxins but by giving much of this work to CEFAS it meant that methodological artefact was not investigated as a possible cause.

— By the autumn of 2002 the FSA were receiving strong representations from both industry and from FRS that solvent carry-over was the most likely cause of the atypical response. FSA rejected this advice and it took almost a year before it commissioned a proper investigation of this possibility.

— Solvent carry-over was demonstrated by these investigations. Despite solvent carry-over being a known cause of artefact in the DSP MBA and causes symptoms similar to those seen in the atypical response, the FSA continued to maintain that solvent carry-over was unrelated to the atypical response, going as far to say that they were satisfied that they had done enough work to eliminate it as a cause.

— The FSA did respond to the findings of solvent carry-over and an audit of procedures by introducing a new SOP which produced minimal solvent carry-over. Since the introduction of this new SOP there have been no atypical positives. Despite this firm evidence that solvent carry-over was involved in producing the atypical response, the FSA are still looking for a novel toxin.

— While the FSA as an organisation has probably acted in good faith throughout this episode, it can be criticised for the lengthy time taken to properly investigate the atypical response and for inconsistent reaction to it. Of particular concern are the public statements made by the FSA to the press and on their web site. These were often misleading and were not justified by the scientific information available, suggesting a lack of objectivity.

— The FSA should be subject to an independent scientific review to highlight lessons from this episode and to recommend robust scientific working practises to help avoid this sort of problem in the future.

Introduction

1. I am a marine biologist with over 20 years professional experience and over 50 scientific publications. In September 1999 I founded Integrin as the first marine biotechnology company in the UK. Integrin is focussed on two areas: drug discovery from marine invertebrates and seafood safety. Our seafood safety activities include providing testing services for marine toxins; contract research and consultancy relating to seafood safety and development of improved methods for the detection of marine toxins.

2. Our customers in seafood safety include shellfish harvesters, processors and retailers and we undertake work for major players including Sainsburys. We also do contract research for the FSA and are currently engaged in a desk study for FSAS on domoic acid testing in scallops. We pride ourselves on our independence, integrity and impartiality.

3. Integrin was by shellfish industry to provide the Committee with our professional opinion on the science commissioned by the FSA. We have had access to the correspondence between Industry and the FSA; have discussed the problem with persons within the FSA and Government laboratories; read the appropriate reports and discussed the matter at length with overseas experts. This letter gives a synopsis of our findings.

4. The Committee should be aware that Integrin were commercially commissioned by Kershaws to produce this piece of research. However, we could equally have been commissioned by the FSA to do this and our findings would have been the same. Kershaws have not asked for any input into the content of this letter and the opinions within it are solely those of Integrin.

5. Integrin are not intending to give verbal evidence to the Committee but I would be happy to attend to expand on any of the points in this letter if the Committee would find it useful.

The Mouse Bioassay and Quality Systems

6. The UK government has a statutory responsibility to test bivalve shellfish for the presence of a number of different toxins that come (mostly) from marine algae. These produce the toxins, are eaten by the bivalve molluscs then humans can become ill when they consume the shellfish. The situation is complex because of the number and variety of toxins that can be found in shellfish and research is continually finding new toxins.

7. The main method used to detect shellfish toxins in Europe is the Mouse Bioassay (MBA). It is not universally used, even within Europe, and a number of countries (eg Germany, Sweden and Holland) prefer alternative methods for ethical or practical reasons.

8. The MBA falls into two main categories. the PSP (Paralytic Shellfish Poisoning) MBA which looks for hydrophilic (water loving) toxins (mostly saxitoxins) and the DSP (Diarrhetic Shellfish Poisoning) MBA which looks for lipophilic (fat loving) toxins. The atypical response relates solely to the DSP MBA. It should be noted that the MBA is not used for all shellfish toxins. For detecting domoic acid a chemical method (HPLC) is used as the MBA is insufficiently sensitive.

9. The DSP MBA is a very crude assay. It involves injecting mice with a large volume of extract produced from shellfish. The extraction method aims to concentrate any toxins present so they can be detected. Extraction of the toxins is a crucial step and is very sensitive to changes in either the shellfish matrix or the extraction conditions.

10. The DSP MBA uses too few mice for any sort of meaningful statistical analysis to be done. It is not a quantitative, nor a discriminatory assay; ie the DSP MBA does not tell us how much of a toxin is present, nor what types of toxins. The assay is so extreme in terms of its severity that if one of the three mice used dies then the assay is considered to have passed. If two or three die then the assay fails.

The assay thus accepts that 33% of the mice used may die by accident. An important point is that the MBA is an analytical assay designed to detect a specific group of toxins. It is not a general toxicity assay for assessing the safety of a foodstuff.

11. Crucially, the DSP MBA as used in the UK did not involve the use of controls. In any scientific experiment there must be adequate controls to guard against artefact. The importance of controls cannot be over-stated. The lack of controls was very important in the genesis of the atypical story.

12. For example, at Integrin we use chemical assays to detect DSP toxins. These are quantitative and always involve the use of both a negative and a positive control. The positive control is a material which is known to contain a defined amount of the toxin of interest. This is usually a reference material. If the assay does not detect the positive control or not at a level that is considered within the assays parameters then the test is rejected. A negative control is a material which is known to lack the toxin of interest. If the negative control produces a positive reaction then the assay is rejected.

13. Proper validation of the assay is important. Ideally this should be done on all the matrices that the assay is to be used on. In practise this can be difficult because of the time and expense involved. However, if an assay has been validated on a single matrix (eg mussels) any unusual result coming from a different matrix (eg cockles) should be subject to a separate validation to eliminate the possibility of a matrix effect.

14. Another important safeguard is the requirement of reproducibility. A sample being tested must always give a positive or a negative result, it must not give both a positive and a negative result. A lack of reproducibility is a clear indication of a methodological problem.

15. The last safeguard is external validation. In short, does another laboratory give similar results to your laboratory when they test the same material? If they do not then attention has to be paid to the reasons why.

16. The FSA has been making UKAS accreditation a formal requirement for laboratories tendering for work from them. They have also been supporting the development of new toxin standards, reference materials and ring trials. However, another crucial element in the atypical history was the relative inexperience of many of the bodies and individuals involved in shellfish toxins; the MBA and in running QA systems.

A History of the Atypical Response

17. Through the '90's up till 2001, responsibility for monitoring shellfish in England, Scotland and Wales rested with the Fisheries Research Services (FRS) Laboratory in Aberdeen (and its progenitors).

18. In 2001 the FSA put out for tender four year contracts for both the Scottish Shellfish monitoring programme and a similar programme for England and Wales. CEFAS were awarded the England and Wales contract and FRS the Scottish contract. DARD maintained the contract to provide testing in Northern Ireland but introduced the MBA to bring them in line with the other laboratories. FRS also host the National Reference Laboratory for marine biotoxins.

19. CEFAS commenced the contract in the Spring of 2001 and almost immediately started having a much higher incidence of mouse deaths in the DSP MBA than FRS had previously encountered. The FSA was informed and they instructed local councils to close affected shellfish areas. Most (though not all) of the DSP MBA deaths were associated with cockle samples.

20. With time it emerged that cockles from all areas sampled by CEFAS were producing deaths despite their wide geographic separation. No seasonality appeared and the deaths were apparently random. It also emerged that the deaths were unusual—rapid, very severe and quite unlike "typical" DSP MBA deaths.

21. No known UK DSP toxins were found in the cockles samples, nor were any of the known contaminants (such as some fatty acids) that cause false positives in the MBA found. Exotic toxins (eg spirolides) were eventually eliminated as possible causes.

22. The FSA announced that continued closures of cockle beds was justified on the grounds of public safety and that the most likely explanation of the atypical positives was the presence of a novel neurotoxin (mostly) in cockles.

23. Between the Spring and Autumn of 2002 there was growing scepticism in many quarters that a novel toxin was responsible. This suspicion was strengthened by the failure of other European laboratories using the MBA to replicate the atypical results.

24. Of particular concern to the FSA was that FRS was not producing atypical responses while CEFAS contaminants (such as some fatty acids) that cause false positives in the MBA found. Exotic toxins (eg between the laboratories, the obvious implication was that the atypical response was an artefact produced by these differences. To head off this criticism, the FSA commissioned a comparative study between the laboratories all using the same cockle samples. This was undertaken in October 2002. FRS found no atypical positives, while a technician from CEFAS undertaking the MBA at FRS managed to kill all bar one of the mice used. At first sight it looked as if DARD and CEFAS obtained the same results but closer inspection reveals that this is because they are using a different scoring system. Depending on who is doing the assay, the same sample could be positive or negative.

25. This was a pivotal moment. FRS reacted strongly to a report from CEFAS on the experiment (that I have not seen but presumably said that FRS methods were inadequate). FRS countered that the lack of an overnight "de-gassing" in the DARD/CEFAS methods meant that the atypical results could be due to solvent carry-over; a known reason for the MBA to be compromised. They also provided some anecdotal evidence that this was occurring. They also suggested a number of other differences that could be producing the atypical responses.

26. The FSA was thrown into a degree of turmoil as evidenced by the summoning of an emergency meeting of the labs and FSA on the 6 November. Despite FRS having more experience than CEFAS, DARD or the FSA combined, the "official" Government line to emerge from this meeting was that the FRS SOP was failing to extract the toxin and that the methodology used in the DSP MBA was not the root cause of the atypical response. All parties were said to have agreed this. FRS, in private at least, certainly did not agree.

27. The main reason that the FSA rejected the possibility of methodological artefact appears to be that they could not square this with the observation that the atypical problem was mostly associated with cockles. Put simply, if it was a method problem why were not all species of bivalves producing the response? And if it was a matrix problem why were CEFAS and DARD obtaining negatives as well as positives? What they had missed was that the same sample of cockles was producing both negatives and positives. a sure indication of a problem with the methodology.

28. Not only would solvent carry-over "in trace amounts" (Quote from Dr Godfrey Howard, FRS) cause mouse deaths, it would also explain the lack of an obvious candidate molecule; the rapid recovery of mice sometimes witnessed and the apparent loss of activity when samples were stored. Despite FRS putting up a number of testable hypotheses, experimental work on solvent carry-over seems to have been put to one side by the FSA.

29. In December 2002, FSA released a detailed "updating report" on the atypical response. It gives a good synopsis of why the FSA rejected ether carry-over as a factor (it did not consider acetone). We see here the emergence of a FSA paradigm based on argument rather than experimental science. This resulted in the "artefact hypothesis" having to pass a much higher bar of proof with the FSA than the alternative "novel toxin hypothesis". This is bad science but it is a crucial factor in explaining FSA's actions.

30. Another contributory factor was the claim by Prof Yasumoto to have isolated a polar toxin from cockle samples. This work has not been published so it is impossible to judge its relevance but it definitely had a major influence in FSA thinking. However, the DSP MBA is designed to look for non-polar (lipophilic) molecules and eliminate polar (hydrophilic) molecules. Polar toxins are checked for by the PSP MBA and no problems have been found with it. Work by the LGC to isolate and identify a toxin in the cockle extracts has so far failed to produce a candidate toxin molecule.

31. The next major development was the attempt by FSA to introduce a common extraction protocol in June 2003. This led to immediate atypical-like responses at FRS from mussel samples. FRS reported solvent carry-over and that the deaths were consistent with solvent toxicity.

32. FSA Scotland funded an immediate study by the Macaulay Institute and FRS. This found carry-over of DEE (ether) but the report was not released until a second and more detailed study, this time funded by FSA London and undertaken by CSL (York), to look at solvent carry-over using head space GC-MS was conducted. This also found considerable solvent carry-over at all three laboratories.

33. The FSA then claimed that the lack of statistically significant correlation between solvent carry-over and the atypical response proved that solvent carry-over was not responsible for the atypical response. This was a misuse of statistics (the report gave no indication of whether or not a statistically significant result could be expected given the very limited data set) and an inappropriate use of the data as the experiment had not been designed to look for correlations.

34. The use of head space GC-MS was appropriate for determining whether solvents were being carried over but, as was made clear in the Macaulay report, it may not provide a quantitative assessment of the amount of solvents actually in the extracts. Also, there must be some sort of cockle "factor" involved. Without knowing what this is and quantifying it, seeking simple correlations is a misleading waste of time.

35. Duplication of analyses showed that the same sample could produce very different levels of solvent carry-over and that the same sample could also produce both atypical results and negatives. All of this pointed to the atypical response being an artefact and the presence of solvent (a known problem) meant that the obvious conclusion was that solvent carry-over was at least involved in the atypical response. Despite this, the summary of the report went as far to say that the FSA was satisfied that solvent carry-over was not a factor in the atypical response!

36. The FSA also commissioned Prof Makin to do an audit of procedures at the different laboratories. He criticised the lack of controls generally and was severely critical of QA standards at CEFAS.

37. The FSA web site acknowledged the problem of solvent carry-over but was emphatic that it was not causing the atypical response. This was not an accurate reflection of the scientific information available to the FSA.

38. The Home Office had been unaware of any solvent carry-over until the release of the report and had immediate talks with the FSA insisting that solvents be removed.

39. Before a stakeholder meeting due to take place in October, the FSA released an addendum to their original report. This was necessary as it transpired that CEFAS had made mistakes in the experiment so that the data from one week was not comparable with the other two weeks and had been producing very high values for solvent carry-over. CSL had produced a new dataset correcting for this and this had been hurriedly re-analysed.

40. After re-analysis, several of the conclusions of the previous report were no longer valid. In addition, analysis of the new dataset by Integrin showed that week three of the CEFAS data was clearly different from weeks one and two, at least for acetone. In the new dataset these data had been produced by a different calculation than for the other two weeks and it was agreed at the meeting that all the data would be recalculated using the same method and re-released for analysis. To date this has not been done.

41. At the stakeholder meeting in October, I outlined how solvents could be causing the atypical results either directly or indirectly and predicted that once solvents were removed the atypicals would disappear.

42. At the end of October a new unified SOP was introduced at all three laboratories. This was designed to eliminate solvent carry-over and the presence of solvents was to be routinely monitored for the first time. Since its introduction there have been no atypical responses reported from any of the laboratories. For the same period in 2002 (November and December) there were 36 atypicals and in the month before the introduction of the new SOP (October 2003) there were 13.

43. The FSA still does not acknowledge that solvent carry-over is the underlying cause of the atypical response.

What is Different About Cockles?

44. It is easy with hindsight to assert that the atypical problem should never have arisen and certainly should not have taken as long as it has to resolve. However, what is clear from reviewing the history of the atypical response is that virtually all of the normal scientific checks and balances that exist to prevent us being distracted into wild goose chases such as this were absent or ignored.

45. These include:

- Controls. there were no controls used in the DSP Mouse Bioassay. This means that there was no way of ensuring the assay was being conducted properly. It is alarming to read that FSA officials did not believe that a negative control was necessary as they were getting negative results. This shows a lack of understanding of what a negative control is and what it is for.
- Blind studies. an important source of artefact is operator bias. This is controlled for by blind studies—the operator does not know which samples are being looked at. This is vital in experiments such as the DSP MBA where subjective endpoints are increasingly used. The only evidence of the use of blind trials was in the Macaulay report.
- Internal reproducibility. samples must always be positive or negative, not both. This was overlooked or ignored.
- External reproducibility and validation. other laboratories must be able to reproduce your results. This was not the case with the atypical response. When other laboratories could not replicate the atypical result the FSA response was that these labs were wrong. The correct response is to critically examine your own procedures with the presumption that these are wrong.
- Proper use of hypotheses to guide experimentation. Basically a hypothesis is an idea that might explain the phenomena under study. A good hypothesis is testable by experiment and a good experiment provides a yes/no answer. Another discipline is that you should design experiments that will reject your hypothesis rather than try to prove it. The FSA studies did not conform to these standards. The FSA were prepared to reject solvent carry-over as a factor without experimentation to test it and did not test their central hypothesis by carrying out an experiment to show that the atypical response could occur in the absence of solvent carry-over.
- Proper understanding of fore knowledge and experience. If we do not learn the lessons of the past we are condemned to repeat them in the future. Solvent carry-over was a well-understood problem and should have been investigated much sooner even if the FSA could not see how this could be squared with the predominance of cockle samples producing atypicals.

46. The FSA were able to diligently eliminate a large number of possible interferences and possible toxins. This left them with their major hypothesis. that the atypical results were being produced by toxin. The null hypothesis that should have been pursued with equal vigour was that the atypicals were the result of some methodological artefact. The Table below shows that evidence for and against both hypotheses. Clearly there is more evidence for a methodological artefact and against the presence of a toxin than the opposites.

Method Problem For	*Method Problem Against*	*Lipophilic Toxin For*	*Lipophilic toxin Against*
Good evidence of solvent carryover (known problem with MBA)	Problem mostly associated with cockles (why not all shellfish?)	Problem mostly associated with cockles	No known algal toxins in samples
Good evidence of water carryover (known problem with MBA)	No simple correlation between individual results and solvent concentrations	New algal toxins are frequently encountered	No association with known toxic algae
Association of atypical response with solvent and/or water carryover	Yasumoto's opinion that atypical response seen by him in cockles not caused by solvents		No candidate lipophilic molecule for toxin despite intensive search
Reproducibility of atypical response from replicate samples poor			Atypical response seen in cockles from all areas studied but not in every cockle sample
Solvent carryover from same samples very variable			No evidence of toxicity in humans or by rat bioassay
Similar problems seen by other labs and cured by improvements to solvent carryover.			"toxin" very labile
Symptoms consistent with solvent toxicity; solvent abuse, saxitoxin poisoning or anaesthetic overdose			Toxicity profile unlike other lipophilic toxins including known alternatives such as fatty acids (too fast)
Toxicity decreases on storage suggesting toxicity associated with volatile compound			Rapid recovery of mice that survive
Atypical responses start when new labs initiate DSP MBA			
MBA protocols between labs confused—perhaps not looking at same thing			

47. If we focus entirely on the evidence supporting the FSA position (Method problem against and lipophilic toxin for columns): Prof Yasumoto has not published his findings so we cannot comment further on his opinion but it may be a red herring; new algal toxins are frequently discovered but usually when humans become sick after eating shellfish; the datasets available do not allow us to explore whether there are simple correlations present or not but in any case the complexity of the problem may mean that simple correlations cannot be found.

This leaves in both columns the observation that the atypical response is associated primarily with cockles. This is the cockle conundrum.

48. To resolve the cockle conundrum we need hypotheses that fit the facts. In particular the suggested mechanisms should fit the atypical profile:

1. Acute and fast acting
2. Volatile or extremely labile
3. Rapid recovery from non-fatal attacks (suggests volatility)
4. Always associated with solvents
5. Cockle factor heightens probability of atypical response

49. At the October 2003 stakeholder meeting I proposed four possible hypotheses of the atypical results. This is not an exhaustive list, nor does it matter which one (if any) is correct.

50. *Hypothesis I: Carry-over of a hydrophilic interfering factor*

A known problem of the DSP MBA is the carry-over into the mouse of hydrophilic molecules which result in mouse death. The best understood problem is with saxitoxin and related molecules. Tiny amounts of saxitoxin will produce an atypical-like response if injected into mice during the DSP MBA. Poor extraction technique will allow this to happen.

This hypothesis would fit three of the criteria, including the cockle factor: cockles live in the sediment and will feed on bacteria at the surface of the sediment that would not usually form the diet of mussels. Saxitoxin can be produced by bacteria as well as algae. However, saxitoxin is not particularly labile nor would rapid

recovery be expected. There is a wide range of other hydrophilic substances that might also be producing the response if they are injected in the MBA. Tightening up extraction procedures should prevent any of these causing the atypical response.

51. *Hypothesis II: Toxicity of solvents*

DEE and acetone are both toxic, and especially so by IP injection. There is scant quantitative data on the toxicity of these molecules and none on their co-toxicity. The mouse deaths could be the result of toxic effects of the solvents present in the injection. This explanation would fit all of the criteria except as to why cockles would be different. It is especially good in explaining the rapid recovery of some mice.

The Macaulay report suggested a possible model that would explain the cockle factor: intra/inter species differences in the water/lipid content could influence the amount of solvent (particularly DEE) trapped in the extract and thus injected into the mice. One of the interesting findings of the solvent carry-over studies was that some solvent could remain in the extracts even after they had been left overnight. This is difficult to understand unless there is a mechanism for trapping the solvent.

52. *Hypothesis III: Drug effect of solvents*

DEE and acetone both have an anaesthetic action and this will be additive if both are present together. Anaesthetic effects can occur at levels well below toxic levels but can be just as deadly. Side effects of anaesthesia include malignant hypothermia; cardiac arrhythmia and ventricular fibrillation leading to sudden death. Not only are the side effects of anaesthesia consistent with the atypical response, vets witnessing it commented on it resembling the effects of poor induction of anaesthesia. This hypothesis would explain all of the atypical criteria but like solvent toxicity requires the invocation of a cockle factor based around some trapping mechanism.

53. *Hypothesis IV: Volatile substance abuse response*

Solvents are abused, mostly by young teenagers (glue sniffing) resulting in fatalities. Over 55% of the fatalities in the UK are associated with "sudden sniffing death" (the rest tend to be accidents while intoxicated, choking on vomit etc). This is manifest by the sniffer being startled and then dropping dead from a heart attack. Clinical presentation is severe cardiac arrhythmia then collapse in ventricular fibrillation with death within 1-2 minutes. This thought to be because the solvents sensitise the myocardium (heart muscle) to endogenous epinephrine or other catecholamines leading to arrhythmias.

This is an interesting hypothesis as it fits all of the atypical criteria including the cockle factor. Shellfish in general tend to have high levels of chemicals that will act as neurotransmitters in humans and cockles may have higher amounts than mussels because of the greater stress on them between harvesting and processing for the MBA. If present in the injection along with solvents, these neurotransmitters could produce a mouse equivalent of the "sudden sniffing death".

54. The symptoms witnessed in the atypical response seem to fit a combination of anaesthetic and cardiac arrest. Working out exactly what is going on would not be a trivial task and probably unethical. The importance of these hypotheses is, however, to illustrate that explaining the atypical response does not require the invocation of an elusive novel toxin. These hypotheses depend on either solvent carry-over or carry-over of water-soluble fractions. Eliminating these should eliminate the atypicals. This is what has happened with the introduction of the new SOP in late October.

55. This is not scientific proof that the atypical response is produced by solvent carry-over as there is no control in the experiment. The new SOP introduced a number of other changes which may also have influenced the atypical response. Nevertheless, the fact that the atypicals have disappeared after the new SOP was introduced demonstrates that they are the result of a methodological artefact. Of the possibilities, solvent carry-over remains the most probable cause of the atypical responses, either directly or indirectly.

Conclusions

56. The nature of the mouse bioassay was a fundamental reason for the genesis of the atypical episode. The lack of controls was especially important. Without the normal QA mechanisms to guard against artefact, experience was the only defence. FRS had this experience but the other laboratories did not draw on it when setting up their DSP MBA programmes and so were deceived into thinking that an artefact was a real result. It is possible that inter-laboratory rivalry played a part here, with the new labs either consciously or unconsciously not wanting to confront the possibility that they were incompetent in running the assay.

57. The nature of the MBA, which involves mice dying, tends to dramatise the result. However, the assay is very subject to a "garbage in—garbage out" scenario. Mice deaths do not necessarily indicate the possibility of human harm and the possibility of artefact must be eliminated before over-reacting to assay deaths.

58. The FSA were not the first regulatory authority to have been foxed by an inappropriate response by the MBA but they were still correct to take the possibility of a new toxin seriously. Previous experience (such as the domoic acid poisonings in Canada) showed that we have to be alert to novel toxins. The FSA response was, however, inconsistent. If there was genuine concern that a health problem was indicated, the FSA

should have shut all cockle beds and banned imports. This would have caused a lot of fuss and triggered European Commission interest but it would have shown consistency. It would also have speeded up finding a solution.

59. The FSA were not guilty of devoting insufficient resources to the problem. There was a lot of good work done to eliminate possible interfering factors and known toxins. Where they did fall down is in not having a structured response that was designed to tackle the question of possible artefact. In particular the decision to fund CEFAS (without tendering) to investigate possible causes of the atypical response when CEFAS was the main originator of these results was a mistake. This meant that the question of artefact was not likely to be properly tackled.

60. FSA was also too reliant on presumption and argument in attempting to unravel the cause of the atypical response. This had disturbing resonance with the original MAFF response to finding scrapie-like disease in cattle where presumption and inter-lab rivalry led to a delay of a crucial year in recognising what was going on. Presumption is no substitute for experiments.

61. FSA did seek help from international experts but they would have assumed that the MBA was being performed correctly as this should have been the first thing checked. I have sympathy with the FSA in regard to Prof Yasumoto's input. An international expert is telling the FSA that he thinks there is a toxin present and he may have isolated one.

62. After October 2002, the FSA's position and conduct of the investigations is much more open to criticism. The comparative study between the laboratories showed a lack of reproducibility in the atypical response. FSA should have paid more attention to the concerns of FRS as they had the most experience in this area. FSA failed to follow up FRS's suggestions to look at methodological artefact for nine months and then only returned to it when more or less forced to by the actions of FRS.

63. Had artefact been tackled seriously from the beginning then it would have taken no more than six months (and probably far less) for the FSA to have resolved the situation to their satisfaction that there was no risk to public health.

64. When solvent carry-over was established, the MBA should have been withdrawn until a new SOP that eliminated solvent carry-over was established and validated. FSA should have concluded at this point that solvent carry-over was the most likely cause of the atypical response. That they did not is worrying as it suggests a loss of objectivity.

65. Also worrying were the public pronouncements of the FSA. Statements were made that a toxin existed when there was no direct evidence for a toxin being present in cockles. The link with solvent carry-over was repeatedly dismissed but the evidence, as opposed to FSA opinion, increasingly pointed to solvent carry-over as the cause. Public presentation of complex scientific issues is always a tricky art but it is crucial that FSA properly represent the science, including areas of doubt.

66. The UK needs a strong, independent food safety body. It should be fearless in protecting public safety and should err on the side of caution. Food safety issues tend to be complex and mistakes will occur. What the atypical episode seems to indicate is that there was a lack of a structured response to emerging issues. This leads to inconsistency and a poor rate of progress to actually solving the problem.

67. I would recommend that an independent scientific enquiry team be brought together to examine the atypical episode with a remit to identify areas of the FSA approach that are inconsistent with good scientific practise and to recommend codes of practise and procedure that will give the FSA the tools it requires to fulfil its role in protecting the UK population.

Dr J Douglas McKenzie
Managing Director

December 2003

Memorandum submitted by Scottish Shellfish Marketing Group Ltd (M3)

BACKGROUND

The Food Standards Agency has a statutory responsibility to carry out a toxin monitoring programme to satisfy the requirements of EC Shellfish Hygiene Directive 91/492/EEC. The level of monitoring is based by the Agency on a risk assessment of the various inshore and offshore sea areas.

In Scotland some 70 inshore shellfish sampling sites, primarily aquaculture sites, have been identified by FSAS for monitoring for the programme. The testing of shellfish from these sites is carried out on behalf of FSAS by Fisheries Research Services (FRS) Marine Laboratory, Aberdeen and the method used for this testing is the mouse bio-assay.

In England and Wales similar testing is carried out by CEFAS, Weymouth and in Northern Ireland by DARD.

LIMITATIONS OF EXISTING TOXIN TESTING REGIME

Despite the fact that the FSA was set up by the Government to inform and protect the consumer FSAS have made it very clear that it is the shellfish industry's responsibility to carry out end product testing to ensure the safety of shellfish placed on the market. FSAS therefore are only prepared to carry out sufficient toxin testing of shellfish to meet their statutory obligations to satisfy the requirements of EC Directive 492. As a tool to protect the consumer the programme is totally inadequate for three principal reasons:

1. FSAS will only guarantee to have test results available within seven working days of receiving the samples. As the bulk of live shellfish are harvested and placed upon the market in as little as two working days and therefore normally in the hands of the consumer within three working days the above timescale is totally inadequate.

2. The Standard Operating Procedure (SOP) for carrying out the mouse bio-assay has recently been changed at the insistence of FSA. The new procedure is fundamentally flawed and the results of the new bio-assay inaccurate and unreliable.

3. FSA accept no responsibility for ensuring that all pre-arranged samples under the programme are in fact taken and tested. If FSA have a statutory responsibility to carry out a toxin monitoring programme then surely they also have a statutory responsibility to ensure that it is carried out correctly.

Examples of current shortfalls in the toxin testing regime are as follows:

(a) *Late reporting*

On Tuesday, 6 May 2003 a sample of mussels was taken from Selivoe Shellfish Mussel Farm in Seli Voe, Shetland Islands and sent to the Marine Laboratory, Aberdeen on behalf of Food Standards Agency Scotland to be tested for shellfish toxins. On Friday, 9 May it was confirmed at the Marine Laboratory that the sample had tested positive for Diarrhetic Shellfish Poisoning (DSP).

At 15.45 hrs on Friday, 9 May Marine Laboratory, Aberdeen informed Food Standards Agency Scotland of the positive DSP test.

At 16.45 hrs on Friday May Food Standards Agency Scotland sent a fax to Environmental Services, Shetland Islands Council informing them of the test result and issuing a Voluntary Closure Order for the harvesting of mussels in Gruting/Seli Voe. This fax was sent at 16.45 hrs despite the fact that the office of Environmental Services, Shetland Islands Council closes at 16.00 hrs on a Friday.

The fax from Food Standards Agency Scotland lay unnoticed in Shetland Islands Council offices until Tuesday, 13 May and no action was taken by Environmental Services, Shetland Islands Council until Wednesday, 14 May when the mussel farms in Gruting/Seli Voe were informed of the Voluntary Closure Order.

On Wednesday, 14 May, five days after the positive result of the DSP test was known, A & C Tait Mussel Farm in Gruting Voe was informed of the Voluntary Closure Order by Environmental Services, Shetland Islands Council. Scottish Shellfish Marketing Group Ltd, for whom the farm was harvesting mussels, were also informed of the Voluntary Closure Order by both Environmental Services, Shetland Islands Council and the Environmental Services Department of North Lanarkshire Council on Wednesday, 14 May.

Scottish Shellfish Marketing Group Ltd were ordered by Environmental Services Department of North Lanarkshire Council to withdraw from sale and destroy any product containing mussels harvested at A & C Tait Mussel Farm from Tuesday 6th May to Wednesday, 14 May.

Under the toxin monitoring programme prior to the involvement of the Food Standards Agency the Marine Laboratory, Aberdeen informed directly Environmental Health Officers, affected farmers and the Scottish Executive in Pentland House, Edinburgh immediately a positive toxin test was found.

Food Standards Agency Scotland however insisted that they would notify the Environmental Health Department responsible for the area in which the farm was located and the EHO would in turn advise the farm.

Scottish Shellfish Marketing Group Ltd (SSMG) had made representations to both Marine Laboratory, Aberdeen and Food Standards Agency Scotland for the Marine Laboratory to contact direct both the farm and SSMG immediately a positive shellfish toxin test was known. That request was refused by Food Standards Agency Scotland. SSMG advised Food Standards Agency Scotland that their complicated method of notification could lead to delays and increase the possibility of contaminated product reaching the consumer. SSMG's advice was ignored by Food Standards Agency Scotland.

Consumers could have been put at risk by consuming contaminated shellfish. Fortunately extensive chemical end product standard testing carried out by SSMG proved conclusively that all live mussels and processed product containing mussels harvested at A & C Tait Mussel Farm were completely free of DSP. This is not surprising as the farm sampled was in excess of three miles distant and in a separate voe from the A & C Tait Mussel Farm. The chemical end product standard testing carried out by SSMG was done at Integrin Advanced Biosystems.

(b) *Flawed Mouse Bio-assay*

For several years the FRS Marine Laboratory, Aberdeen has carried out the statutory monitoring programme for toxins in shellfish using the Mouse Bioassay. The laboratory has refined and improved the methodology for this test over several years and the results from this test have provided safe and reliable information to the seafood industry. Industry has come to rely on this testing in conjunction with its own chemical end product standard testing to ensure that only safe and wholesome product is offered to the consumer.

Recently two other Government Laboratories, CEFAS in Weymouth and DARD in Northern Ireland, changed the methodology they used for the Mouse Bioassay. The result of that change was that atypical positive results (false positives) were produced principally from cockles with excessive numbers of live mice being used and shellfish grounds closed for no good reason.

The Food Standards Agency insisted that FRS, Aberdeen used the new method. FRS found, as in Weymouth and Northern Ireland, that false positive results were obtained and, on advice from the Home Office, they stopped using the new methodology and reverted to the tried and tested method.

FSA cannot explain the reason for the false positive results and all the experienced staff in FRS, Aberdeen are convinced that the new methodology is fundamentally flawed. Despite this Food Standards Agency were determined for some perverse reason to make the new method mandatory in all UK laboratories which they did with effect from Thursday, 13 November 2003.

This could have serious consequences for the United Kingdom in general and Scotland in particular as shellfish grounds throughout Scotland and the rest of the United Kingdom would be closed for no good reason. This would threaten the viability of a growing and vital industry to Scotland's rural communities and put an established and prosperous industry at risk in coastal areas of England and Wales.

Since the new SOP was introduced at FRS, Aberdeen we have had three false positive results as follows:

Test date	*Farm*	*Site*	*FRS Mouse Bioassay*	*Integrin Chemical*
14/11/03	M16	Busta Voe	Positive	Negative
14/11/03	M15	Loch Leurbost	Positive	Negative
28/11/03	O7	Seil Sound	Positive	Negative

We understand that FRS also carried out chemical tests on these shellfish but the fact that they are not prepared to release the results of those tests is yet another example of FSA's refusal to work in harmony with industry.

(c) *Responsibility for samples*

In August/September 2001 one of our farms based in Sutherland despatched mussels to the factory in Bellshill which we in turn sent out to wholesale customers throughout the UK. A number of food poisoning incidents occurred in various parts of the UK affecting consumers who had eaten the mussels. We discovered that a sample of mussels from the farm in question was lying in The Marine Laboratory in Aberdeen having been sent there for testing for *E coli* for water classification purposes. This sample was tested at our request for toxins and tested positive for DSP.

The previous DSP test on mussels sent by the farm to the Marine Laboratory had been carried out a month earlier and had tested negative. Under the official shellfish toxin monitoring programme, which is the responsibility of Food Standards Agency Scotland, a sample should have been sent to the Marine laboratory for testing two weeks later but no sample had been sent. Despite the fact that the FSAS is responsible for the monitoring programme they claimed that it was the responsibility of the farm, not the Agency, to send in the sample.

In light of this incident SSMG decided that it was necessary to set up our own testing regime, in addition to the official monitoring programme, to make the overall testing regime more robust and effective.

The Way Forward

It is critical for all concerned, the shellfish industry, the Government (FSA) and the consumer to have in place a robust, comprehensive, accurate and fast reporting toxin monitoring regime that quickly identifies problems and prevents contaminated product being placed on the market. It is in no-one's interest, particularly the industry, to make people ill and lose the confidence of the consumer in healthy products that are daily growing in popularity with today's knowledgeable Public.

It is frankly unacceptable for the FSA to shun cooperation with industry, to promote outdated and inaccurate testing methods and to accept that seven days is a reasonable timescale in which to report results thereby potentially putting the consumer at risk.

It is time that FSA worked with and not against industry to protect the consumer and pool its resources together with those of industry to set up a testing regime based on modern mutually agreed chemical methods that reports results quickly and accurately.

Philip A Marshall
Vice Chairman

6 January 2004

Memorandum submitted by Borough Council of King's Lynn and West Norfolk (M4)

EXECUTIVE SUMMARY

The shellfish industry is an important historical and vibrant part of the life of the Borough of King's Lynn and West Norfolk and needs to be maintained

So too does Food Safety and Public Health

There is no clear evidence to support a conclusion as to the reasons for the atypical results from the mouse bioassay in shellfish testing. The Council make the following recommendations:

— Recognition, including financial recognition should be given for the role that just a few food authorities across the nation play in monitoring this important international industry.

— That there be an urgent review of the methodology used in all UK laboratories with a view to ruling out any risk of results obtained being affected by testing methods as opposed to the shellfish product and that EFRA urge a standardised method across Europe based on the MBA.

— That while the principle of the offer of voluntary testing is welcomed, the Council believes that the disadvantages of the CIVIT proposals outweigh the benefits at this time and recommend that the Industry put resources in together with the FSA and food authorities to seek to improve the reference method and in the future to look at new alternative and improved reference method rather than a raft of different tests with different results.

— That a partnership be developed between the FSA, food authorities and the industry to expedite proper interpretation of atypical results and concerns over methodology and UK laboratories and sampling procedures being adopted. That this partnership be given genuine delegation to secure joint working between the three groups and that this partnership develop to look at other areas in due course.

— That a genuinely independent National Reference Laboratory be established for the UK. If it is to remain based at Aberdeen then it should be wholly independent from the FRS and that it should undertake urgent work to carry out tests to discover a conclusive explanation for these atypical results as a matter of priority and should be accountable, Food Authorities and the Industry in that regard.

1. *Introduction*

1.1 This is the submission on behalf of the Borough Council of King's Lynn and West Norfolk (BCKL&WN). It should be read in conjunction with the submission on behalf of Boston Borough Council, which also forms part of the Wash inlet and in respect of which report BCKL&WN have had an input. These submissions have also been made, having read the joint submission on behalf of Canterbury City Council, City & County of Swansea and the Corporation of London, the contents of which this Council generally support and in particular agree the background to the issue in that report which is fully accepted and referred to as background to our submission but not repeated here.

1.2 BCKL&WN covers the largest part of the Wash area, predominantly on the east and south of the Wash and would appear to be the administrative area covering the home of two of the largest cockle harvesters and processors in the UK. King's Lynn's history is steeped in the shell fishing industry and is a fundamental part of the fabric and culture of the Borough. All shellfish caught and landed locally are required to undergo heat treatment within a Fishery Products Approved Premises. Norfolk is also a prime tourist area and the press interest has led to numerous concerns about the safety of cockles and indeed the coastal waters in the Wash.

1.3 Shellfish harvesters are severely affected by the toxins in shellfish issue. Cockle harvesters and processors are continually worried that closures may lead to product recall and are frustrated that they cannot plan harvesting or supply customers with a product which is reliably available. Long-term closures could also damage the future viability of harvesting areas by overcrowding and potential for killing cockle stock.

1.4 For food authorities since 2001 the atypical DSP issue has become a major drain on resources. Sampling, while necessary, is expensive, time consuming and often difficult where boat hire is needed. When closures are in place this is a weekly process. There is also the enforcement of closures and advertising of the problem locally. Enforcement is not easy particularly in a large sea area when most food authorities do

not maintain their own sampling vessels or crew. In the Wash we rely heavily on Eastern Sea Fisheries Joint Committee to deliver this service for us. In addition the dispute over the cause of the atypical problem has meant repeated meetings in London and the appointment of Counsel for legal advice and a scientific advisor. Food authorities have a legal duty to sample and enforce the legislation and so are a key player in the process but receive no additional funding for this particularly expensive area of food enforcement.

RECOMMENDATION

Recognition, including financial recognition should be given for the role that just a few food authorities across the nation play in monitoring this important international industry.

2. *Issues of Concern*

BCKL&WN broadly concur with the issues raised in the joint submission by Canterbury, Swansea and London and therefore specifically raise the following additional points which have been drawn out in large part from a report prepared in December 2003 by the Biotoxin Unit of the Marine Institute in Dublin to the 6 food authorities who are principally affected by this issue in England and Wales namely:

— BCKL&WN
— Boston BC
— Canterbury City Council
— City & County of Swansea
— Carmarthenshire
— Corporation of London

2.1 Methodology

2.1.1 The results of the various reports produced for the Food Standards Agency (FSA) and the industry indicate that the methodology used at all of the laboratories in the UK gives cause for concern. The Council welcomes the actions being taken by the FSA to standardise SOP's at the three laboratories but feel that more work needs to be done urgently to address the methodology used and to remove any risk that results obtained are affected by testing methods rather than the shellfish product itself.

2.1.2 A number of possible further tests are outlined in reports from the industry and by the Marine Institute report and these are generally commended.

2.1.3 This is not to say that this Council fully aligns itself to the findings of experts engaged on behalf of the Industry and considers many of those findings speculative or even misleading in places. Perhaps typical of this and key to this issue is the example pointed out by Dr McMahon in the Marine Institute Report where he states:

> "Dr. McKenzie (in the Review of the FSA report on the atypical response seen in the DSP MBA—Integrin Advanced Biosystems) appears to misquote the FSA conclusion of this work. As written above the FSA concluded that ". . . the findings suggest that on its own DEE is not the cause of the atypical positives produced cockle extracts" and not ". . . DEE is not the cause of the atypical positives produced cockle extracts" as stated by Dr. McKenzie."

Dr McMahon goes on to say:

> "The different results obtained in tests on the same sample using either DEE or DCM are difficult to interpret. They could be due to inadequate homogenisation of the test sample, variability in the bioassay or to differences in the ability of the different solvents to extract shellfish components. As acknowledged by the FSA it is not possible to clearly establish the causes of the different results obtained and as such the results of this experiment contribute little to establishing the cause of the atypical responses."

2.1.4 The need for a robust and consistent methodology across not only the UK but the whole of Europe (large quantities of the cockles extracted from the Wash are on sale in markets in the Netherlands within 24 hours of catch for example) is paramount. Clearly the first priority for the UK is to ensure a consistent and robust methodology in the UK but should be urging that same consistency across Europe in the interests of public health.

2.1.5 In terms of what form that test should take, Article 5 of Commission Decision 2002/225/EC states "When the results of the analyses performed demonstrate discrepancies between the different methods, the mouse bioassay should be considered as the reference method." For reasons developed below this Council believes therefore that concentration should be focussed on improving the methodology in the MBA test until such time as an alternative and improved method is found to supersede the MBA test and so revoke the decision of 2002/225/EC.

RECOMMENDATION

That there be an urgent review of the methodology used in all UK laboratories with a view to ruling out any risk of results obtained being affected by testing methods as opposed to the shellfish product and that EFRA urge a standardised method across Europe based on the MBA.

2.2 Cockle Industry Voluntary Initiative on Toxin Testing (CIVIT)

2.2.1 This is a draft proposal produced by the Industry in October 2003. While the Council welcomes any voluntary initiative by the Industry to impose stricter limits than set out under legislation, it believes that in view of the current uncertainty it would be more productive to focus on existing testing methods to seek to resolve uncertainty to the benefit of the industry as a whole.

2.2.2 The CIVIT proposals would be voluntary and yet would run alongside a statutory enforcement regime using different but prescribed testing methods. Thus rather than seeking to resolve uncertainty it is likely to escalate which cannot be in the interests of public health.

2.2.3 There is already a concern in the industry at the time delays created by the MBA testing procedures. In fact this is one of the quickest tests to complete and publish. Additional testing as proposed in CIVIT would in all probability lengthen the time taken to receive all the results and compare. Although this does not affect product going to market since cockles are not prevented from going to market pending test results (which itself is curious in terms of public health) nevertheless further time delay simply adds to overall uncertainty.

2.2.4 CIVIT proposals are silent as to who pays for additional testing. It is presumed that the costs would be met by the industry. It is interesting to note however that to date the costs are borne by the FSA and food authorities for statutory testing, whereas elsewhere, for example New Zealand, the Industry contributes to the costs of the testing regime.

2.2.5 As explained above, although other testing methods may be used, the mouse bioassay should be considered as the reference method. Therefore it is questionable what more these additional tests add in terms of determining the outcome. Indeed in so far as they may produce conflicting results they do nothing more than to undermine the reference method, which the Council believes is unhelpful.

RECOMMENDATION

That while the principle of the offer of voluntary testing is welcomed, the Council believes that the disadvantages of the CIVIT proposals outweigh the benefits at this time and recommend that the industry put resources in together with the FSA and food authorities to seek to improve the reference method and in the future to look a new alternative and improved reference method rather than a raft of different tests with different results.

2.3 Towards a Partnership between the FSA, Food Authorities and the Industry

2.3.1 Linked to the points raised in 2.2, this Council believes there is a need for far greater partnership working between the FSA, food authorities and the Industry than exists at present. It is clear that all three groups have a stake in this issue. The present situation has led to an increasing level of mistrust between the three groups, when it is acknowledged that all three are committed to ensuring improved standards of public health and food safety—indeed it is in all of their interests. It is regrettable therefore that the responsibility for monitoring the work of the laboratories (UKAS accreditation and SANCO inspection aside) is seen as the exclusive responsibility of one agency. The Council would welcome a joint inspection and monitoring regime between the FSA, food authorities and the industry, with representatives from each together inspecting and making decisions on processes and methodology used in these tests.

2.3.2 Similarly in terms of sampling procedures, while the FSA may be regarded as the competent authority under Council Directive 91/492; it is believed that this would be more effectively delivered by the FSA, food authorities and the industry, all of whom have a stake and interest in the procedure, to develop these in partnership.

2.3.3 This Council does not take this as far as setting up a separate body or structure although a joint panel of representatives may emerge from such proposals. It is however believed that this approach would relieve some of the inertia which is perceived exists. It would make the relevant parties more accountable to each other and ensure the better sharing of information than exists at present. Two years have passed without any clearer indication as to the cause of these atypical results and the potential impact on public health. Instead there have been threats of judicial review proceedings against food authorities who are themselves complying with guidance and requirements issued by the FSA. It is believed that such a partnership would expedite this process and remove the need for such challenges. Laboratory process monitoring and sampling procedures are highlighted as key areas for joint working but these could be expanded and developed. Any such partnership needs to be genuine with real attempt by the participating parties to delegate their responsibilities into this partnership and it is believed that this could be achieved within Council Directive 91/492.

RECOMMENDATION

That a partnership be developed between the FSA, food authorities and the industry to expedite proper interpretation of atypical results and concerns over methodology and UK laboratories and sampling procedures being adopted. That this partnership be given genuine delegation to secure joint working between the three groups and that this partnership develop to look at other areas in due course.

2.4 Towards a genuinely independent National Reference Laboratory.

2.4.1 When this Council was first approached by solicitors for the shellfish industry about the possibility of a legal challenge, there was a discussion about reference testing via another UK laboratory in light of these atypical results and the possible use of the reference laboratory as a comparator. It quickly became apparent that such approach was fruitless. Firstly because of the lack of a consistent methodology or standardised SOP's across the three laboratories and secondly because of the lack of a genuinely independent national reference laboratory.

2.4.2 The Council is concerned that the NRL in Aberdeen is too closely linked to the FRS laboratory to the extent that the two are almost indistinguishable. While there may be concerns about CEFAS and DARD, these concerns could easily be overcome by reference to the National Reference Laboratory. The reality is that although such a laboratory exists, it is not genuinely operating in that capacity. It is interesting to note that when recently a modified and improved standard SOP was agreed, the model chosen was one broadly based on the DARD methodology, not one developed by the NRL and the initiative for this came from the FSA under pressure from the industry and food authorities.

2.4.3 The conclusion from Professor Makin and from Dr McMahon and in reality from all those scientists engaged by the Industry is that there is no clear and unambiguous evidence available to explain the atypical responses seen. There are numerous suggestions and few of these have been thoroughly tested. If ever there was a case for a genuinely independent national reference laboratory to address such issues then it is now. It is doubtful whether this Committee will be able to discover a conclusive explanation for these atypical results but it can put in place measures to ensure that every effort is made urgently to reach such a position and this recommendation would go a long way to reaching that goal.

RECOMMENDATION

That a genuinely independent National Reference Laboratory be established for the UK. If it is to remain based at Aberdeen then it should be wholly independent from the FRS and that it should undertake urgent work to carry out tests to discover a conclusive explanation for these atypical results as a matter of priority and should be accountable to the FSA, food authorities and the industry in that regard.

3. *Conclusions*

3.1 The above recommendations may seem at first structural rather than scientific in addressing this issue. This is principally because the scientific evidence does not appear to be conclusive. The need therefore is to ensure structures and partnerships exist to ensure such an outcome is achieved and the situation is closely monitored for the future.

January 2004

Memorandum submitted by Rory Parsons, Leslie A Parsons and Sons (Burry Port) Ltd (M7)

INTRODUCTION

Besides having been the MD of the above Company for some 25 years I have also been a Fishery Member of the South Wales Sea Fisheries Committee for the last six years, having been appointed to this position by the Welsh Assembly Government because of my particular knowledge of the shellfish industry. My Company which has been in existence for 56 years, having been originally founded in 1947 by my late parents, is unique in that it is the only one of its kind in the whole of the UK bottling and pickling both cockles and mussels in glass jars. The Company supplies three major UK multiples, all other similar competitive products having to be imported. The operation of my business has been severely damaged and has been put in a precarious position because of the on-going crisis that has been caused by the continuing allegation by the FSA of "Atypical" DSP affecting cockles. I fear that this long lasting saga will irreversibly damage the reputation and public perception of the product at least in the UK.

Executive Summary

The UK cockle industry has been very detrimentally affected by the actions of the Food Standards Agency (the FSA) whose approach to this problem, from the very beginning has been from a commercial perspective, has been amateurish, unprofessional and disproportionate. For the last three entire commercial cockle seasons grave and well justified doubts have existed concerning the accuracy of the test that is being used and the frequent failed results that have been obtained from these tests. More than sufficient evidence has existed from the beginning to strongly indicate that it was the test methodology that was wrong and not the product being tested. Matters have been made especially worse by the FSA being recklessly slow in following up possible alternative causes for these failures and neither have the Agency been prepared to have meaningful or purposeful discussions with industry representatives or their scientific advisors. The FSA has used the "Precautionary Principle" to enforce closures but the use of this principle is being abused by the Agency: the Agency has a moral obligation and duty of care to industry and the consumer alike to resolve this issue of questionable toxicity in a timely manner and which it has not done. Clearly the Agency has accepted that there have been problems with the test method by making so many separate changes, over a period, to the procedures and test methods being used by the various labs which they control. Were there nothing wrong surely these changes would not have been made. The Agency has continually taken the very blinkered and bizarre approach that because cockles that are being tested by the mouse bioassay are failing the test the product is not safe to eat. This is not the necessarily the case. Professor Yasumoto himself, who is a World expert on the subject of the mouse bioassay and the workings of the test says, and I quote from an e-mail from him in respect of our particular problem—"There are many substances that are toxic by intraperitoneal injection but are non-toxic by oral administration—the final goal of my study is to determine the structure of the toxin and develop a rapid screening method for the toxicity. However, at certain stage of purification, I can ask my friend toxicologist to test the oral toxicity. If no significant oral toxicity is proven, then we may propose to the health officials to lift the ban on harvesting or to set a lenient legal limit". These were his exact words in early December 2002, more than a year ago—yet he was never sent samples to carry out the work that he wanted to do and even now these studies have still not been done by the FSA (Annexe 6 refers). **Why?** The mouse bioassay test itself has an established and notorious reputation in the scientific world for giving false positives and as such any results that are provided by it need to be treated at least with caution and some scepticism but sadly the FSA has been a victim of its own dogma in this regard. Professor Yasumoto himself makes it clear that the mouse bioassay test is not definitive.

Zoning

1. The Burry Estuary cockle fishery directly employs some 55 plus full time cockle gatherers and on average typically produces in the region of 3,500 tons of live cockles per annum. At least an equal number of individuals are employed shore-side in processing and the carrying out of value added work on the local catch. The Fishery is controlled via a Regulating Order being managed by the South Wales Sea Fisheries Committee. The Committee via the Regulating Order is able to set and vary catch quotas and issues annual licences to gatherers. The Burry Estuary is unique in the UK in that it is the only cockle fishery in the whole of the UK that remains open for 12 months of the year hence making it a very important cockle resource on both a local as well as a national level. Prior to June 2001 the only other occasion that the fishery has ever been completely closed for a significant and extended period was during the period between 15 February 1996 and 3 July 1996 immediately following the Sea Empress marine tanker oil spill which occurred in Milford Haven, Pembrokeshire. A peculiarity of the fishery is that from an Environmental Health perspective it is controlled by two separate local authorities, Carmarthenshire in respect of the North side and the City of Swansea in the case of the South side.

2. As from 1 June 2001 the responsibility for algal testing and monitoring was transferred, following a tendering exercise, by the FSA from the Marine Laboratory Aberdeen to CEFAS Weymouth (See Annexe 1) [Not printed]. The first indication of a problem was when on the 8 July 2001 a DSP fail was declared for the North side of the fishery with another fail being declared in respect of the South side of the Fishery the very next day, this consequently resulted in the complete closure of the entire fishery. This situation was to continue for some 14 months with the entire fishery remaining completely closed, with the exception of a few limited weeks, for almost the entire period between July 2001 and August 2002 when zoning was eventually allowed. Industry although having a limited knowledge of DSP was at an early stage unable to accept that this was a genuine case of DSP as typically such incidents when genuine, are known to be short lived and are restricted to long hours of daylight incorporating extended sunny weather conditions, additionally this particular problem had never arisen locally before, and most importantly of all, despite cockles from affected areas continuing to be eaten by the gatherers themselves (and others) not a single case of illness arose—importantly being an illness that is easily, readily and rapidly apparent. In spite of industry comment and criticism the local authorities, on the advice of the FSA, continued to maintain that this was a case of DSP affecting the cockle beds and only after an extended period of criticism and supposedly to protect their position, changed the classification from DSP, to "atypical DSP". Industry however were convinced that this problem was more to do with the recent change of laboratory from the vastly experienced Marine Laboratory Aberdeen to the inexperienced CEFAS lab in Weymouth. Eventually because of growing concerns and the continuing socio-economic difficulties that were being created by this long enforced closure Carmarthenshire County Council called a meeting of interested parties which was held in Llanelli Town Hall

on 12 February 2002 (Annexe 2) [Not printed]. It was apparent from the question and answer session at the meeting that even the most basic and rudimentary scientific checks were not in place at the CEFAS lab and there was a clear reluctance by the FSA to introduce any such checks into the procedures being used. Of greatest concern it had been admitted that strangely there were no negative controls in place and also it was advised that they were unable, for reasons of animal welfare, to introduce any such checks, questions were also asked about whether intra laboratory checks had been instigated to see if the problem was as a direct consequence of the change of laboratory and at that time despite the problem having gone on for some eight months no such comparisons had been made or were planned for by the FSA. Ironically although this alleged "DSP" was simultaneously affecting and disrupting all of the individual and remotely placed UK cockle fisheries, ranging from the Welsh fishery in the very west of the country to the Thames fishery in the extreme east, some 250 miles apart, cockles coming into the UK from Dutch fisheries, only some 60 or so miles away from the Thames cockle fishery, were said by the FSA to be safe.

3. Given the inordinate and exceptional amount of time that was being taken to resolve this issue (and most importantly of all the socio economic effect that the closure was having on the local industry) I personally on a number of occasions discussed with Dr Jonathon Back, who at that time was the FSA interface with industry (and who incidentally had also attended the Llanelli Town Hall meeting), the possibility of zoning the Burry Estuary cockle fishery but despite my arguments in support of zoning I was frustratingly unable to persuade him to allow zoning to be introduced, his contention being that the fishery was too small to zone and besides this he stated that it was also an exceptionally difficult fishery to police. I informed Dr Back that his arguments were totally unacceptable to me as the fishery was in any event naturally divided North/South by a river of considerable size which never drained and this being the case the situation lent itself well to zoning at least on the basis of two zones via a North/South divide. Concerning the question of policing I informed him that contrary to what he said the fishery was undoubtedly the best policed cockle fishery in the whole of the UK as it was a Regulated cockle Fishery being gathered and worked by hand, with Fishery Officers always being present whenever cockle gathering was taking place. It was clear that there was to be no movement from the FSA on this question of zoning and the status quo continued.

4. It subsequently came to light that the Burry Estuary was secretly being used as a research area by the FSA which severely disadvantaged the Stakeholders of the Fishery (See Annexe 3) [Not printed]. This information had been intentionally witheld by the FSA and having been informed of what was going on I e-mailed Dr Back informing him of my feelings in respect of this situation (Annexe 4) [Not printed]. On the 29 July 2002 I together with others from the industry met with Mrs Reena Owen the Director of Swansea City Council and presented her with the salient information in respect of comparatives with other fisheries (we had determined that the Burry Estuary was being over tested by a ratio of 40:1 when compared with the combined Thames and Wash fisheries). As a direct consequence of this Mrs Owen contacted FSA Wales on the 2 August 2002 (Annexe 5) [Not printed] which resulted in the fishery being zoned almost immediately. Also importantly as a direct consequence the number of regular samples being taken was immediately reduced from seven to three which had the added benefit of also reducing the probability of failures arising again in the future. It is my submission that far from being open and transparent, as is proclaimed by the organisation, the FSA deliberately concealed what had been going on and, had the arguments not been forcibly put, the fishery in all likelihood would still be being treated as a test area with excessive samples being taken so keeping the fishery totally and completely closed. It is clear from this that the FSA does not have a policy for determining the number of samples that are to be taken from a fishery of a given size and instead appears to make up the rules for this as and when it becomes necessary, in other words it is all down to luck and not through any expected statistical risk assessment.

5. Interlaboratory Comparisons

In spite of strong and early protests from industry that the most likely cause of the problem was as a direct result of the change of laboratory (in June 2001) and not because of any toxic condition industry's concerns were ignored for an inordinate amount of time. The first occasion that the FSA meaningfully discussed with the labs the question of carrying out inter lab comparisons was during a meeting on or about 28 February 2002 when it was agreed to arrange to send comparative samples to the labs, this being eight months since the Burry Estuary had been continuously closed. Despite this decision being reached on or about 28 February 2002 the actual cockle samples for carrying out the comparisons were not in fact delivered to the labs until 8–9 October. This extraordinarily being some seven months after the decision to carry out these essential, but rudimentary checks being reached. An inexcusable and unforgivable delay given the damaging effect that this had been having on industry for the previous 15 months.

6. Samples for Professor Yasumoto

Professor Yasumoto is the individual who has refined the mouse bioassay test for the testing for toxins in shellfish and as such is considered to be the world expert in this particular field. In late October 2002 Yasumoto attended a Shellfish Toxin Conference in Florida and whilst at the conference discussed our particular problem with Dr Wendy Higman of the CEFAS Weymouth laboratory who at that time was a senior technician in charge of the DSP "project" at CEFAS Weymouth. Yasumoto had apparently already

previously been sent a small sample of cockles for analysis by Higman but it was too small a sample for Yasumoto to carry out the full range of meaningful tests that he wanted to do. In spite of Higman's promise to send Yasumoto more samples when she returned to the UK further samples to him were not forthcoming. Had these samples been provided Yasumoto would most importantly also have carried out oral toxicity tests to properly determine the extent, if any, of the toxin (Annexe 6) [Not printed]. Some six months later, on 2 May 2003 industry and EHO's were invited to a seminar that was being given by Yasumoto at FSA headquarters in London. During the Q&A session at the end of the meeting I asked Yasumoto why he had not been sent the further samples (which he had requested Higman to provide six months before) he informed me that the difficulty was due to the quantity of shellfish flesh that was required by him as neither he, Yasumoto, or the CEFAS lab in Weymouth had sufficient staff to carry out the work of removing the live flesh from the shells. I informed Yasumoto during the meeting that industry would willingly help and I myself would carry out trials at my premises to see if I could assist and I would revert to him in due course. After carrying out the trials I informed Yasumoto and the FSA (Annexe 7) [Not printed] that I would be able to assist in the exercise by supplying him with the flesh he needed but in spite of this the FSA never took up my offer to help, as far as I am aware Yasumoto to this day has not been sent the extra samples that he requested. In an e-mail update from Claire Boville of the FSA to Dr Peter Hunt on 7 July 2003 it is stated that further samples had not been sent to Yasumoto as he had been away since April and had only recently returned to Japan—this is in direct contradiction to the information that I have where Yasumoto himself e-mailed me on 13 May 2002 and stated that he had returned to Japan on 11 May, being some months before Boville of the FSA had said (Annexe 8 refers) [Not printed].

7. Delays in Results leading to Public Health Risks

The present system of sampling and testing is inadequate in that when samples are taken the results do not become available typically for four days. On a personal level this has discriminated against my particular operation, in that unlike the fresh cockle trade, I carry out a value added exercise by pickling and bottling the cockles and placing them into a lengthy supply chain process which means that because of the delay in results being declared there is always the possibility of the local authority carrying out a product recall whenever a failed result is given. Should this occur I am obliged to destroy at very great expense whatever product has been bottled and is "affected". Because of this and the historically high number of fails previously affecting cockles from the Burry Estuary I have not been able to afford to take the financial risk of using locally caught cockles resulting in the removal of a very important source of supply to my particular company. However in the case of the continuing sale of locally caught fresh cooked cockles these typically are processed, sold and are consumed within not more than a few days of processing so preventing a recall taking place if a fail is subsequently declared. Most importantly and bizarrely of all if the FSA concerns are to be believed, that being that this is an unknown toxin that is affecting the cockles and which could have serious public health implications; why is it that the fishing of cockles is allowed to continue **at all** given that a very large quantity of cockles are frequently sold that have subsequently been found to have been "affected" and failures are still arising from time to time. Whilst this continues the public is still being left to consume cockles that the FSA say are unfit for consumption. What of the "Precautionary Principle" here. Additionally in spite of fails having arisen on a great number of occasions the number of product recalls are few and far between, regardless of this there have anyway never ever been any illnesses that have been directly attributed to having been caused by eating these particular shellfish.

8. Contrasting Approaches

As a company and because of my concerns I independently sought professional scientific advise from Integrin Advanced Biosystems who themselves are experts in the area of marine bio-toxins. All along they have approached the question of alleged DSP toxicity professionally which has sharply contrasted with the way that the FSA have conducted themselves. To illustrate what I say I provide copy of a letter from the lab being dated the 28 November 2002 (Annexe 9) [Not printed].

January 2004

Supplementary memorandum submitted by Rory Parsons, Leslie A Parsons and Sons (Burry Port) Ltd (M7a)

1. I would like to apologise to the Committee for making this addendum to my earlier submission but since finalising my original submission further information of importance has subsequently been received by me that I consider that the Inquiry should be made aware of.

2. The accompanying document (Annexe 10) [Not printed] has today been provided to me in my capacity as an appointed Member of the South Wales Sea Fisheries Committee, being the organisation which is responsible for controlling the fishing activity that occurs within the Regulated Burry Estuary cockle fishery.

3. It will be noted from the information contained under the heading that is titled For Information that particular reference has been made to a reduction in fishable cockle stock as a combined result of the alleged DSP condition and hot summer weather.

4. This has a direct, immediate and detrimental effect on the livelihoods of the stakeholders of the fishery in that important fishable cockle stocks have been lost and fishing quotas have been reduced because of the resulting damage.

5. Whilst the document does not mention it, that particular area of ground that has been affected will take an exceptional period of time to become fishable again because of the quantity and burden of dead cockle shells that will lay both above and immediately below the surface of the affected area.

6. For clarification the Fishery was completely closed for a many weeks during this last summer which coincided exactly with the time when the FSA tried to introduce to the UK a revised and unproved testing method, being a method which was almost immediately totally rejected as being unworkable by the Aberdeen lab. Peculiarly whilst the Aberdeen lab was permitted by the FSA to immediately revert to using the old test method the CEFAS lab (which is the lab that is responsible for cockle fisheries in England and Wales) continued to use the replacement method until it was subsequently changed again some time later. Had the fishery not have been closed because of this allegation of DSP these valuable cockles would otherwise have been fished and importantly this long term consequential damage would not have occurred.

7. My purpose in bringing this to the attention of the Committee is to help illustrate the long term damage that is being caused to this fishery and the wider cockle industry as a direct consequence of the actions of the FSA.

January 2004

Further supplementary memorandum submitted by Rory Parsons, Leslie A Parsons & Sons (Burry Port) Ltd (M7a)

Critique of the Evidence Given to the Committee on Monday the 19 January 2004

I was present throughout the Inquiry, I have also read the written submission that was presented in advance to the Committee by the FSA and where quotations are used by me within this document these are taken from the BBC television recording of the proceedings.

Para 36 States as Follows:

1. Data from the Local Authorities and Sea Fisheries Committees for the main fishing areas indicate that, despite the closures, quota uptake in the Thames Estuary and Wash fisheries was at least 91% in all areas in 2001 and 2002, and approaching 100% in most. Comparable data on fishing against quota for the Burry Inlet, which has been the area most affected by closures caused by the atypical response, are not readily available. However, in August 2002 zoning arrangements were put in place, and since then the whole of the Burry Inlet has only been closed for two weeks in 2002, and three weeks in 2003.

2. This paragraph is worded so as to deliberately "play down" the damage caused to industry and in my view the wording used intentionally misleads the Committee for the purpose of a damage limitation exercise.

3. Breaking down the paragraph into three main components and dealing with each sentence in order I advise as follows:

4. Whilst fishing from these particular areas (The Thames and Wash) may possibly have achieved the stated levels, because of zone closures fishing would not have taken place from the better and more usual areas, for example, but not exclusively, zone 5A & 5B in the Thames was kept shut for the majority of the time in 2003 and to achieve quotas the cockle dredgers had to work areas that contained inferior cockles which commercially were less good and therefore of less commercial value. As an example, because of this, my particular Company out of sheer commercial desperation and need, was forced to bottle cockles of a size of 2,500 pieces per kilo whereas the smallest size that would normally be bottled would have been 1,500 pieces. Bottling cockles of such a small size was previously unheard of within my particular operation and also importantly using cockles of such a small size damages my reputation for producing a quality product.

5. Contrary to what is said comparable data for the Burry Estuary was available and in fact the FSA was in possession of this in sufficient time for it to be included in it's submission to the Inquiry. In support please refer to Annexes 1 and 2 [Not Printed] that accompanies this document. (Annexe 1 being an e-mail being dated the 11 December 2003 from FSA (Wales) to Phil Coates, the Director of the South Wales Sea Fishery Committee, requesting him to confirm the figures in their (the FSA's) possession and Annexe 2 being the document that was returned to the FSA showing Phil Coates hand written annotations correcting the figures where relevant). It is clear from these attachments that the information was actually in possession of the FSA in advance of the Inquiry. It is also apparent from the information that in the case of the Burry Estuary the actual take up of the permitted quota at the time in question was down to 29% because of the frequent and lengthy closures that restricted and limited the gathering effort.

6. The final sentence of the paragraph deliberately sets out to play down the effect of closures. Whilst what is said could perhaps be correct (and given more available time I would otherwise have checked it) that the whole of Burry Estuary was only shut for two weeks in 2002 and three weeks in 2003 it does not spell out the reality of what actually happened. The Burry Estuary is divided into three zones and these are opened

and closed individually depending upon the declared "atypical" results. It will be noted from the accompanying attachment (Annexes 3 & 4) [Not Printed] which has been drawn up from information provided me by the Environmental Health Department of Swansea City Council that in the case of the Burry Inlet South East Zone this was shut for a total of four weeks during the few remaining months of 2002, after zoning had been introduced, and during the same year the South West Zone was closed for a total of eight weeks. Weigh and balance this against the FSA comment that the whole of the Burry Estuary was only shut for two weeks in 2002. The situation was even worse in 2003 when it is said by the FSA that the whole of the Burry Estuary was only closed for a total of three weeks—in the case of the South East Zone in 2003 this was shut for a total period of 11 weeks and in the case of the South West Zone this was shut for a total period of 21 weeks. Combined, two thirds of the Fishery had been closed for a total of 32 weeks. Importantly and unfortunately equivalent information for the one other remaining zone (the North Side) is not available to me from Carmarthenshire County Council, had it been it would most certainly have painted a much worse and bleaker contrast against what has been said by the FSA. The declaration by the FSA that the whole of the Fishery was only closed for two weeks in 2002 and three weeks in 2003 can therefore only be considered to be contemptible in that via a play on the use of words the FSA tries to conceal and paint over the true facts and the nightmare that it created for industry. It is behaviour such as this that has brought about a climate of mistrust and suspicion that prevents Industry from having a harmonious relationship with the various Officers of the FSA.

Critique of the Oral Evidence given by Dr Jon Bell of the FSA

7. It was said by Jon Bell that the banning of imported cockles from other EU countries was not easily possible for the FSA. I would strongly challenge this remark as both Belgium and Spain have previously successfully stopped the import of British Scallops on the basis of elevated levels of prescribed toxins being found ie ASP/DSP. There is of course also the well documented case of France (and other European Countries) stopping the import of British beef on the basis of the product possibly being affected by CJD. A precedent therefore surely exists for banning the import of cockles into the UK from other EU countries.

8. It was said by Jon Bell that regardless of the fact that late in 2003 a new SOP had been adopted by the various labs results were already improving. I would seriously challenge this remark as during July and August 2003 another altered SOP was used by the labs which resulted in the wholesale closure of many areas, this was so bad that at one particular time the whole of the Thames fishery was entirely closed for about two weeks.

In Summary

9. The FSA has tried to gloss over the serious damage that it has caused to the British cockle industry, the two largest processors have suffered badly as a consequence. David Kershaw of Kershaw's Frozen Foods who gave oral evidence stated that in his own particular case he had made redundant 75 employees and were it not for the product diversification that his Company has he probably would not now be in business. In the case of my own Company were it not for my relationship with a Dutch Company I would not have remained in business after last Christmas. I am now entirely dependant on obtaining approximately 200 tonnes of frozen cockles from Holland at a time when cockles are exceptionally scarce to so enable me to survive until the start of the new cockle season in the UK, which is scheduled to start in June 2004. It is also a matter of recent record that the Burry Estuary has been badly damaged by closures, brought about in 2003, by the allegation of "Atypical" DSP occurring whereby individual quota's for cockle gatherers has been recently reduced by 28% (reduced from 350 kg per day to 250 Kg) for the indefinite future.

10. Dr Jon Bell said to the Inquiry Committee, and I quote, "We are not ruling out a whole range of possible explanations for this including the presence of a toxin" and "we don't know for certain that there is a toxin there, we are doing work to try to be clear about that". Those remarks must be measured against the time scale involved—this is not something that has recently arisen, this first started in July 2001 and has continued through 2002, 2003 and we are now into 2004, can I ask what industry or Company can hope to survive against such a background of delay, indifference and ineptitude? In New Zealand's case, when a similar problem arose there that equally threatened the future of their mussel industry they were able to resolve it within six months—It is my submission that the FSA are chasing shadows to stave off the inevitable.

January 2004

Memorandum submitted by Boston Borough Council (M8)

Executive Summary

The shellfish Industry is an important historical and vibrant part of the life of the Borough of Boston and neeeds to be maintained. So too does Food Safety and Public Health.

There is no clear evidence to support a conclusion as to the reasons for the atypical results from the mouse bioassay in shelfish testing. The Council make the following recommendations:

— A fundamental precursor to any study of atypical results is the creation of clear definitions of positive, negative and atypical results since, in the absence of these Food Authorities are unnecessarily exposed in having to determine whether or not to issue a TPO. It should be urged upon the European Union that any such definition should be Europe wide.

— Care needs to be taken with some of the scientific evidence submitted particularly with regard to false conclusions being drawn. There is however an urgent need for further research to come up with an explanation for the atypical results which are having such an adverse effect of the shellfish industry and local communities. It has to be remembered that this could still result in a new toxin being discovered.

Introduction

This is the submission on behalf of Boston Borough Council. It should be read in conjunction with the submission on behalf of King's Lynn & West Norfolk Borough Council (KL&WNBC), which also forms part of the Wash inlet and with whom we have worked closely throughout. KL&WNBC made a number of recommendations as follows:

— Recognition, including financial recognition should be given for the role that just a few food authorities across the nation play in monitoring this important international industry.

— That there be an urgent review of the methodology used in all UK laboratories with a view to ruling out any risk of results obtained being affected by testing methods as opposed to the shellfish product and that EFRA urge a standardised method across Europe based on the MBA.

— That while the principle of the offer of voluntary testing is welcomed, the Council believes that the disadvantages of the CIVIT proposals outweigh the benefits at this time and recommend that the industry put resources in together with the FSA and food authorities to seek to improve the reference method and in the future to look a new alternative and improved reference method rather than a raft of different tests with different results.

— That a partnership be developed between the FSA, food authorities and the Industry to expedite proper interpretation of atypical results and concerns over methodology and UK laboratories and sampling procedures being adopted. That this partnership be given genuine delegation to secure joint working between the three groups and that this partnership develop to look at other areas in due course.

— That a genuinely independent National Reference Laboratory be established for the UK. If it is to remain based at Aberdeen then it should be wholly independent from the FRS and that it should undertake urgent work to carry out tests to discover a conclusive explanation for these atypical results as a matter of priority and should be accountable to the FSA, Food Authorities and the Industry in that regard.

This Council would support those recommendations and have included further recommendations in this report arising from local experience, which has been similarly shared by KL&WNBC.

These submissions have also been made, having read the joint submission on behalf of Canterbury City Council, City & County of Swansea and the Corporation of London, the contents of which this Council generally support and in particular agree the background to the issue in that report which is fully accepted and referred to as background to our submission but not repeated here.

Submissions

1. As one of the Local Authorities likely to be the subject of a judicial review in respect of actions in placing Temporary Prohibition Orders (TPOs) on shellfish fisheries within our jurisdiction it is prudent that our observations on the current sampling and testing regime and, more importantly, the actions we are obliged to take following a positive atypical DSP result are made.

2. Over the past two years this Authority has issued 21 TPOs, the effect of which has been to put in jeopardy the livelihoods of the local fishermen.

3. For food authorities since 2001 the atypical DSP issue has become a major drain on resources. Sampling, while necessary, is expensive, time consuming and often difficult where boat hire is needed. When closures are in place this is a weekly process. There is also the enforcement of closures and advertising of the problem locally. Enforcement is not easy particularly in a large sea area when most food authorities do not maintain their own sampling vessels or crew. In the Wash we rely heavily on Eastern Sea Fisheries to

deliver this service for us. In addition the dispute over the cause of the atypical problem has meant repeated meetings in London and the appointment of Counsel for legal advice and a scientific advisor. Food Authorities have a legal duty to sample and enforce the legislation and so are a key player in the process but receive no additional funding for this particularly expensive area of food enforcement.

4. Whilst we and the other Authorities involved in the judicial review have followed the letter of the law and instructions from the Food Standards Agency and placed TPOs on fisheries immediately a positive result has been notified this action has been carried out with little confidence. Until it was "zoned" recently one positive result anywhere in The Wash necessitated closure of the whole of this fishery and even now a single positive result from a particular zone necessitates closure of that zone. This is hardly representative when the zone may be over ten miles in length. Furthermore, we are advised that results are unpredictable and it is likely two samples taken at the same time from the same place may give conflicting results. Needless to say such anomalies hardly give officers from the Authorities confidence in their formal actions and, not surprisingly, the fishermen are unconvinced by our actions.

5. It is worthy of note that in July 2003 a positive atypical DSP result was notified to us in respect of one of The Wash cockle fisheries. When the result was received the fleet had already left port to fish the particular cockle bed. Later that day their catch was landed and legal advice we sought told us that these "live animals" could not be seized or detained in their present "live" form.

6. The cockles were processed at a local cannery whereupon we were able to detain them for further investigation as they then fell within the definition of "food for human consumption".

7. With the agreement of the FSA and the CEFAS laboratory samples of the detained cockles (four cans from 27,000) were sent to the CEFAS Laboratory for testing using the same mouse bioassay test performed on live shellfish. The result of each can tested was negative and the FSA authorised their release for human consumption.

8. Understandably the fishermen questioned why the fishery from which these cockles had been harvested was now the subject of a TPO preventing further fishing, yet the end product (after processing) had been declared fit for human consumption. This casts serious doubt over the whole sampling and testing regime.

9. Alongside this there is a need for a clear definition across all UK laboratories and indeed across the whole of Europe as to what constitutes a positive or a negative result. Indeed it is, we would submit impossible to clearly declare an atypical result when there is not a clear definition of a positive and a negative result consistently used across laboratories. Any such definitions should include the number of mice affected and an agreed time frame, presumably 24 hours as the European preferred rate which has not been consistently applied in the UK.

Recommendation

A fundamental precursor to any study of atypical results is the creation of clear definitions of positive, negative and atypical results since, in the absence of these Food Authorities are unnecessarily exposed in having to determine whether or not to issue a TPO. It should be urged upon the European Union that any such definition should be Europe wide.

10. There is a suggestion in the scientific evidence on behalf of the Industry that the absence of any known toxin or toxic algae is evidence in itself against a toxin being the cause of the atypical response. Evidence from Ireland in 1995 when azaspiracid was first detected, demonstrates that this is a false conclusion since there too no other known toxins or toxic algae was found.

Recommendation

Care needs to be taken with some of the scientific evidence submitted particularly with regard to false conclusions being drawn. There is however an urgent need for further research to come up with an explanation for the atypical results which are having such an adverse effect of the shellfish industry and local communities. It has to be remembered that this could still result in a new toxin being discovered.

11. Conclusion

Three key issues arise from the recommendations in this report. The need to remember the reason behind testing and resultant TPO's—namely food safety and public health and if further treatment of the product renders it safe then the product should be capable of release on to the market in that treated form. Linked to this is the need for clearer definitions of positive, negative and atypical results and there needs to be care taken with false conclusions being drawn from the scientific research. To date all we can conclude is that we do not know what is the reason for these atypical results and further research is urgently needed.

January 2004

Memorandum submitted by Carmarthenshire County Council (M9)

Executive Summary

1. In order to fulfil food safety and public health standards, Carmarthenshire County Council submits Shellfish samples for Diarrhetic Shellfish Poisoning (DSP) as directed by the protocol drawn up by the Food Standards Authority (FSA), being the Central Competent Authority. The cost of sampling is borne by FSA and it is FSA that directs to which laboratory the samples are submitted for testing.

2. The Authority has at all times issued Temporary Prohibition Orders (TPO) in accordance with the advice and knowledge of FSA. In fact, after the issuing of the initial TPO, permission has to be sought from FSA to issue further TPO's. Local Authorities have been given clear advice from the FSA that "atypical" DSP should be considered as a potential threat to public health. In line with this advice Carmarthenshire County Council has continued to issue TPO's on receipt of positive results. Not to have done so would have been a failure in protection of the public.

3. In collaboration with its neighbouring Authority, the City and County of Swansea, Carmarthenshire County Council has taken such steps as it can in to assist the Industry—by offering a sum of £10,000 towards research into DSP in the Inlet and in putting the case forward for zoning the Inlet, thus, hopefully, allowing areas of the Inlet to be open at any one time.

4. At the very start of the problems with DSP, local authorities were not allowed direct access to the testing laboratory. On occasions delays in receiving results were experienced as results had to be transferred from London to Cardiff and then to the Welsh Local Authorities. This problem was then resolved.

5. Although FSA have sponsored research into the cause(s) of "atypical" DSP, to date, there has been no definitive answer as to the cause of the positive results to the mouse bio-assay. It is important that the research continues in order to determine if the "causative agent" has a deleterious effect on public health.

1. Introduction

1.1 Carmarthenshire County Council is the "food authority" for the implementation of the requirements of EC Directives 91/492/EEC and 91/493/EEC which have been converted into the Food Safety (Fishery Products and Live Bivalve Molluscs) (Hygiene) Regulations 1998 (as amended).

1.2 The Council and its predecessor Authorities have been responsible for the enforcement of the original regulations since their coming into force in 1992.

1.3 The Council is responsible for the monitoring of classified harvesting areas in its area and is also involved in the DSP/PSP/ASP monitoring programme. There are two main areas for the commercial harvesting of shellfish on Carmarthenshire's area—The Three Rivers Area, which is only occasionally harvested, and the Burry Inlet. Carmarthenshire County Council is responsible for the northern side of the Inlet. The natural boundary between Carmarthenshire and the City and County of Swansea it the main channel of the River Loughor.

1.4 The Burry Inlet has historically been a harvesting area for bivalve molluscs and in particular has been famous for the harvesting of cockles (there is evidence that shellfish were harvested in Roman times). The Inlet, particularly on its southern shores, was the site of numerous small processing plants. Those smaller units have disappeared and given way to larger, more sophisticated shellfish processing plants. The Burry Inlet shellfish industry is worth millions of pounds annually and unlike its counterparts in other regions of the United Kingdom harvesting is undertaken on a year round basis ie there is no closed season.

2. Carmarthenshire County Council Experience

2.1 In line with other Local Authorities with classified shellfish harvesting areas, Carmarthenshire County Council submitted samples of live shellfish and seawater in order to comply with the agreed DSP/ASP/PSP sampling protocol issued by D.O.H. (subsequently FSA). The Authority is responsible for complying with the sampling protocol and must submit samples to the accredited laboratory designated by FSA, (since June 2001 this has been the CEFAS laboratory at Weymouth). Over a number of years the sampling regime had thrown up an occasional isolated positive result for diarrhetic shellfish poisoning (DSP), but positive results were rarely reported on re-sampling.

2.2 The 2001 sampling protocol required Carmarthenshire County Council to submit three samples of shellfish from Burry Inlet (North) and the City and County of Swansea to submit four samples.

2.3 On 11 July 2001 Carmarthenshire County Council were notified that a sample of cockles submitted that week had proved positive for the presence of DSP. The Authority immediately issued a Temporary Prohibition Order for that area of the Burry Inlet which fell within the jurisdiction of Carmarthenshire County Council as the food authority empowered under the directive (91/492/EEC). The City and County of Swansea and Carmarthenshire County Council worked together on this issue and it was agreed that one positive result (either from the three samples submitted from Carmarthenshire or the four samples submitted from Swansea) would require the closure of the whole Inlet.

2.4 The Temporary Prohibition Order (TPO) ceases 28 days after the date of service, unless revoked previously. Authority to serve further TPO's requires consent from the Minister (in the Welsh context, FSA Wales).

2.5 Following more positive results on both sides of the Inlet further TPO's were issued by Carmarthenshire county Council (with the consent of FSA Wales) on 8 August 2001, 5 September 2001, 3 October 2001 and 31 October 2001.

2.6 Industry, in turn, blamed a stored "reservoir" of water being discharged on occasions into the Inlet, the increased "cleanliness" of the water following the commissioning of the new sewage treatment works and also various discharges into the Inlet.

2.7 Having received a series of negative results on the North Side (5 November 2001, 12 November 2001 and 18 November 2001) enquiries were made as to whether that area of the Inlet could be opened. After first having some positive comments and implied agreement, Carmarthenshire Council took the decision to revoke the order in order for harvesting to recommence. Support for this move was unfortunately withdrawn due to a misunderstanding over the nature of the situation. A further TPO was issued on 30 November 2001.

2.8 Obviously by this time the shellfish industry within the Burry Inlet was in uproar and could not accept that the positive results were purely as a result of an algal bio-toxin giving a positive result for DSP using the mouse bioassay (MBA).

2.9 Increasingly, however, Industry were questioning the validity of the DSP test, which is a mouse bioassay test, being undertaken by the CEFAS Laboratory at Weymouth in Dorset, Industry's concerns centred around the increased number of "positives" since the contract for DSP testing had been won by the laboratory at Weymouth at the expense of the Fishery Research Service at Aberdeen (FRS).

2.10 The Local Authorities involved and Industry were also concerned about the length of time following sampling and receiving results. Local Authorities were not allowed to have direct contact with the testing laboratory and results were first reported to FSA before cascading to Local Authorities. This could mean a period of 4 days from sampling to result and the consequential problems that could ensure of recall of product was required.

2.11 In February 2002 Carmarthenshire County Council convened a meeting of interested parties in order to fully discuss the implications of the problems within the Burry Inlet. The meeting included representatives of local government, FSA, National Assembly for Wales, Sea Fisheries and Industry. The purpose of the meeting was to find a way forward and to receive information as to the current state of knowledge.

2.12 In this meeting Carmarthenshire County Council offered a sum of £10,000 in order to assist with a possible research project centred around University of Wales, Swansea—which would hopefully receive a grant from Objective 1 funding. Unfortunately, there has been no further development on that front and it would appear that the project is not going ahead.

3. "Atypical" DSP

3.1 New information was also being received to the effect that the positive results for DSP were due to a novel toxin, which was causing, on numerous occasions, rapid death in the mice with severe neurological symptoms. These symptoms were not typical of the normal DSP syndrome caused by known algal bio-toxins. Results were therefore reported as "atypical" DSP.

3.2 Guidance from FSA was to continue to treat the "atypical" DSP response as a possible risk to public health as the "toxin" was causing symptoms in the laboratory mice. Local Authorities were advised to issue TPO's on the basis of an atypical response, as this novel toxin, could at a future date, present itself as a human infection. It was wise to err on the side of caution and protect any possible effects on public health. Such action was consistent with other novel agents and the actions to control BSE, for example.

3.3 The Industry, through the Shellfish Association of Great Britain, was becoming increasingly angry at the perceived lack of progress in identifying the novel toxin and were convinced that there was a fundamental flaw in the sampling technique at CEFAS, Weymouth. The Association's contention was that the positive results were in fact "false" positives due to the carry over of diethyl ether (DEE) into the mouse inoculant and it was this that provided the results for "atypical" DSP. Local Authorities were also becoming increasingly concerned with the lack of progress in identifying this novel toxin and were becoming under greater pressure to discount all positive results from CEFAS.

3.4 Local Authorities were continually being lobbied by Industry as to their concerns in respect of the "flawed" testing methods.

4. Zoning

4.1 A total of seven samples for a relatively small area (when compared to the Thames Estuary and the Wash) appeared to be excessive, especially when one positive sample on either side triggered off a new or continuing TPO. Because of the high number of positive results being found in the Inlet, the area was utilised as an ideal source of positive material for further research by FSA into the atypical DSP and we were advised to maintain the level of samples submitted.

4.2 However, in August 2002, both the City and County of Swansea and Carmarthenshire County Council were in negotiations with FSA as to the zoning of the Burry Inlet into distinct, easily identifiable and easily controlled zones.

4.3 Agreement was reached with FSA that the Burry Inlet could be zoned into three zones—the zones would reflect, to a large extent, the main harvesting areas. The zones were (and still are):

- Burry Inlet North (West)—north of the main river channel (Carmarthenshire County Council)
- Burry Inlet South West—to the western end of the harvesting area, south of the main river channel (City and County of Swansea)
- Burry Inlet South East—to the eastern end of the harvesting area, south of the main river channel (City and County of Swansea)

A buffer zone would be provided between the two south zones.

4.4 One sample from each of the zones would be submitted for analysis. A positive result in one zone would only require the closure of that zone. In this way it was hoped that the gatherers would at least be able to harvest one or more zones of the Inlet at any particular time (dependant on results).

5. Further Research

5.1 As part of its research effort as to the actual cause of the atypical DSP found in the mouse bio-assay FSA invited Professor Yasumoto (one of the world's experts on marine bio-toxins) to the United Kingdom from Japan in order that he could observe the response in the mice during the mouse bio-assay. The Professor observed the test being carried out and was of the opinion that it could well be a novel toxin causing the observed response. He offered to undertake further tests on positive sample at his laboratory in Japan, provided that sufficient sample material could be transported to him. Unfortunately, to date, because of various circumstances no samples have yet been forwarded to Professor Yasumoto for analysis.

5.2 Increasingly the shellfish industry was being advised by organisations such as INTEGRIN Advanced Bio-systems and others whose advice to the Industry was in direct contrast to the advice being offered by FSA through its contracted laboratory; CEFAS at Weymouth

5.3 Again, Local Authorities were under increasing pressure to question results received via the FSA and the laboratory in Weymouth.

5.4 Such were the concerns of the FSA that they commissioned an independent audit of all three laboratories testing for DSP in the United Kingdom in order to establish if there were any "significant" differences in the way the mouse bio-assay was being undertaken in the three testing laboratories :-

- CEFAS, Weymouth.
- DARD, Northern Ireland.
- FRS, Scotland.

5.5 Professor Makin who undertook the audit, did not severely criticise any of the laboratories, but did indicate weakness in each. In particular, a standard operating procedure (SOP) should be adopted in all three laboratories and the SOP should be instituted in all three centres without delay.

5.6 The Industry perceives that Local Authorities, having received the advice and information from the Industry's own scientific advisors, consider it now untenable for those Authorities to continue to support the results of the FSA's contracted laboratories. In the opinion of the Industry those Authorities who do so are acting in contravention of their legally defined duties—in effect are acting ultra vires.

5.7 Representatives of Industry are adamant that their argument lies firstly and foremostly with the FSA, but can only take action against the "Food Authority" ie the Local Authority.

5.8 Six Local Authorities in England and Wales have been threatened with a Judicial Review of their enforcement functions under the Directive, particularly in the light of the "scientific evidence" presented to those Authorities by the Industry's scientific advisors at a meeting in London on 15 October 2003.

5.9 Local Authorities are receiving advice from both the FSA and Industry, and that advice appears to be contradictory. In considering the situation the Local Authorities found themselves in, it was agreed to obtain the advice of an independent expert who could hopefully advise the Local Authorities. The Marine Institute in Ireland has been identified and all relevant papers, both from FSA and Industry have been forwarded for advice. Obviously, Local Authorities find themselves in an increasing dilemma—FSA is the

"central competent authority" for food related matters in the United Kingdom and the mouse bio-assay it still the standard reference test under the directive—on the other hand Local Authorities are being threatened with Judicial Review for relying on, as the Industry perceives it, a flawed and discredited test.

5.10 To its credit the FSA is undertaking a series of research programmes in order to look at particular areas of concern eg does the carry over of diethyl ether (DEE) have an effect on positive results for atypical DSP?

5.11 In the light of concerns raised about testing, the laboratories met to discuss any possible differences in operating procedures. As a result, in June 2003 a new procedure was implemented in the laboratories. There followed a spate of positive results and the Burry Inlet (North) was closed for eight weeks during the summer time. This period coincided with a period of very hot weather which killed off a high proportion of cockles exposed to the heat during times of low water. Following an audit of procedures further discussions were held and a standard operating procedure, based mainly on the DARD procedure was implemented in September 2003. During the period 8 September 2003 to 1 December 2003 only one positive result was recorded for the north of the Inlet (6 0ctober 2003). In fact recently there have been some weeks where no positive results for DSP have been recorded in the United Kingdom.

6. Communication

6.1 Communication between the FSA, the Shellfish Industry and local authorities has been less than satisfactory.

6.2 Initially when the first traunch of positive results were received, Local Authorities were not allowed direct communication with the testing laboratory. On occasions this meant an increased delay in reporting results and arranging for the issuing of TPO's (on positive results). Local authorities were increasingly receiving complaints that this was an increased pressure on gatherers due then need to recall product gathered between the time of sampling and receiving the results (anything up to four days).

6.3 This matter was resolved, to some extent, in 2002, and Authorities received results directly from the laboratory.

6.4 A major cause for concern was the exchange of information between all three parties. There has been little openness or transparency. The Shellfish Industry received information which would have benefited local authorities, yet it was not shared and on some occasions, the FSA communicated with the Industry and failed to share the information with the local authorities.

6.5 FSA have also stated in a recent Welsh stakeholders meeting that it is unfortunate that the Agency had been a little remiss during the first two years of the DSP problem before taking the steps to ensure that necessary action was implemented.

7. Conclusion

7.1 Carmarthenshire County Council has undertaken its responsibilities under the regulations diligently and always with reference to its neighbouring Authority, the City and County of Swansea. The Council continues to be advised by the Food Standards Agency on the matter of DSP (the Agency being the central competent authority) and until it is advised differently cannot envisage that advice being ignored.

7.2 The Authority is aware of the controversy raised by the mouse bio-assay test and the increased pressures to opt for chemical testing. However, the mouse bio-assay (MBA) continues to be the base reference test for countries within the European Union and must therefore accept the results of MBA testing, unless otherwise advised by a change in the directive.(Even though the mouse bio-assay is apparently not universally utilised within all member states of the Community).

7.3 Carmarthenshire County Council has attempted to assist the Industry during this particularly difficult period and did offer a sum of £10,000 for research into the causes of DSP in the Inlet in February 2002. To date this offer has not been taken up and unfortunately, there does appear to be little commitment and urgency by other partner organisations to achieve a resolution of the problem. The Council would welcome an intervention at the highest possible level, to ultimately determine the implications for public health.

January 2004

Memorandum submitted by Canterbury City Council (M11)

Executive Summary

Canterbury City Council members and officers have a great commitment to maintaining a thriving shellfish industry which contributes a safe and high quality product to our local economy. In light of the hardship which has resulted from the atypical DSP closures we would like to make the following recommendations:

Recommendation 1

Roles must be clarified and Food Standards Agency must be made accountable for their choices with regard to sampling programme and testing rather than food authorities. Communication must be improved between FSA, FAs and the Shellfish Industry. All must be represented and play equal parts to ensure a system, which can effectively control potential public health problems.

Recommendation 2

All laboratories in Europe should agree to use the same testing methods. There should also be agreed EU operating procedures. The FSA has already commissioned some work on alternative testing methods, we would like to see the UK leading the way for a replacement of routine mouse bioassay tests with accredited analytical techniques.

Recommendation 3

The UK must have an active effective NRL which co-ordinates sampling in UK and also keeps it in line with the rest of Europe.

The FSA is the competent authority in the UK and must ensure they have the necessary resources to carry out the functions outlined in article 2 of the council decision 93/383/EEC. This includes aspects of consistency, communication and quality assurance and control. It is recognised that some improvements have been made recently.

Recommendation 4

The FSA should lead a review of how the sampling programme and result communication works with all interested parties, before the main harvesting season in summer 2004.

In conclusion CCC has conscientiously undertaken its food enforcement responsibilities during a troubled period for the shellfish industry and has continued to follow the advice of the FSA. We have also listened to the concerns of the local shellfish industry and tried to prevent controls and restrictions placing unnecessary burdens on struggling local businesses.

This commitment to following FSA guidance has been challenged by the shellfish industry and to retain an impartial view of conflicting reports it has been necessary to employ expert advice on legal and scientific issues.

We accept that as competent authority the FSA is now taking steps to identify and assess the implications of this possible new toxin which initially became apparent in 2001. After reports in 2003 the FSA is also implementing better controls of testing procedures.

As stated in our report it is hoped that in future communications between the appropriate authorities and the industry will be improved to ensure more effective control of this issue and any new public health concerns.

1. Introduction

1.1 This submission is on behalf of Canterbury City Council. Canterbury is a food authority with responsibility for enforcing food safety legislation within its food premises and shellfish harvesting areas—Whitstable Port Health Area. This is a well-known shellfish producing area on the North Kent coast. Three shellfish companies and various harvesters farm private and public shellfish beds. Oysters, clams and cockles are commercially harvested and processed and the waters are a good source of seed mussels, which are grown on elsewhere.

1.2 Since 2001 repeated positive results for the DSP test have lead to 12 closures on the advice of the Food Standards Agency this has meant approximately 270 lost harvesting days for cockle harvesters. In July 2003 representatives of the cockle industry threatened six food authorities, including Canterbury City Council with judicial review on the grounds that these closures were outside the scope of the legislation. The five other affected food authorities are:

Boston Borough Council

Carmarthenshire County Council

City and County of Swansea

Corporation of London

Kings Lynn and West Norfolk Borough Council.

2. Background

Since the Shellfish Hygiene Directive (91/492/EEC) was adopted by the UK in 1992 there has been a legal requirement for the council to carry out sampling for naturally occurring bio-toxins in shellfish. The directive is currently translated into UK legislation by the Food Safety (Fishery Products and Live Shellfish) (Hygiene) Regulations 1998 (as amended). Under these regulations the responsibility for controlling shellfish bio-toxins, such as Diarrhetic Shellfish Poisoning (DSP), is shared between the government, Food Standards Agency (FSA) since 1999, and food authorities (FAs). The sampling programme and testing arrangements are the responsibility of the FSA and the sampling and any necessary closures are the responsibility of the Food Authority. This division means FAs have no choice or direct control over the sampling programme or testing laboratory.

2.1 Since 2000–01 shellfish, specifically cockles, within the Thames, Wash and Wales have tested positive for Diarrhetic Shellfish Poisoning (DSP). Bivalve shellfish such as cockles and oysters filter seawater to feed on microscopic algae, which grow naturally. Some types of algae when concentrated can make the shellfish poisonous to people when eaten. In the case of DSP the symptoms are stomach ache and diarrhoea shortly after consumption of affected shellfish. No cases of illness have been linked to closures or shellfish consumed during the time closures have been in place. It seems the problem identified since 2001 is a new toxin which triggers a positive DSP result, the source and identity of this "a typical" DSP toxin are not yet known. Research funded by the FSA to identify the toxin and assess risk to consumers is ongoing.

2.2 Prior to 2001 all samples for the UK were analysed in Aberdeen, at the Fishery Research Laboratory. Only occasional positive results were detected. The programme included water samples to identify algae known to be toxic and a rolling programme of shellfish meat samples to analyse for the toxins. In 2000 some positive results for DSP were received in the Thames and Canterbury district. As the programme intensified testing work was divided between other UK accredited laboratory. CEFAS in Weymouth took over the programme for England and Wales in summer 2001.

2.3 There are several testing methods allowed by EU law to detect DSP. Classic DSP is usually caused by one of a group of 5 recognised toxins and these can be recognised by chemical methods. The reference method under Commission Decision 2002/225/EC remains the use of mice, which are injected with an extract from the shellfish. DSP toxins are found in the fatty tissue of the shellfish and therefore the toxins will be removed from the flesh by using solvents such as ether and acetone. The extract should then be cleaned of solvents before injecting into mice. If the mice die this indicates DSP is present.

2.4 A large increase of atypical positives since summer 2001 coincided with the testing work for England and Wales being moved to CEFAS. This lead to concerns from the industry and some Food Authorities that increased number of positives were due to a problem with the testing method in the new laboratory. These worries were voiced to the FSA who agreed that the following work would be carried out; 1. Work to audit the testing protocols used in the three different laboratories 2. Commission a standard test protocol for all UK (and possibly European laboratories) 3. Consider if there was ether carry over which could be causing positive results 4. Also carry out work to identify the toxin and establish if it posed a risk to human health.

2.5 The FSA have, in October 2003, produced two reports which they consider show there are no reasons why testing methods 1 above or ether carry over 2 above, are responsible for the atypical positives. Enforcers facing possible judicial review and the industry are still concerned. The audits show that there is significant ether carry over produced by testing methods—although the FSA conclude the amount is insufficient to cause mouse deaths.

2.6 The audits of all three laboratories also show major problems with quality assurance and practises including reports of dirty extract containing water and ether being injected into mice at CEFAS. Again the FSA consider the reports do not show the atypical results are due to testing problems. Many of the issues surrounding the testing are very technical.

2.7 The Shellfish industry has commissioned their own review of these reports by Dr McKenzie at Integrin and certainly draw different conclusions to the FSA. Food authorities have been in the centre of these arguments and have felt it necessary to commission their own scientific advisor to obtain an impartial interpretation of these detailed technical discussions and papers. These are included as an appendix to this submission.

3. Impact of Closures Due to Atypical DSP on Canterbury City Council and Local Shellfish Industry

3.1 Canterbury City Council covers Whitstable Port Health Area. This well known shellfish producing area contains important cockle harvesters and processors operating from the harbour. Since 2001 repeated positive results for the DSP test have lead to 12 closures on the advice of the Food Standards Agency. Cockle harvesters have lost approximately 270 harvesting days. Clam, oyster and whelk harvesters have also been affected although they have still been able to operate. The media and public often overlook the fact these species are unaffected.

3.2 Within the Canterbury district Shellfish growers had to decommission one harvesting vessel making two fishermen redundant. There were also two small processors dependant on cockles from the privately owned A class cockle harvesting area who have not processed cockles since 2001. In addition to DSP the grounds have been reclassified as B and can only be processed by an approved fishery establishment. For the remaining shellfish industry press interest in the closures have too frequently raised a negative profile of Whitstable, making the shellfish appear blighted. Also DSP is often associated with dirty, polluted waters, which discourages families and water sports users as much as "gastro tourists". Shellfish are an important incentive for visitors to come to the Canterbury district particularly for the coastal areas.

3.3 Remaining shellfish harvesters are affected too—cockle harvesters and processors are continually worried those closures may lead to product recall and that they cannot plan harvesting or supply customers with a product reliably available.

3.4 Long-term closures can also damage the future viability of harvesting areas by overcrowding and killing cockle stock. This is particularly true in the Burry Inlet, Wales where hand raking is an important part of the environmental management of the Inlet ecology.

3.5 For food authorities since 2001 the atypical DSP issue has become a major drain on resources. Sampling is expensive, time consuming and often difficult where boat hire is needed. When closures are in place this is a weekly process. There is also the enforcement of closures and advertising of the problem locally. Enforcement is not easy particularly in a large sea area when most food authorities do not maintain their own sampling vessels or crew. In addition the dispute over the cause of the atypical problem has meant repeated meetings—particularly In London and appointment of various experts for impartial advice.

3.6 Food Authorities have a legal duty to sample and enforce the legislation but no additional funding is available for this particularly expensive area of food enforcement.

4. The Following Issues have Been Raised as Major Concerns by Food Authorities

4.1 Arrangements for enforcement of legislation are divided between the Food Standards Agency and food authorities legislation dealing with shellfish is split between Food Standards Agency and Food Authorities. The FSA is the competent authority for programme and testing and the food authorities sample and enforce closures on FSAs advice. There are also concerns over the wording and possible interpretation of some of the legislation and commission decisions.

4.2 There are complexities in the way the legislation is enacted, which cause difficulties for authorities and FSA although food authorities have no influence on testing scheme because they implement closures they are legally accountable for the choices made. This is highlighted by the fact the industries proposed judicial review targets food authorities.

4.3 FSA have access to the funds and scientific expertise. They are responsible for arranging the sampling programme, appointing testing laboratories, choosing the testing methods and issuing guidance to FAs. These FAs have been made responsible for carrying out sampling although they receive no additional funding. Also for implementing temporary closures if they are satisfied there is a risk to public health.

4.4 Under the Food Safety Act 1990, the FSA may issue codes of recommended practise as regards the execution and enforcement of the Act and regulations and orders made under it. The FSA may also under the Act give a food authority, such as ourselves, a direction requiring them to take any specified steps in order to comply with the code. Under the Act we have to have regard to any relevant provision of any such code and comply with any direction. If we don't have regard or comply the FSA can take action through the courts to make us comply. The FSA also has default powers where it or another authority (if we have failed to discharge any duty imposed by or under the Act and the failure affects the general interests of consumers of food), discharge that duty in place of the authority and to determine this, a public inquiry may be held.

4.5 FAs are required by the FSA, to regularly collect and send shellfish for testing. If the test results are DSP positive than we must issue a Temporary Prohibition Order (TPO) to close the harvesting area. FSA guidance is to treat positive results for atypical DSP positive results the same. Recently new advice was issued by the FSA including standard wording for the TPO.

4.6 There are concerns in some districts, such as Canterbury, where shellfish are farmed that the new guidance issued by the FSA on the drafting of TPOs causes unnecessary burdens for our local shellfish industry. Previously Canterbury chose wording, which focussed on restricting gathering for sale for human consumption. The wording in the guidance prevents collection for any reason. Canterbury has three shellfish

companies who farm private shellfish beds. If they are prevented from selling for food they can still grade and relay shellfish on their grounds. In the past they have also gathered and sold on genuine seed shellfish. The wording now laid down in the FSA guidance prevents any collection for whatever reason. FAs are concerned that individual circumstances are not taken into account when considering guidance and the wording of TPOs.

4.7 This division of responsibilities and funding are complex. Enforcement is at a local level but decisions are made on the FSAs advice. Any dispute over closures is therefore directed through the FAS. This is made slow and cumbersome by slow and unwieldy communication between FSA, laboratories, FAs and shellfish industry. It is not easy to find a mechanism for making the FSA accountable for actions.

Recommendation 1

Roles must be clarified and FSA must be made accountable for their choices with regard to sampling programme and testing rather than FAs. FAs must not be placed in this "piggy in the middle" role.

Communication must be improved between FSA, FAs and the shellfish industry. All must be represented and play equal parts to ensure a system, which can effectively control potential public health problems. Major shellfish producing countries such as New Zealand have already made this commitment.

5. Food Authorities are concerned about the use of the mouse bioassay (MBA) test for DSP and some other toxins—some EU states and other shellfish producing countries do not use this method.

5.1 At present all EU countries should follow the EU commission decision dated 15 March 2002. This has set down testing methods for DSP. These include chemical methods, High Pressure Liquid Chromatography, Liquid Chromatography—Mass Spectrometry(LC-MS) and phosphatase inhibition assay but if when the results of the analyses performed demonstrate discrepancies between the different methods, the mouse bioassay (MBA) should be considered as the reference method. Food authorities accept that currently MBA must have a role in toxin testing.

5.2 The FSA is the competent authority to decide on testing and the sampling programme for bio-toxins. They have chosen the MBA for all UK testing. Many other EU countries do not apparently routinely test all DSP samples in this way. Holland use a rat bioassay and Germany only chemical testing methods. Even where countries used the MBA standard operating procedures appeared to differ. Countries such as New Zealand and Canada are moving towards replacement of mouse testing with a LC-MS test. A presentation by Prof Yasumoto, the scientist who developed the MBA, in May 2003 indicated he is working on alternative testing methods for known toxins and that he anticipated MBA would only remain important for detecting unknown or new toxins in the future.

Recommendation 2

All laboratories in Europe should agree to use the same testing methods. There should also be agreed EU operating procedures. The FSA has already commissioned some work on alternative testing methods, we would like to see the UK leading the way for a replacement of routine mouse bioassay tests with accredited analytical techniques.

6. Food Authorities are concerned that differences in testing existed in the three UK laboratories as highlighted in the FSA reports issued on 2 October. The hierarchy of laboratories and communication between them was also confused; the National reference Laboratory status was unclear. Also EU SOP for any procedures.

6.1 In 2001 two new laboratories were appointed by the FSA to carry out the toxin testing as the programme expanded. FRS Aberdeen had previously done the testing for all UK. DARD Belfast and CEFAS Weymouth were appointed to cover Northern Ireland and England and Wales respectively. It became clear after the visit of EC auditors in July 2002 that the role of the national reference laboratory was not being carried out and that quality assurance and control procedures in the two laboratories visited then (not CEFAS) were inadequate. It later became clear that the testing procedures differed significantly between the three laboratories and rather than the NRL co-ordinating methods and procedures the two new laboratories were responsible for changing established testing methods.

6.2 FSA reports published in October 2003 indicated improvements requested by the State Veterinary Officers had still not been implemented. The NRL still seemed to lack its lead role to ensure consistency in UK laboratories—in fact the process seemed to be that the DARD and CEFAS laboratories were dictating changes. The three laboratories were still testing for DSP using different protocols. Also there also seemed to be little quality control or assurance procedures in place in the 3 testing laboratories again a role the NRL should lead on.

6.3 Article 2 of Commission Decision 93/383/EEC on the National Reference Laboratories sets tasks of each member states NRL which include co-ordinating activities of other UK biotoxin testing laboratories and assisting the competent authority (FSA) in each member state to organise sampling programmes.

Recommendation 3

The FSA is the competent authority in the UK and must ensure they have the necessary resources to carry out the functions outlined in article 2 of the council decision 93/383/EEC. This includes aspects of consistency, communication and quality assurance and control. It is recognised that some Improvements have been made recently.

The UK must have an active effective NRL which co-ordinates sampling in UK and also keeps it in line with the rest of Europe.

7. Weakness of Operation of Testing and Sampling Programme.

7.1 There is scope to make improvements to the sampling and testing programmes at all levels. Good communication is a key factor and to be effective industry, food authorities, laboratories and the FSA must be involved and have equal access to data about results, closures and sampling programmes. At present testing is slow and communication of results unwieldy. To have good product recall system during closures this is vital. The industry has made proposals (CIVIT) for an alternative testing and communication system and although it is unclear how this proposal will fit with the statutory sampling programme it is important all parties work together at how this can be incorporated. Ireland and New Zealand have already adapted sampling programmes in this way.

Recommendation 4

The FSA should lead a review of how the sampling programme and result communication works with all interested parties, before the main harvesting season in summer 2004.

8. *Conclusions*

CCC has conscientiously undertaken its food enforcement responsibilities during a troubled period for the shellfish industry and has continued to follow the advice of the FSA. We have also listened to the concerns of the local shellfish industry and tried to prevent controls and restrictions placing unnecessary burdens on struggling local businesses.

This commitment to following FSA guidance has been challenged by the shellfish industry and to retain an impartial view of conflicting reports it has been necessary to employ expert advice on legal and scientific issues.

We accept that as competent authority the FSA is now taking steps to identify and assess the implications of this possible new toxin which initially became apparent in 2001. After reports in 2003 the FSA is also implementing better controls of testing procedures.

As stated in our report it is hoped that in future communications between the appropriate authorities and the industry will be improved to ensure more effective control of this issue and any new public health concerns.

January 2004

APPENDIX 1

References

Agency's response to the findings of Professor Makins report.

Also Shellfish industries critical reviews of the 2 FSA papers dated 1 October 2003 by independent scientific advisors.

Commission Decision 93/383/EEC on the National Reference Laboratories.

Commission decision of the 15 March 2002 laying down detailed rules for the implementation of the CD91/492/EEC as regards the maximum level and the methods of analysis of certain marine biotoxins in the bivalve molluscs, echinoderms, tunicates and marine gastropods 2002/225/EC.

Council Directive of the 15 July 1991 laying down the health conditions for the production and the placing on the market of live bivalve molluscs (91/492/EEC).

DG (SANCO) /8614/2002–MR final report of a mission carried out in the UK from 8-17 July 2002 regarding the implementation of Council Directive 91/492/EEC (Live Bivalve Molluscs) and Council Directive.

Food Safety (Fishery Products and Live Shellfish)(Hygiene) Regulations 1998 (as amended) Guidance to Food Authorities that have designated Bivalve Mollusc production areas in their district 29/08/2002 amended 3 September 2003 with additional guidance in the light of atypical DSP problem (Service of TPOs)

Food Safety Act 1990.

Food Safety (Fishery Products and Live Shellfish)(Hygiene) Regulations 1998 (as amended).

FSA report 1 October 2003 "Investigations to assess whether diethyl ether or acetone carry-over during the DSP standard operating procedure is responsible for the atypical response in mice".

Professor H Makin 1Oct 2003 "An audit of methods and procedures for lipophilic toxin analysis used by Laboratories at CEFAS, FRS and DARD, which undertake the statutory monitoring of shellfish toxins in the UK".

Memorandum submitted by the Centre for Environment, Fisheries and Aquaculture Science (CEFAS) (M12)

Executive Summary

1. CEFAS was appointed in 2001 on a four-year contract to carry out the statutory monitoring programme for shellfish toxins in England and Wales. This involves testing for toxins in the flesh of all commercially harvested species, using chemical assays and a mouse bioassay.

2. Atypical results were observed in tests for Diarrhetic Shellfish Poisoning (DSP), principally in cockle samples, and were also observed in Northern Ireland. This problem coincided with the extension of cockle testing in the surveillance scheme in 2001, and was drawn to the attention of the FSA in October 2001.

3. Scrutiny of procedures at CEFAS and the testing laboratories in Scotland and Northern Ireland identified variations that could affect the likelihood of detecting toxic responses in the mouse test. We have worked with the Food Standards Agency, the UK National Reference Laboratory (NRL) and the other testing laboratories on a unified methodology to ensure comparability. We also took part in exercises designed to reveal whether atypical results were due to methodological problems.

4. The independent Makin audit in July 2003 examined the operation of an interim Standard Operating Procedure (SOP) for the DSP test. We responded to Professor Makin's seven conclusions about procedures at CEFAS by introducing changes to local practice and by adopting the unified UK SOP. Subsequent testing of cockles continued to produce unusual symptoms of intoxication, though less frequently.

5. There is no evidence to indicate that atypical toxicity is an artefact of the testing methods or the way that they are applied. Investigations so far have failed to attribute the results to the presence of any known toxin.

Toxins Work at CEFAS

6. Toxins work began at CEFAS (then the Directorate of Fisheries Research) in 1968 and CEFAS scientists provided a monitoring programme for Paralytic Shellfish Poisoning (PSP) for the UK until the early 1990's. Research was conducted in order to develop analytical alternatives to animal tests, including High Performance Liquid Chromatography (HPLC) and Liquid Chromatography—Mass Spectrometry (LC-MS). We also collaborated with Universities to improve understanding of the environmental triggers for toxic algal blooms and to provide tissue culture techniques.

7. During most of the 1990's the national monitoring programme was operated from Aberdeen (the Torry Laboratory, and subsequently Fisheries Research Services, FRS). CEFAS took on testing for England and Wales in June 2001 when the Food Standards Agency let the contract in open competition. In preparation for this CEFAS gained UKAS accreditation to ISO 17025 for biotoxins analysis.

8. CEFAS is currently responsible for an annual programme of testing shellfish taken from harvesting areas in England and Wales. The contract specifies the range of toxins to be monitored (PSP, DSP and Amnesic Shellfish Poisoning), the test methods to be used, the number of samples to be analysed, the reporting requirements and the quality assurance requirements. Testing for PSP and DSP is based on protocols for the chemical extraction of material from shellfish flesh and testing toxicity on mice, in accordance with the requirements of the European Shellfish Hygiene Directive (91/492/EEC). Similar responsibilities apply to FRS in Scotland, and the Department of Agriculture and Rural Development (DARD) in Northern Ireland.

9. We continue to engage in research, including collaboration with Irish and Canadian scientists, and recently using LC-MS we have identified a number of toxins new to the UK present in coastal waters. We have also developed a screening method for toxins using insects, which may contribute to reduction in the use of the mouse test.

Occurrence of Atypical Results

10. The biotoxin monitoring programme in England and Wales was expanded in 2001, to cover all harvesting areas and all shellfish species. This followed an inspection of the UK implementation of shellfish hygiene controls by the European Union Food and Veterinary Office in 1999. Their report criticised the programme in England and Wales for incomplete coverage.

11. As a consequence, the scale of DSP analysis increased considerably at the time that CEFAS took over the monitoring. CEFAS started to observe an unexpectedly high number of positive results in DSP tests on cockles, associated with unusual clinical symptoms in mice, suggesting that the results were not due to classical DSP. The DARD laboratory in Northern Ireland reported similar findings in cockles. In October 2001 CEFAS wrote to the FSA detailing these unexpected findings.

12. The cause of the problem has been investigated by looking for known toxins, by examining whether toxicity could be an artefact of the method, and by reviewing the quality of the work carried out by the testing laboratories.

Absence of Known Toxins

13. Initially it was thought that the cause might be the emergence of a new toxin, Azaspiracid, which had recently been recognised in the Republic of Ireland and had caused human health incidents in the UK. Laboratory investigations revealed traces of azaspiracid in a few samples, but insufficient to explain the problem.

14. Subsequent investigation funded by the FSA demonstrated that the toxicity findings could be independently replicated by an international DSP expert—Professor Yasumoto of Japan. However neither we, nor others, were able to document by LC-MS the presence of any known DSP toxins in samples showing the atypical response. We were similarly unable to find any correlation of cockle toxicity with high concentrations of known toxic phytoplankton or zooplankton species in the water column. Cockle extracts were sent to international experts specialising in particular toxins but they too were unable to determine the presence of any known algal toxin.

15. In order to explore other possibilities, cockle extracts were tested for unusually high levels of trace metals, heavy metals and other substances (free fatty acids) that might have caused interference in the mouse test, but concentrations were well below those that would have toxic effects. As yet, no specific agent extracted from cockle flesh has been identified as the cause of the atypical response.

Extraction and Testing Methodology

16. The extraction of DSP toxins from shellfish tissue is a simple procedure involving acetone extraction, centrifugation or gravity filtration, partition to ether, water wash of the ether fraction, evaporation, take up of the residue in surfactant and injection to a mouse. This procedure has been carried out regularly on shellfish other than cockles, without producing frequent atypical results. Clearly there is something specific in cockle samples that causes the problem.

17. Between June and October 2003 the testing laboratories moved towards a common "interim" extraction protocol for DSP, leading to the development and adoption in November 2003 of a unified UK SOP specified by the NRL. This protocol has elements of all approaches, and incorporates new requirements to ensure minimal solvent carry-over into final extracts. An optimised UK protocol is being developed by the Central Science Laboratory (CSL), focussing on the extraction and particle removal stages of the procedure.

18. The industry has postulated that carry-over of solvents into the final extract might cause the atypical results, possibly involving synergism with histamines derived from cockles. We confirmed that effects were not specific to the use of di-ethyl ether as the partitioning solvent—positive results were also seen when dichloromethane was used. It is not possible to completely remove all traces of solvent, but the methodology introduced in the unified UK protocol is designed to ensure that there is minimal carry-over. Monitoring of solvent levels using Gastec is now routine, and sample extracts are used only if no solvent is detected. In addition, CSL made measurements of solvent levels in CEFAS, DARD and FRS extracts before the introduction of the new protocol. This showed that some high concentrations were found in samples that gave no mouse response, whereas some samples that produced an atypical response had low concentrations. This demonstrates that there is no simple link between solvent carry-over and toxicity.

19. Details of the methods used for acetone extraction and removal of solids are likely to affect the range of compounds extracted from samples. The current unified UK SOP uses two acetone extractions and a gravity filtration step, whereas the previous CEFAS/DARD protocols employed two extractions with acetone followed by centrifugation, while FRS made one acetone extraction followed by filtration. Nevertheless, all protocols derived from the published method of Yasumoto 1984 as required by European legislation.

20. Sequential extractions with acetone draw out a wider polarity group of compounds than a single extraction, while compounds loosely bound to the shellfish matrix are more likely to be recovered by centrifugation than by gravity filtration. Therefore, the previous CEFAS/DARD method would be expected

to extract additional material than the FRS method, and the unified UK SOP might be expected to extract fewer compounds than the CEFAS/DARD methods but more than the FRS method. Results obtained since the change in methods are consistent with this prediction. Both CEFAS and DARD have reported a much lower incidence of atypical symptoms of intoxication,and it seems that the concentration of whatever is responsible for the mortality is now much lower in the extract from cockles. Conversely in Scotland there are preliminary indications of an increase in the reporting of (typical) symptoms in the DSP assay.

Quality Assurance in CEFAS

21. At CEFAS, quality assurance for the biotoxin assays is covered by internal systems and by UKAS accreditation to the international standard ISO 17025. This entails:

- A Quality Manual identifies the individuals responsible for specific tasks and trained in their use.
- A series of Standard Operating Procedures describe the tasks in a clear, step by step approach. SOPs are written to be fit for purpose and carried out by competent trained staff.
- An internal audit team led by scientists on a different site perform regular checks that the content of the SOPs is aligned with scientific practice and examine training records. There have been 20 internal audits covering toxin work in three years.
- An external audit team from UKAS perform regular checks that the testing performed is of a quality consistent with ISO 17025. All aspects of procedures are audited and testing is witnessed in practice in the laboratory. UKAS report on performance and require non-conformities to be addressed within a set timetable. There have been six audits of toxin work in the past three years, which confirmed that the quality of CEFAS work complies with international standards.
- A Home Office audit team carry out inspections on the animal house and ensure that practice is aligned with the terms of Project Licenses.
- Standardisation is overseen by the National Reference Laboratory to ensure that the science carried out in the UK is aligned with practice dictated by the Shellfish Hygiene Directive.

22. In addition, a special audit of all three testing laboratories was organised by the FSA in the summer of 2003 to address concerns about the atypical DSP test results. The report by Professor Hugh Makin included a set of overall findings and recommendations, and seven conclusions specific to his observations of procedures at CEFAS. We have responded to these by introducing changes to local practice, and by collaboration with the NRL, the FSA and the other testing laboratories to introduce the unified UK SOP. Some appropriate changes (standardisation of the assessment of toxic symptoms, and the use of positive and negative controls in the mouse test) await further discussion between the FSA and the Home Office to take account of animal welfare issues.

23. Of Prof. Makin's specific conclusions relating to CEFAS systems, three relate to the style and authorship of SOPs. While this identifies scope for improvement, there are no implications for the integrity of the data produced. Another conclusion refers to the risk of potential overload if large numbers of samples exceed the laboratory's capacity. This has never happened, and has no relevance to the occurrence of atypical test results.

24. The remaining three conclusions could potentially influence results. One relates to the lack of negative "controls" (ie extra tests on shellfish material known to be free of toxin) and positive controls (ie a "clean" sample to which a standard amount of toxin is added) in the DSP mouse test. We agree that such controls are important in routine assay work. In this case, there are practical difficulties, particularly in relation to the detection of unknown toxins, and the Home Office does not currently permit the use of additional animals for control tests. This issue remains under discussion.

25. However, substantial alternative evidence provides some assurance that the testing reliably detects DSP. First, the method has been developed through research involving experimental controls. Second, a large majority of samples of most species in the monitoring programme give negative results, which demonstrates that the method itself does not systematically cause symptoms of toxicity. Third, where sample size allows, typical DSP responses are confirmed by chemical analysis using LC-MS, showing that the method is capable of detecting known DSP toxins.

26. The sixth conclusion deals with the presence of fluid in the final extracts, which was also observed during the audit of DARD. It is well recognised that extracts do not always evaporate to dryness, and the risks of solvent carry-over have been fully addressed in the new UK protocol, as described above.

27. Finally, he documented a list of deviations between written procedures and practices observed on the occasion of the audit visit. Only a few of these were reported by internal auditors or by UKAS. Many were a result of the wording of the SOPs, or delays in updating the documents, rather than scientifically inappropriate practices. The remainder were points of specific detail that could not have caused significant errors in the results. Nevertheless, we have taken steps to ensure that written procedures and actual practice now correspond exactly.

28. Therefore, we believe that deviations from current protocols are minor, and in the context of the Makin report, have no significant implications regarding the scientific conclusions reached on causation of the atypical DSP results. Prof Makin concluded that no evidence emerged that the atypical response is a methodological or procedural artefact.

Improvements to Current Methodology

29. In addition to developing the unified UK SOP for the current method, it is desirable to move towards approaches that do not involve the mouse test, although there are constraints on how easily changes could be introduced.

30. An amendment to the legal framework (Commission Decision 2002/225/EC) clears the way for implementation of non-mammalian test methods for DSP. It defines a number of toxins associated with DSP and lays down maximum permitted levels for each toxin in shellfish. The mouse bioassay is specified as the reference method but alternative or complementary methods are permitted providing they detect all specified analogues and provide an equivalent level of health protection. Important caveats are that standards must be available before chemical analysis is possible and that methods should be validated according to international protocols. Significantly, where test results are discrepant between methods, the mouse test shall be considered to give the definitive result. Thus it might be possible to reduce the scale of mouse testing, if an alternative was used as a preliminary screening assay. To completely replace the mouse test would require amendments to the existing legislation.

31. The most advanced alternative is liquid chromatography—mass spectrometry (LC-MS). A significant obstacle to its wide scale adoption has been the unavailability of a full suite of standards for the analogues specified in Commission Decision 2002/225/EC. However, standards are now, or will shortly become available, for representative analogues from each group in the DSP complex. This is sufficient coverage to begin validation of LC-MS as an alternative assay. Also, LC-MS could be considered as a primary screen with positive samples tested using the mouse test or another biological assay for confirmation.

32. LC-MS alone would not be capable of detecting unknown toxins. Other biological assays are therefore required. Options include cell culture, enzyme reactions, and tests on whole animals. Invertebrates are more acceptable and more tractable for standardised toxicity test protocols than mammals. In some cases the biochemical modes of action are known to be similar, and insects have been shown to be good surrogates for assessing certain effects on human health. CEFAS has been exploring the use of an assay for PSP and DSP using the American Cockroach that would also be capable of detecting the effects of unknown toxins. This work has produced encouraging preliminary results, soon to be published.

January 2004

Memorandum submitted by the National Federation of Fishermen's Organisations (M13)

1. The fishing industry welcomes this investigation, and in line with Government encouragement of stakeholder participation, has endeavoured to work with the regulatory authorities to provide advice and clarification on these issues. However, we regret that we are not in a position to report anything other than minimal progress regarding the controversy surrounding the UK administration of the regulatory screening regime for bivalve mollusc toxins, required under EU Legislation (2202/225/EC). Serious doubts remain regarding the Mouse Bioassay (MBA) applied to test cockles for Diarrhetic Shellfish Poisoning (DSP)

2. Since June 2001, the cockle industry has in England and Wales has endured closures of fishing beds, disrupted markets and eroded consumer confidence with consequential severe economic losses. The cockle fishing industry has endured this catastrophic turn of events, not as a result of identified shellfish toxins and contaminated product but as a result of what are widely considered to be fundamental weaknesses in the approach adopted by the regulatory authorities, namely the Food Standards Agency (FSA) and the Centre for Environment, Fisheries and Aquaculture Science (CEFAS).

3. In June 2002 this Federation, having noted the incidence of positive DSP results and consequent closures during the previous twelve months, was advised by cockle fishermen that they no longer had any confidence in the UK screening regime.

4. After seeking professional and technical advice, we quickly learned that the issue was of a highly technical nature and, aware that the Committee will draw on similar expertise, will not duplicate that detail. However, the advice obtained highlighted a number of fundamental and critical areas of concern and concluded that the screening programme conducted by the FSA and CEFAS was characterised by inconsistent scientific process; e.g. non-reproducible results and non-standardised testing protocols.

5. Further investigation by the fishing industry, including the commissioning of independent chemical and bioassay tests, duplicate tests on samples tested "positive" by CEFAS (which generated contradictory results), discrepancies between testing at Government laboratories in England, Scotland and Northern

Ireland, also suggested that the screening programme was flawed. Moreover, a number of EU and third country regulators, experiencing similar anomalies when using the MBA, amended their testing methodology to eliminate conspicuously similar false positives.

6. The situation moved beyond comprehension when simultaneous "outbreaks" of DSP affecting three unconnected areas, in the absence of algae blooms, were reported. Understandably, this development undermined any residual confidence in the FSA and CEFAS, cast further doubt on the UK screening programme and clearly indicated the urgent need for a comprehensive and independent review.

7. The industry formally drew these matters to the attention of the FSA. However, rather than acknowledge the legitimacy of the industry's concerns, and seek a collaborative solution, the agency instead embarked on a misguided and expensive search to defend their premise that a "novel toxin" was present.

8. The stance adopted by the FSA might be understandable if there were evidence of an impact on human health but we are unaware of any incidence of DSP outbreaks from either domestic or imported within the UK.

9. Faced with such intransigence, an increasingly frustrated, fishing industry brought the issue to the attention of UK Government Ministers, DEFRA and the Home Office (the latter on animal welfare grounds) and sought assistance from UK Parliamentarians and the European Commission.

10. In the meantime, as a number of contentious studies and reports of a highly technical nature appear, the acrimonious debate continues and a solution that would allow cockle fishermen to continue their traditional activities is not apparent.

11. However, the fishing industry remains committed to identifying a mutually acceptable resolution to the situation.

Summary of Industry Concerns

1. The closure of the cockle fisheries has been applied on the basis of an ultra-precautionary approach to consumer protection.

2. The screening methods employed by the FSA have been rejected by other EU member states and third countries as unreliable.

3. The actions by the FSA has damaged the domestic and international market for UK cockle product, whilst simultaneously facilitating the import of product (subject to modified testing) from EU member and other states.

4. Instead of accepting that the MBA produced unreliable results, the FSA has sought to limit the damage to its reputation (and possible compensation claims) by resisting sensible alternative approaches.

5. A defensive position has led the FSA to be resistant to industry and alternative scientific paradigms and perspectives.

6. This has delayed development of a robust screening programme which has the confidence of all parties.

January 2004

Memorandum submitted by Mr J H Loose (M14)

This evidence relates to the foreshore on the eastern side of the Wash, near to Hunstanton, identified as areas 1 and 28 on the enclosed DSP Zone Map, where there is private fishing for shellfish, including cockles.

I write as tenant of this fishing and it is my practice to licence the boats of Mr John Lake of King's Lynn to harvest the cockles, when stocks allow. Such should have been the situation in 2002.

But in January of that year we were issued with the first of what was to be a series of monthly closures by the King's Lynn & West Norfolk Borough Council (KLWNBC). As these orders continued, I notified the Council that I was hoping to start fishing in August and could they sample the fishing as a separate entity. This was refused, though in July the Food Standards Agency (FSA) authorised that the Wash was to be divided into two zones.

In conjunction with John Lake, independent sampling was arranged at Aberdeen National Reference Laboratory with Mr Godfrey Howard, using the standard mouse test. The KLWNBC was informed and invited to oversee the sampling, and even take one themselves. But no one came. The samples were packed in ice, taken to Norwich Airport, flown to Aberdeen and collected by the laboratory staff. I notified the Council of the results each time—all were negative, ie no DSP detected.

After two results, I met Mr Murphy from KLWNBC and suggested that we should be allowed to fish the cockles. He rejected the results out of hand. But, after many lengthy telephone calls to FSA, their attitude suddenly changed and a split sample was proposed; one half the Council sent to Weymouth, the other we sent to Aberdeen. Weymouth results were positive, Aberdeen negative.

The KLWNBC, to be fair to them, proposed a further joint sample; but it seems—and I do not know quite what happened— FSA contacted Aberdeen and we could get no more samples done there.

It was clear the FSA was not going to take any notice of results, other than at Weymouth. This in itself is bad science practice. Mr Howard had carried out further testing on the third sample and he could detect no DSP, and his evidence may be helpful. The next week a fourth sample was sent to Holland, where the rat test is used and, again, with a negative result. This shows, if nothing else, that if these cockle beds had been in Scotland or Holland they could have been fished and subsequently the cockles sold in England or Wales, regardless of the FSA,

By this time the boats had been lying in port for two weeks and the decision was taken to abandon fishing for that season. The beds were clear for a short time Oct/Nov 2002, but then closed until the end of February 2003. By now the Wash was divided into four Zones (see Zone map) [Not printed]; four being sampled at the junction of areas 1 and 28, which is what I asked for in 2002.

From the end of February 2003, the beds have been open, except for three weeks mid-June/early-July. As we were again hoping to fish in August, Aberdeen was contacted about testing and we were told we had to get consent from the FSA, who in turn said Aberdeen did not need their permission and that they would contact Aberdeen to sort it out. But no more was ever heard. We were able to fish the end of July/August until the quota allowed by English Nature was taken, when all fishing ceased:

The events of July/August 2002 raise several questions:

1. how could a split sample, 150 cockles each, produce opposite results;
2. why did not the FSA continue duplicate testing;
3. why were we prevented from having further samples tested at Aberdeen in August 2002; and
4. without answers how can the industry have any confidence in the implementation of these tests or the FSA.

January 2004

Memorandum submitted by the Department for Environment, Food and Rural Affairs (Defra) (M16)

Executive Summary

1. Defra and the Food Standards Agency (FSA) are liaising closely on the urgent action that is being taken to bring about a scientifically based resolution to the complex issues arising from atypical responses in the mouse bioassay (MBA) used to test for diarrhetic shellfish poisoning toxins (DSP). While investigations are taking place Defra will continue discussion with all interested parties to see what management measures, in addition to the zoning of fisheries, may be introduced to help alleviate pressure on the shellfish industry.

Introduction

2. Defra has policy responsibility for the promotion of the shellfish industry in England within a framework of sustainable management and prudent use of natural resources. Part of that responsibility is consideration of regulatory and other measures from within and outside the Department which may have an adverse impact on the viability of individual shellfish businesses.

3. The testing of shellfish for toxins in the UK in compliance with EU law (Commission Decision 2002/225/EC) is a public health matter and the policy responsibility of the Food Standards Agency (FSA). The testing programme exists to protect the health of consumers of shellfish. However, in implementing that policy the FSA consults widely with stakeholders wherever possible including the industry and other Government Departments before reaching conclusions. The Centre for Environment, Fisheries and Aquaculture Science, an Executive Agency of Defra, carries out statutory biotoxin monitoring in England and Wales on behalf of the FSA.

4. The UK uses the mouse bioassay method (the EU reference method) for detecting diarrhetic shellfish poisoning in shellfish. However, tests using that method have produced atypical results in the DSP MBA, which the FSA advises may be indicative of an unknown toxin with the potential to cause illness in humans. The FSA's policy is to recommend the temporary closure of shellfish beds returning positive DSP results and it has adopted the same closure policy in respect beds returning atypical DSP results until more is known about the cause of that response and its implications for human health.

Industry and Defra Concerns

5. Defra Ministers and officials have received detailed written and oral representations from members of the shellfish industry, their representative organisations, and Members of Parliament about the FSA's toxin testing arrangements. These argue strongly that the atypical DSP results are caused by flaws in the MBA testing methodology, that shellfishermen are suffering serious economic disadvantage because of FSA's policy of closing fisheries returning atypical results, and that there are distortions in trade because of the lack of harmonisation of toxin testing arrangements in the EU.

6. In response to the representations Defra has made it clear that the organisation of testing arrangements in the UK and detailed issues relating to methodology are essentially matters of public health policy and, as such, would be referred direct to the FSA for further consideration. Regarding the other issues raised, Defra has expressed concern to the FSA that there may be scope for some disparity in trade within the EU because more than one method is permitted for use in the testing of toxins in shellfish. The UK and, we are advised, a number of other Member States use the MBA because it is established in EU legislation as the EU reference method for DSP testing and is currently the only method capable of detecting the entire range of known toxins. However, the same EU legislation also allows Member States to operate testing surveillance programmes using other methods providing these can detect the toxins specified in the legislation and the MBA is used as the reference method where analysis demonstrates discrepancies between different methods. Defra has also expressed concern to the FSA that in spite of the status of the MBA as a EU reference method for DSP testing, there is currently no agreed standard international protocol for operating it.

7. Following FSA's consideration of the need for a single protocol early last year and publication of Professor Hugh Makin's independent scientific audit of DSP testing methodology and the FSA's separate investigation into the use of solvents in testing in October, the FSA introduced in November a harmonised MBA standard operating procedure (SOP) for use by the three UK laboratories involved in toxin testing. We note that following representations made by the FSA to the European Commission and to the European Community Reference Laboratory, discussions are scheduled in the coming months on both the development of a EU SOP for the MBA and a non-animal based alternative to the MBA. Like the FSA, Defra is keen to move away from animal-based testing wherever practicable.

The Cockle Fisheries

8. The closure of cockle beds in England in the main harvesting areas of the Wash and Thames Estuary has been disruptive to the industry because the closures have generally occurred at the height of the summer harvesting season. Claims have been made by industry that the closures due to atypical DSP results have caused serious financial hardship to shellfishermen but no detailed evidence has been submitted to Defra in support of these claims.

9. The Thames Estuary fishery is managed by the Kent and Essex Sea Fisheries Committee and the Wash fishery by the Eastern Sea Fisheries Joint Committee (SFCs). Both manage their respective areas on the basis of powers granted to them under separate Regulating Orders made by the Defra Minister under section 1 of the Sea Fisheries (Shellfish) Act 1967. The powers enable the SFCs to better manage and enforce rules of conservation and exploitation of certain shellfish stocks for the improvement of natural shellfisheries.

10. Since the emergence of atypical results in both the Thames Estuary and the Wash, FSA has permitted the operation of zoning arrangements in both fisheries to enable fishermen to prosecute cockle beds testing negative to DSP and atypical DSP. The zoning arrangement was already in operation in the Thames Estuary when the first atypical results were obtained in 2001 and, following the detection of atypical results in the Wash in 2002, Defra consulted urgently with FSA with a view to allowing zoning to apply in that fishery also.

11. In spite of the intermittent closure of cockle beds in both fisheries following the detection of atypical DSP, there has been a very high uptake of the total allowable catch (TAC) of cockles agreed annually by each SFC for its area. Details are as follows:

	Year	*TAC tonnes*	*Actual Catch tonnes*	*% Catch*
The Wash Fishery	2001	7,800	8,901	114
	2002	3,865	3,827	99
	2003	3,060	3,045	99
The Thames Estuary Fishery	2001	9,800	9,687	99
	2002	8,900	8,200	92
	2003	10,600	10,530	99

12. In Wales, policy responsibilities relating to the shellfish industry are a matter for the Welsh Assembly Government. The Burry Inlet cockle fishery was closed for prolonged periods during 2001 and 2002 due to atypical DSP results. In the light of negotiation with the European Commission, the Welsh Assembly

Government, working with the Welsh European Funding Office, secured funds under Objective 1 of the Financial Instrument for Fisheries Guidance (FIFG) to a financial support scheme for licensed gatherers affected by the closure of the cockle beds. The support made available is based on income generated from gathering prior to closure. In August 2002 zoning arrangements were introduced into the fishery to help alleviate pressure on the industry in the event of further cockle bed closures due to atypical DSP results.

13. Defra has no similar scheme of financial assistance available to cockle gatherers in England. Moreover under EU proposals to amend Council Regulation (EC) No 2792/1999 laying down detailed rules and arrangements regarding Community structural assistance in the fisheries sector, Member States would not be eligible for community funding for assistance to shellfish farmers in the event of recurrent seasonal suspensions which may be necessary for the protection of human health due to contamination of a fishery by toxic algae (Defra Explanatory Memorandum 14463/03 refers).

Defra
Fisheries Division II
(Aquaculture, Salmon and Freshwater Fisheries)

January 2004

Memorandum submitted by the Corporation of London, The City Remembrancer's Office (M17)

1. Executive Summary

1.1 The Corporation of London, acting in its capacity as the London Port Health Authority (LPHA), is the Food Authority for the Thames Estuary Shellfish Layings and as such has issued many Temporary Prohibition Orders (TPOs) preventing the collection of shellfish affected by Atypical Diarrhetic Shellfish Poisoning (DSP) in the shellfish beds.

1.2 The Authority has concerns over the methodology employed by the statutory testing laboratories and the consistency of the protocols employed by the different laboratories. It has concerns about the response of the Food Standards Agency (FSA) to the Atypical DSP problem and the costs to local authorities that enforce the legislation and control the shellfish beds. It believes there is a need for other chemical tests to be developed and, in the interim, a need for standard operating procedures to be carefully monitored to ensure consistency. It considers that there is an urgent need for definitive studies to be completed into the causes and toxicity of Atypical DSP.

2. The London Port Health Authority

2.1 The LPHA is the Food Authority for the whole of the tidal Thames including the Thames Estuary. As such it is responsible for the control of the shellfish industry under the provisions of the Food Safety (Fishery Products and Live Shellfish) (Hygiene) Regulations 1998. In recent years it has had to issue many TPOs under the regulations prohibiting the collection of any live shellfish from different areas within the Estuary. Historically it has had considerable involvement with the shellfish industry, and prior to a change in legislation this extended to the shellfish processing plants near the wharves where the shellfish are discharged. It provides the Chairman and secretariat for the Thames Estuary Shellfish Group and the views contained in this submission have been echoed by other participants in that forum.

2.2 The Authority, together with the local authorities, has been threatened with a Judicial Review in connection with the TPOs it has issued following to the identification of Atypical DSP in the Thames Estuary shellfish beds. This has resulted in considerable expense for the authority in legal fees and it has recently agreed to contribute up to £2,500 towards the costs for collaborating local authorities to obtain an independent report from an expert with an international reputation to:

— review the FSA reports published to date and to determine whether or not there are serious methodological problems with the laboratories and;

— review the methodologies, and if appropriate visit the labs to undertake an independent audit.

Consideration of this report, which has only very recently been received[1], will determine any further action the local authorities involved decide to take.

2.3 The LPHA reports to the Corporation of London Port Health and Environmental Services Committee whose members have a considerable interest in the shellfish industry and the action that its officers have to take in that regard. At its meeting in November 2003 the Committee agreed to raise the issue with the European Food Safety Agency to ensure that a consistent approach is taken throughout the European Union, and to request the development of other chemical tests which can be applied throughout the EU to detect biotoxins in shellfish and that do not involve the use of mammals. It also agreed to lobby the FSA for adequate funding to enable local authorities to undertake the shellfish biotoxins sampling programme and for the FSA to expedite investigations into the causes and toxicity of Atypical DSP. A senior delegation from the FSA will be invited to consider this issue with the Chairman of the Port Health and Environmental Services Committee.

3. Toxicity/Public Health Implications of Atypical DSP

3.1 One of the problems for local authorities when issuing TPOs is that they must be satisfied that the consumption of live shellfish taken from a production area is likely to cause a risk to public health. In the case of DSP, there is little current evidence to suggest that consumption of cockles affected by DSP would cause illness to consumers. This is one of the grounds on which a Judicial Review could challenge TPOs issued by local authorities.

3.2 In December 2002 the FSA published a report entitled "Updating Report on the Atypical DSP Results in Cockles"[2]. In this report the Agency stated it was in the process of commissioning toxicity studies, which were scheduled to begin in early 2003. These were due to investigate what effects toxic substance have on the central nervous system and other major organs and tissues, and hence to determine any possible human health implications. It is not clear whether these studies have commenced and the FSA advice to local authorities continues to rely on the precautionary principle. This places local authorities in an invidious position when issuing TPOs and leaves them open to a challenge from the shellfish industry.

4. Laboratory Procedures

4.1 The Makin report[3] identified that different protocols were operated for routine DSP assays at the various UK laboratories. This had already been identified when comparative testing was undertaken between UK laboratories for the report published in December 2002. In view of the fact that the comparative testing of identical cockle samples produced different results between the laboratories when undertaken for the December 2002 report, it is surprising that an optimised standard operating procedure for the DSP was not initiated earlier by the FSA.

4.2 Some work has been done to determine whether heating or freezing of cockles would remove the toxin. As far as can be ascertained, although the initial tests indicated that freezing can reduce the initial toxicity, the tests were inconclusive. It is clear that further research is required to determine whether cockles affected by Atypical DSP toxins can be processed to eliminate them.

4.3 Another difficulty for enforcement authorities is the inflexible hours operated by the CEFAS laboratory (weekly samples need to be at the laboratory by midday on Wednesday of each week) which mean that authorities are severely restricted as to when they can obtain samples. The practical aspects of obtaining samples which often involve working in a hostile marine environment are not appreciated when contracts are awarded to laboratories, and this necessitates sampling being carried out at weekends which incurs overtime costs for the authority. In addition if a sample is lost or inadvertently spoiled at the laboratory the costs of a replacement sample have to be borne by the local authority.

4.4 There is also a firing range in operation in the early part of the week that covers part of the estuary where shellfish beds are located. To complicate the situation shellfish samples are also required for classification purposes, but these samples can be delivered to Health Protection Agency laboratories on any week day except Fridays.

4.5 As stated above, there is a need for alternative testing procedures to be identified for detection of DSP and the Authority supports the recommendation in the Makin report for research into alternative assay systems.

5. Zoning of Shellfish Beds

5.1 The LPHA pioneered the use of zones by splitting the estuary into zones that were considered to be separate, divided by the different tidal flows that occur around each area. Satellite imagery by the Institute to Terrestrial Ecology at Monkswood was also used for bed definition. TPOs are issued for those zones in which Atypical DSP is detected and further testing is carried out from adjacent areas. This approach has the advantage of enabling fishing to continue in areas where toxins have not been identified and could be applied more widely in the UK. This system enabled 10,541.29 tonnes of cockles to be landed during 2003 when the total available catch set by the Kent and Essex Sea Fisheries Committee was 10,600 tonnes.

6. Financial Implications for Local Authorities and the Shellfish Industry

6.1 As a result of the increased levels of Atypical DSP in the Thames Estuary, it has been necessary for the LPHA to take considerably more samples than those required by the routine monitoring programme. In addition, it has provided samples for the FSA to enable these to be used for research purposes. The Estuary covers an area of approximately 300 square miles so the fuel and staffing costs for LPHA launches to obtain these samples have increased substantially in recent years. No additional Government funding has been provided to assist local authorities and this funding is sought.

6.2 The outcome of any Judicial Review could also have serious financial implications for the local authorities involved. If the authorities are found to be culpable, there could be issues regarding compensation for the shellfish industry as well as the payment of legal costs. In view of the fact that the LPHA, in common with other local authorities, has acted directly on the advice provided by the FSA, it is contended that in the event of legal action, any such costs should be borne by the Government or the FSA.

6.3 As there is still considerable doubt over the public health risks associated with the consumption of shellfish affected by Atypical DSP, the shellfish industry may also have a legitimate claim against the FSA if no evidence is obtained to demonstrate the toxicity to humans of Atypical DSP.

7. Other Issues

7.1 Local Authorities are well placed to obtain the samples that are required under the Shellfish Waters Directive but the discharge of these requirements is currently the responsibility of the Environment Agency. The shellfish flesh that is obtained as part of the microbiological sampling programme undertaken by local authorities is already used for this purpose at no cost to the Environment Agency. There is clearly room for more "joined-up" approach to the issue, with local authorities obtaining the samples, but being properly funded to do so.

7.2 Difficulties are often experienced by local authorities over the time that results are received—it can often be very late in the week giving little time for new TPOs to be issued. If a TPO is to be renewed, FSA approval is required and this too can be difficult to obtain over weekend periods.

7.3 Occasionally there appears to be a significant time lapse between the FSA receiving a result and it being reported to LPHA, especially on 2nd negative samples that do not seem to be considered as important. This severely delays the issue of the Revocation Orders that open the shellfish beds, which in turn causes increased pressure from the shellfish industry.

References

1. "Review of reports on the Atypical response seen in the DSP mouse bioassay", commissioned in November 2003 by Canterbury City Council, Borough Council of King's Lynn and West Norfolk, Boston Borough Council, Carmarthanshire County Council, City and County of Swansea Council and the Corporation of London, was produced by Dr. Terry McMahon and colleagues from the Biotoxin Unit, Marine Institute, Dublin.

2. The "Updating Report on the Atypical DSP Results in Cockles" was raised during the Food Standards Agency's Board Meeting which took place on 12 December 2002.

3. The Makin Report was issued on 1 October 2003. It was produced by Prof. Hugh Makin of St Bartholomew's & the Royal London School of Medicine and Dentistry following his audit of methods and procedures for lipophilic DSP toxin analysis used by laboratories at CEFAS, FRS and DARD, which undertake the statutory monitoring of shellfish toxins in the UK.

The material contained in this memorandum has been provided by Jon Averns, Port Health Services Director, London Port Health Authority.

January 2004

Memorandum submitted by the City and County of Swansea (M18)

1. Introduction

1.1 This submission is made on behalf of the City and County of Swansea, a Welsh unitary authority with responsibility for enforcing Food Safety legislation. The Council is responsible for the monitoring of classified harvesting areas in its area and is also involved in the DSP/PSP/ASP monitoring programme.

1.2 The main area for the commercial harvesting of shellfish is the Burry Inlet. This is the tidal channel of the River Loughor, forming the boundary between the City and County of Swansea (with responsibilities for the South side of the Inlet) and its neighbouring authority of Carmarthenshire County Council (with responsibilities for the North side of the Inlet).

1.3 The Burry Inlet shellfish industry is worth millions of pounds annually and unlike other areas of the United Kingdom harvesting is undertaken on a year round basis ie there is no closed season. Gatherers move freely between the two sides of the Inlet dependant upon local conditions, and both authorities work closely together to ensure consistency of enforcement.

2. Background

2.1 In line with other local authorities with classified shellfish harvesting areas, the City and County of Swansea has submitted samples of live shellfish and sea water in order to comply with the agreed DSP/ASP/PSP sampling protocol issued by Department of Health (subsequently Food Standards Agency Wales). The Authority is responsible for complying with the sampling protocol and must submit samples to the accredited laboratory designated by Food Standards Agency. Since June 2001 this has been the CEFAS laboratory at Weymouth.

2.2 On 11 July 2001 Carmarthenshire County Council were notified that a sample of cockles submitted that week had proved positive for the presence of DSP. Carmarthenshire immediately issued a Temporary Prohibition Order (TPO) for that area of the Burry Inlet falling within their jurisdiction. At that time it was agreed by both authorities and FSA Wales that one positive result from either side of the Inlet would result in the closure of the whole Inlet. Consequently on 12th July 2001 the City and County of Swansea issued a TPO for the area of the Burry Inlet falling within its jurisdiction.

2.3 From July 2001 cockle sampling was undertaken at weekly intervals to try to obtain the necessary two consecutive weekly negative results necessary to lift the TPO. With the exception of a short period in November 2001 when the TPO on the North side of the Inlet was lifted by Carmarthenshire and then re-instated at the advice of the FSA Wales, the whole of the Burry Inlet was closed for gathering from 12 July 2001 to 17 May 2002, and again from 12 June 2002 to 1 August 2002.

2.4 During this time the local gatherers and processors suffered considerable commercial and financial hardship, not knowing from one week to the next whether they would be able to work, or where they could obtain their raw material for processing. This was compounded by the frustration of not knowing the source of the toxin and there being no identifiable pattern to the positive and negative results being obtained from the total of 7 sampling points across the whole of the Burry Inlet.
Also of growing concern to enforcement officers and gatherers was the toxicity of the toxin itself. Although originally classified as Diarrhetic Shellfish Poisoning (DSP) by the testing laboratory, information was obtained from FSA Wales in a letter dated 1 February 2002 which indicated:

"Whilst the tests for DSP have been positive since July, because of the prolonged toxicity and some unusual aspects of the positive tests, further work has been carried out at the Centre for Environment, Fisheries and Aquaculture Science (CEFAS) to investigate the toxicity. Their tests so far have confirmed the toxicity but suggest that it is not due to classical DSP toxins. They have been asked to put together further proposals for investigating the problem and this is therefore an area where there might be room for a collaborative study."

This same letter also advised that:

"The cockles are showing evidence of marked toxicity in the tests and therefore the Agency considers it essential to continue to keep the beds closed whilst trying to find out what is causing the problem."

2.5 Since the start of the problem in July 2001 the authority had worked consistently to ensure that food safety was not compromised. This had entailed working closely with officers at FSA Wales regarding renewal of TPOs after the initial 28 day period, and in ensuring that sampling results were passed promptly to the gatherers.
However gatherers were becoming increasingly sceptical about the sampling methods, and felt that the mouse bioassay test being promoted by FSA was flawed, in that it was the effect of the test itself that was causing the positive result, and not the presence of any toxin. Officers were at times subjected to pressure from the gatherers, who threatened to gather cockles despite the bans being in place. Gatherers also staged a media event where they ate cockles allegedly gathered from a prohibited area to demonstrate to the public their belief that there was no toxin present.

2.6 At a meeting with representatives of the local shellfish industry at the end of July 2002 concern was expressed that the sampling regime for the Burry Inlet was more onerous than in other areas of the UK.

In support of their argument the following statistics were produced:

- The Wash had a fishery acreage of 164,635, is divided into three zones, and has three testing points for DSP.
- The Thames had a fishery acreage of 288,123, is divided into 20 zones, and has four testing points for DSP.
- The Burry Inlet had a fishery acreage of 11,184, is not zoned, and has seven testing points for DSP.

2.7 Following this meeting the authority proposed that the Burry Inlet be split into three zones (these were North, South East and South West) for the purposes of sampling, and that a positive result in any of the zones would not result in the closure of the other two zones. It was felt that this compromise would help to alleviate the considerable financial hardship being experienced by local industry without compromising public health.

2.8 This proposal, which was initially resisted by FSA Wales, was put into effect in August 2002.

3. Current Position

3.1 The zoning of the Burry Inlet in August 2002 has meant that the gatherers have had more opportunity to gather, although there have still been some weeks where the whole of the Inlet has been closed. At the present time there have been no positive results on either side of the Burry Inlet since 13 October 2003.

3.2 However hand raking is an important part of the environmental management of the Burry Inlet ecology, and overcrowding and death of cockles during the long periods of closure, together with the extremely hot weather of summer 2003, are having a detrimental effect on the future viability of the harvesting areas.

3.3 Research funded by the FSA to identify the toxin and assess risk to consumers is ongoing. As part of this, the FSA invited Professor Yasumoto (one of the world's experts on marine bio-toxins) to the United Kingdom from Japan in order that he could observe the response in the mice during the mouse bioassay. The Professor observed the test being carried out and was of the opinion that it could well be a novel toxin causing the observed response. He offered to undertake further tests on positive sample at his laboratory in Japan, provided that sufficient sample material could be transported to him. Unfortunately, to date this has not been possible.

3.4 In July 2003 the City and County of Swansea was one of six food authorities in England and Wales threatened with judicial review by representatives of the cockle industry on the grounds that their closures of the gathering areas were outside the scope of the legislation.

3.5 Industry representatives are still firmly of the opinion that the increase in positive results since summer 2001, which coincided with the testing work for England and Wales being moved to the CEFAS laboratory, are a result of laboratory error.

3.6 As a result of pressure from both industry and local authorities the FSA produced in October 2003 a report by Professor Makin which identified weaknesses at all three laboratories used by FSA throughout the UK for shellfish testing. The FSA conclude that the methodology of the mouse bioassay test is not responsible for the positive results.

3.7 The shellfish industry have commissioned their own review of these reports by Dr McKenzie at Integrin, and draw different conclusions to the FSA. They remain firmly of the view that the mouse bioassay as carried out by the laboratory at CEFAS is causing the positive results, and that the cockles are toxin free.

3.8 As a result food authorities have felt it necessary to commission their own scientific advisor to obtain an impartial interpretation of these detailed technical discussions and papers. The City and County of Swansea is concerned about the weaknesses of the laboratory testing regimes identified in Professor Makin's report.

4. Conclusion

4.1 The Council believes it has acted diligently in its enforcement role, has striven to ensure public safety whilst recognising the commercial pressures faced by the local shellfish industry, and has continued despite local difficulties to act in accordance with the advice of the Food Standards Agency.

January 2004

Memorandum submitted by Allan W. Berry (M19)

Executive Summary:

Biotoxin production in North European waters is promoted by pollution. The Committee is asked to recognise that the best interests of public health can only be served by action to reduce the risk of the production of known and novel marine biotoxins by organisms subject to pollution induced stress.

Public recognition of the problem will allow those responsible for the control of discharges to remove the cause of toxin production by eliminating those discharges associated with toxin production.

1. The Food Standards Agency tests for presence of biotoxins in shellfish, carried out over the last three years, appear to show that an unidentified lipophilic toxin may be the cause of atypical responses in the DSP Mouse Bio Assay.
This submission comments on the implications of this within the terms of reference set by the Committee.

2. Biotoxin accumulation in shellfish is associated with the presence of toxigenic algae, bacteria and their microplanktonic consumers in the food they filter from the coastal waters in which they live.

3. The presence of a new unidentified biotoxin. has implications for public health. Without specific testing regime or toxicity data over a range of consumers, any consideration of the relationship between toxin accumulation in shellfish and public health, must pursue the possibility of eliminating the risk at source.

4. The NUTOX project, part of the European Commission , Marine Science and Technology programme (Contract MAS3-CT97-0103)
Concludes: "Decreasing both N and P loading to European coastal systems is the ultimate solution to reduce algal toxin production",

5. Examination of the historical evidence for links between pollution and the presence of biotoxins in shellfish, reveals that in Northern European waters, the production of biotoxins is associated with pollution induced environmental stress.

6. It is known that the production of Sodium channel blocking toxins such as PSP, by both bacteria and algae increases where Nitrogenous inputs relieve Nitrogen limitation, resulting in Phosphorus limitation.

7. Domoic acid which causes ASP is produced by certain pinnate diatoms affected by silicate limitation. Silicate limitation in coastal waters is promoted by the relief of N limitation. Again caused by nutrient inputs.

8. The lipid soluble biotoxins, many of which are Protein Phosphatase inhibitors are mainly produced in waters in which heterotrophy has replaced autotrophy. Environmental stress is recognised to promote DSP production. These lipophilic toxins are known tumour promoters.

9. Stress from pollution may be the cause of most known and novel biotoxin production in our coastal waters. Political and Commercial pressures on Polluters, Regulators and their scientific advisers have led to denial of the pollution link. An unsustainable position which is a threat to public health.

10. Valuable evidence of the link between pollution and toxic events appears to have been suppressed by regulators, intent on protecting both the polluter and their own decisions to licence the discharge.

11. It is unwise to assume that a testing/harvesting ban policy suffices to protect public health. Individual suspect cases are discounted and no blood tests available to confirm the presence of any of the above toxins. Proper diagnosis of mild poisoning is unlikely as samples tested for seafood poisoning only identify bacteriological contamination.

12. Public health is best served by decisions made on proper scientific examination of the events leading to a reduction in the production of biotoxins accumulating in the food supply.

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