

MINUTES OF THE OPEN BOARD MEETING, 15 AUGUST 2005, CONGRESS CENTRE, LONDON

Executive Summary

1. Draft minutes of the open Board meeting held on 15 August 2005 at the Congress Centre, London are attached.
2. The Board is asked to **confirm** that the minutes are a true and accurate record of the meeting.

Board Secretariat

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MINUTES OF THE OPEN BOARD MEETING, 15 AUGUST 2005, CONGRESS CENTRE, LONDON

OPEN SESSION, 11:00 – 12:25

Present: Dame Deirdre Hutton, Chair
Julia Unwin, Deputy Chair
Sati Ariyanayagam
Richard Ayre
Chrissie Dunn
Maureen Edmondson
Michael Gibson
Valerie Howarth
Iain MacDonald
Graeme Millar
Christopher Pomfret
Sandra Walbran
Nelisha Wickremasinghe

Officials attending:

Jon Bell – Chief Executive
Chris Lawson – MHS Chief Executive (item 4 only)
Alan Harvey – Head of TSE¹ Division (item 4 only)
Nick Carson – Board Secretariat
Sue Johns – Board Secretariat

Others attending:

Patrick Wall – Chair of the Independent Advisory Group (item 4 only)

Chair's Introduction

1. The Chair welcomed all observers attending the open Board meeting and invited the Deputy Chair to introduce the meeting. The Deputy Chair reminded those attending the meeting and watching the webcast that the FSA Board discussed policy issues at its open meetings to meet its commitment to transparency and accessibility. There would be an opportunity for questions immediately after the

¹ Transmissible Spongiform Encephalopathies

formal session and those watching the webcast could also send questions to the Board.

2. The Chair thanked Julia Unwin and Richard Ayre for their work as Acting Chair and Acting Deputy Chair respectively over the last few months. They had initiated some tremendous work, in particular on governance and science.
3. The Chair noted that apologies had been received from Ann Hemingway and reminded Board members of their obligation to declare interests before discussion of relevant items.
4. There were no items raised for discussion under Any Other Business.

Item 1 - Minutes of the Meeting on 14 July 2005, Hilton Hotel, Cardiff

(Paper FSA 05/08/01)

5. The Chair asked that the reference to the illegal dyes task force on page 9 of the minutes be correctly referred to as the Incidents Task Force.
6. One Board member asked that paragraph 72 be amended to reflect that there was a need to have a discussion in open session to clarify whether there were any circumstances in which it would be appropriate for the FSA to withhold, from the public, advice it gives to Ministers, given its existing commitment to publishing all such advice on policy matters.
7. One Board member asked that paragraph 21 be amended to reflect that the Chief Executive had agreed to consider the views expressed by Board members when finalising his action plan.
8. The Board agreed the Minutes of the meeting held on 14 July 2005 at the Hilton Hotel, Cardiff, as an accurate record subject to the changes requested.

Item 2 - Chair's Report

European Food Safety Authority (EFSA)

9. The Chair informed Board members that Geoffrey Podger was leaving EFSA to take up the position as Chief Executive of the Health and Safety Executive. She

added that it would take some time to appoint his successor as Executive Director at EFSA due to the complex recruitment procedures.

Consumer Engagement

10. The Chair updated Board members on the actions taken since they had discussed the Consumer Engagement Strategy at the July open meeting. It had been clear from the July discussion that there was a wide range of views among Board members as to the way forward. Following the Board meeting, the Chair had written to Consumer Committee members to establish whether or not they would be prepared to continue in their role for the time being. Responses so far had all been positive. The Chair also informed Board members that she had discussed these issues with the Deputy Chair and Chief Executive and had spoken to the majority of Board members. On reflection, she saw the Consumer Engagement Strategy as part of the new Strategic Plan and felt that developing it through a small sub group of the Board would not be adequate. It was important to identify what we were trying to achieve, what outcome the Board wanted and what were the forms and structures that would allow that to happen. A discussion at the Board's retreat in November, with an independent facilitator, would be more appropriate. A paper had been commissioned from the Executive which would outline the mechanisms the Agency currently used with an honest assessment of how successful they were.

Item 3 - Chief Executive's Report

Resumption of the commissioning and publishing of technical surveys
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11. The Chief Executive informed Board members that, further to his report at the last meeting, he had recently given the go ahead for the commissioning and publishing of surveys to resume. Since the July Board meeting, a series of refresher seminars for staff had been held and more would follow in September. Over 100 staff had so far attended. Reports from the seminars showed that staff considered them to be useful and there was a good two-way flow of information with staff highlighting what aspects of the guidelines they thought worked well and what less well. Much of this would be considered further when the survey guidelines were revised in the autumn. There would be an opportunity for the Board and stakeholders to engage in this process.

12. In the meantime, having taken account of what came out of the seminars, the Chief Executive had agreed that work on surveys could resume subject to the following conditions:

- the guidelines must be strictly adhered to, with each survey being overseen by someone who had attended the refresher course;
- all new staff must attend a training course;
- for all new surveys, a protocol must be produced by the lead official before commissioning the survey. This should clearly describe the aim of the survey, and the methodology to deliver it (and sampling methodology where appropriate). Relevant stakeholders would then be given time (normally 4 weeks) to comment. The final protocol must be signed off by the relevant Head of Division before the survey begins;
- all brand owners should be given sufficient time (3 working days) to see their brand results in the form to be released to enable them to be able to comment on their accuracy and be ready to respond to press comment, if necessary; and
- where results were outside the expected ranges or beyond an established limit, brand owners should be informed and, except where urgent action is needed, given 3 weeks to provide comments, which would be published alongside the results.

13. Management changes had been introduced to reinforce the new procedures. No new surveys were likely to be published in August but there were likely to be some in September. These would be checked against the new criteria before release.

14. One Board member suggested that the Board should still look seriously at the purpose and use of surveys and the publication policy for them. The Chair thought that there would be an opportunity to discuss this as part of the Board's discussions on regulation in November.

15. The Chair thanked the Chief Executive for setting out the action that he had taken and noted the importance of surveys to the FSA's evidence base.

Item 4 – Progress Report on Possible Transition towards a Robust BSE Testing regime

(Paper FSA 05/08/02)

Prior to the discussion of this item Michael Gibson declared an interest as a primary producer and butcher, which he considered sufficient to warrant his exclusion from the discussion of this issue. The Chair agreed that this was a material conflict of interest and that Michael Gibson should not participate in the discussion and determination of this issue. Michael Gibson left the table for this item.

16. The Chair welcomed Alan Harvey (Head of TSE Division), Chris Lawson (Chief Executive of the Meat Hygiene Service (MHS) and Patrick Wall (Chair of the Independent Advisory Group).

17. The Chair informed Board members that she had spent some considerable time familiarising herself with the background to this important decision. She thought it would be helpful for all to outline the background to put today's decision into context.

18. The height of the bovine spongiform encephalopathy (BSE) crisis had been in 1996, with a link with variant CJD² then being identified. In that year, 8,013 clinical cases of BSE were reported in Great Britain. The link with variant CJD was a key factor that had contributed to the creation of the FSA with its emphasis on public health and protecting consumers. At that time a number of arrangements had been put in place or strengthened to protect the public from BSE:

- removal of all cattle over 30 months from the food chain because BSE was typically a disease of older animals;
- removal of the parts of the animal which harboured the Specified Risk Material (SRM); and
- prohibition of the feeding of farm animals with mammalian meat and bone meal.

The SRM controls already remove over 99% of the risk. Removing all over 30 month cattle from the food chain in addition was therefore a highly precautionary

² Creutzfeldt-Jakob Disease

approach. BSE was now in steep decline; there had been only 82 clinical cases in 2004. After a request from Government to consider the changing risk situation, the FSA Board had recommended in 2003, and again a year later, that the Government could move to a system of testing to allow over 30 month cattle into the food chain. The Government had accepted this advice in December 2004 and announced that, subject to a robust testing system being identified, over 30 month cattle born after July 1996 could be reintroduced to the food chain where they tested negative. The announcement made clear that the final switch from the OTM rule to testing should happen only when the FSA had advised Ministers that the testing system would be robust.

19. The decision now before the Board was whether an effective and reliable testing regime had been identified.
20. The Chair invited Alan Harvey to introduce the paper.
21. Alan Harvey explained that the paper set out the story of the Over Thirty Month (OTM) rule.
22. The Government had announced in December 2004 its intention to start a managed transition towards replacing the OTM rule with testing. That event meant the case for rule change had been accepted in principle. It also meant that the agenda had moved on – to that of putting in place an effective testing system.
23. Last December, Patrick Wall, Chairman of the Independent Advisory Group (IAG), set up to advise the FSA on robustness of testing, had made a presentation to Board members about the components of such a testing system. The Board had agreed at the time to trials of the testing system and these had been held between March and June. The final report from the IAG was attached as an annex to the paper.
24. Alan Harvey went on to explain that the Agency had recently held a series of open meetings with stakeholders, including the public, in London, Edinburgh, Cardiff and Belfast in order to explain the work that had been undertaken to identify and trial the testing regime now being recommended. These meetings had included presentations from the FSA and Patrick Wall. In the question and answer sessions that followed, people had raised a number of issues:
 - the scope for fraudulent activity;

- the distances animals would need to travel in the early days with fewer abattoirs approved for OTM testing;
- the impact on the export ban;
- the effectiveness of the test itself; and
- the importance of an effective communications strategy.

25. Alan Harvey explained that the trials had demonstrated that all the key elements of the recommended BSE testing regime operated effectively and that it would be robust if effectively implemented, complied with and enforced. The paper addressed those three aspects in turn.

Implementation

26. Alan Harvey informed Board members that one key implementation issue was whether the numbers of abattoirs authorised at the start would have the capacity to meet the demand. The intention was to have up to 30 abattoirs in Great Britain, with 6 in Northern Ireland, set up and running by the end of the first week following any rule change. Others would progressively come on stream. Rural affairs departments planned to continue with the present purchase-for-destruction scheme in parallel. This would provide crucial back up and the Board might wish to recommend that this was a prerequisite to any rule change. Likewise, the Board would wish to consider whether to recommend that guidance on casualty animals was issued before any rule change.

Compliance

27. Alan Harvey advised Board members that to ensure compliance, the IAG had recommended the FSA set up a new Implementation Review Group (IRG) to oversee the implementation of the BSE testing system. This would fit in well with decisions made by Ministers last year that the FSA should be responsible for audit and review. The report proposed that an independent audit of the system is undertaken during the critical first 6 months and the results reported to the IRG. The proposed group would also have responsibility for oversight of how the recommendations in the IAG report were being taken forward. It was recommended that the IRG, which would bring together representatives from the relevant Government departments, would be in place for a period of 12 months.

28. The paper also set out the new MHS veterinary supervision arrangements for BSE testing. The new area official veterinarians (AOVs) would have a key role in authorising abattoirs to process OTM animals. It was proposed that AOVs be on site at an abattoir on each of the first 2 days of operation, first when the OTM animals arrive and then the next day when carcasses would be released on the basis of test results. The Board would wish to consider whether to recommend that this should be a mandatory requirement.

Enforcement

29. Alan Harvey reminded Board members that the risk assessment³ took account of the risk of failure to test. A 1% failure, or 5,000 animals, would make a negligible difference to the risk. More recently, Imperial College had extrapolated their projections still further and reported that a 10%, or 50,000, failure rate would add 20% to the variant CJD figures. This would lead to the central estimate of additional cases attributable to OTM rule change that would arise over the next 60 years, increasing from 0.5 in the earlier risk assessment to 0.6, and the corresponding worst case figures increasing from 2.5 to 3.0.

30. The paper proposed putting in place a two day pass or fail test for any abattoir wishing to process OTM animals. In addition, it would become an offence to send a pre-August 1996 animal to an OTM fresh meat abattoir and this new law would be in place before rule change could happen.

31. Alan Harvey reminded Board members about the other streams of assurance that the Board had requested before coming to a view:

- a satisfactory report from the European Commission Food and Veterinary Office's (FVO) following their visit to the UK in June; and
- no new issues being identified at the open meetings held with stakeholders, including the public.

Both of these had been met as explained in the paper.

32. Finally, the paper recommended that the Board advise Ministers that a reliable BSE testing regime had been successfully designed and trialled, and

³ FSA 04/07/06 Review of the Over Thirty Months Rule

arrangements identified to ensure it would be able to operate to the highest standards.

33. The Chair invited Patrick Wall to comment on his report.

34. Patrick Wall reminded Board members that the IAG held within it a diverse range of professional skills and backgrounds. He complimented the staff and secretariat of the FSA, the MHS, the Northern Ireland Department of Agriculture and Rural Development (DARD) and the Department for Environment, Food and Rural Affairs (Defra) for their timely provision of information to exacting deadlines. He commented that the IAG had inherited the word “robust” and had interpreted that to be a regimen that included:

- simple design, which was compatible with existing industry processes and may be standardised and easily implemented and operated;
- sufficient internal controls and cross checks to ensure the correct identification of the animals to be excluded and the animals to be tested, and that only carcasses that test negative be released onto the market for human consumption or any other purpose;
- adequate supervision and enforcement, mechanisms for continuous performance monitoring of all the parties involved, with measurable criteria for demonstrating reliability and effectiveness, and periodic audit.

35. Patrick Wall noted that the IAG had welcomed the additional legislation to deter fraudulent practice. He explained that all other Member States of the European Union (EU) had been testing since 2001 but that for them this was an additional mechanism as OTM cattle were previously allowed into the food chain.

36. The IAG report was prescriptive in terms of what was required of operators and what was required by regulatory agencies. The report made 20 recommendations and highlighted a further 10 challenges which would need to be met. He identified 3 crucial areas:

- the commitment of industry;
- the supervision and enforcement of testing in slaughterhouses by MHS/DARD; and
- the need for an effective communications strategy.

37. The Chair informed Board members that she had attended the public meeting in London and Graeme Millar had attended the meeting in Edinburgh. She had also met with Janet Gibb of the Human BSE Foundation and Professor Chris Higgins, Chair of the Spongiform Encephalopathy Advisory Committee (SEAC). With Alan Harvey, she had visited the Laboratory of the Government Chemist (LGC), the organisation that would carry out the tests and she invited him to summarise the issues that had arisen as a result.
38. Alan Harvey informed Board members that several points had been raised by the visit to LGC. One was the rejection rate of samples. Out of 800,000 tested so far as part of ongoing surveillance of OTM cattle, less than 0.006% had had to be rejected. LGC were accredited to ISO 17025 and were audited by UKAS⁴ and, from time to time, the FVO.
39. The Chair invited comments from Board members.
40. Some Board members asked for clarification on whether there would be sufficient national and regional capacity. Scotland was highlighted as having a particularly difficult geographical issue in terms of the Highlands and Islands where there was a potential risk that some operators may not switch to testing because of the distance that would need to be travelled to a testing slaughterhouse. One Board member also asked whether blue and white tagging would be adopted. The Chief Executive of the MHS explained that the MHS was also concerned about a potential large demand and the risk of not having enough approved plants in place from day one. He would not therefore be prepared to move to BSE testing without some OTM plants continuing to run in parallel. It was anticipated that there would be 30 abattoirs ready in the first week with a geographical spread throughout Great Britain. There were currently only 19 plants handling OTM animals, which meant that animals were already travelling some distance. He confirmed that blue and white tagging would be used and in cases where the tag had fallen off, the vertebral column would be removed regardless of the age of the animal.
41. Some Board members asked for clarification on the process to ensure that cattle born pre-August 1996 would not enter the food chain. The Chief Executive of the MHS explained it would be an offence in law to present for slaughter pre-August 1996 animals for human consumption and this legal provision would also need to

⁴ United Kingdom Accreditation Service

be in place before any rule change. In terms of identifying these animals, there would always be a chance that people would try to pass off such animals as post-August 1996, but the challenge would be to prevent them getting through. Alan Harvey added that passports included the date of birth but where animals predated the passport system and no passport had been issued, the certificate of registration also included the date of birth. If a pre-August 1996 animal were to arrive by accident, the animal would be treated as fallen stock.

42. One Board member asked for more details about the communications strategy that would be in place before the proposed rule change. The Chief Executive explained that the FSA was liaising with the Department of Health and Defra and that various actions would be put in place including the production of a leaflet for consumers explaining the process. Information would also be disseminated through the media and the website and the aim was to ensure that the reports on implementation were transparent.

43. One Board member was concerned about the proposal to set up the IRG and asked whether this was, more properly, a role for the MHS Board. It would be important to clarify the role of the IRG, its accountability and where decision making took place. The Chief Executive explained that the primary reason for needing to have an IRG was implementation involved more than just the MHS. For example, the proposed audit would also need to cover laboratories, the transport side and the DARD operation. He agreed that the MHS Board had an important role to play and that this should be factored in.

44. One Board member raised a concern over the timing of the Board's discussion in the absence of the final report from the FVO. The Chief Executive explained that a draft of the final report had been sent, in confidence, to the FSA for comment and that this supported the conclusion reached in the paper.

45. One Board member asked for clarification regarding the need to remove vertebral column from younger animals than at present. This was currently set at thirty months in the UK whereas the current harmonised age in the rest of the EU was 12 months. Alan Harvey confirmed that the introduction of testing would not, in itself, lead to a change in the age for removal of vertebral column but there would be pressure for the UK to harmonise at the point when the ban on UK exports was lifted. The EU was proposing to harmonise at 24 months but the UK aim was to secure harmonisation at 30 months or obtain a UK derogation. This was

underpinned by a risk assessment by SEAC which had found no significant difference between removing vertebral column at 12 months or 30 months.

46. One Board member welcomed the funding from Defra to meet all the costs associated with implementation and asked whether this would be sustained. Another Board member asked whether there were sufficient resources to ensure 100% compliance. The Chief Executive explained that Defra was committed to fully funding the implementation.
47. One Board member noted the timetable for training AOVs and highlighted the importance of having experienced veterinarians in these positions. The Chief Executive of the MHS explained that although AOVs were new posts they would be filled by experienced people. He added that the operator was responsible for compliance and the role of the MHS and DARD was to inspect, verify and enforce. In addition to the AOVs, there would be additional resources for the verification and inspection role. In addition to the training of MHS staff, there was also the need to train plant operating staff and the MHS was recommending that plants be closed for a day to enable this training to be done. One Board member suggested that the ongoing regular visits by AOVs should be unannounced.
48. One Board member asked whether SEAC would have a brief to identify any changes in disease patterns. Alan Harvey confirmed that SEAC would continue to fulfil an important role in addressing remaining BSE knowledge gaps and the emerging science. Alan went on to say that, in view of declining levels of BSE, a “road map” had been published at a European level. This looked at BSE controls and how they might change to take account of possible reductions in levels of risk. Interested parties were currently being consulted about this. Meanwhile the FSA was taking the position that any move to relax the BSE controls would need to be looked at very carefully, and would certainly need to be put to SEAC, to inform UK negotiators. He stressed the importance of putting the consumer first.
49. One Board member asked for clarification that the paper took account of all the issues raised at the open meetings with stakeholders and the public. Patrick Wall confirmed that nothing had been raised at the meetings that had concerned the group but noted that there had not been a very high level of consumer representation.

50. Some Board members asked what contingency plans were in place should there be a catastrophic failure of testing facilities, for example, as a result of a fire, logistical delays or terrorism, and whether the intention was to achieve 100% compliance or to aim to achieve 100%. Alan Harvey explained that the organisation of transport and provision of consumables were the responsibility of abattoir operators. LGC were planning to offer a transport service with an insurance option which would, for example, cover situations such as a motorway accident causing a delay. In the absence of a negative result, the carcasses would have to be condemned with the operator bearing the cost in the absence of insurance. Patrick Wall explained that no health mark could be applied by the MHS until the animal received a negative result. There would be a number of controls in place to achieve this. Alan Harvey added that the intention would be to aim for 100% compliance but the FSA would, as ever, be open about any breaches that might occur.
51. One Board member asked whether the IRG would have the power to stop the process if any problems emerged with the robustness of the system in practice. The Chief Executive explained that any advice to stop the process would be put to the Chair who, acting on the Board's behalf, would make the decision whether to recommend to Ministers to suspend testing.
52. One Board member asked if the IAG's 30 recommendations had been accepted across Government. Alan Harvey explained that although the fine detail had not yet been looked at there had been no dissent amongst departments about any of the recommendations.
53. The Deputy Chair noted that Ann Hemingway had asked that some additional points be raised in her absence. The first was to ensure that the communications plan allowed sufficient time for translation into Welsh. This was especially important in light of the major use of Welsh in the farming community in Wales. The second point was that there should be a deadline to move to the new system or a number of review points in order to provide some motivation. Thirdly, the frequency of reports from the IRG to the FSA Board should be clarified. Finally, the timetabling of business for devolved administrations should be taken into account when working towards a common UK implementation date. Board members took note.

54. The Chair noted that the Board had asked:

Executive

- that a communications strategy should be drawn up as a matter of urgency, and notified to the Board;
- that the Terms of Reference of the IRG be drawn up and the role of the MHS Board in the implementation review clarified;
- for confirmation of the arrangements for pre-August 1996 cattle and that the planned disposal scheme would remain in place for 3 years;
- that the aim would be for 100% compliance with transparency over any breaches;
- for the Executive or IRG to report back to the Chair if problems arose over the FVO report or capacity;

Rural Affairs Departments

- that legislation to make it an offence for a producer to send pre-August 1996 cattle for slaughter for human consumption should be a prerequisite for rule change;
- that there should be long term funding by Defra for the implementation;

Implementation Review Group

- that there should be break points in the review of the operation of the new system;
- for plans to cover catastrophic breakdowns in the systems;
- that the frequency of reports to the FSA Board by the IRG should be agreed.

SEAC

- that there be a continued focus by SEAC on BSE and any development in disease patterns.

55. In summary, the Chair noted that the Board had agreed to advise Ministers that:

- a reliable BSE testing regime for OTM cattle had been successfully designed and trialled;
- arrangements were in place to ensure that, should the BSE testing regime be implemented, it would be able to operate across the UK to the highest standards.

The Board had also agreed, in the event of rule change:

- that an OTM testing Implementation Review Group be set up, chaired by the FSA and involving all the UK Government departments concerned, to oversee implementation of the BSE testing regime for its first 12 months of operation before ceasing its activities, and report to the FSA Board;

and that as prerequisites to implementation of OTM rule change:

- rural affairs Departments must keep the current OTMS scheme operational until such time as it was clear that there were sufficient fresh meat plants approved to meet the demand for the slaughter of OTM animals;
- guidance on the new rules for emergency slaughter of bovine animals must be distributed;
- an MHS Area Official Veterinarian (and the DARD equivalent in Northern Ireland) must visit every OTM fresh meat plant on both the first two working days of OTM BSE testing operations, and thereafter at regular intervals;
- legislation must be in place to make it an offence for a producer to send animals born before 1 August 1996 for slaughter for human consumption;

and noted:

- that an independent audit of the BSE testing system, to report six months following OTM rule change implementation, and arrangements for FSA ongoing audit which would supersede it, would in each case report both to the Implementation Review Group and to the Board; and that following the

Implementation Review Group ceasing its activities, the latter audit body would continue to report direct to the Board.

56. It was agreed that the Terms of Reference and membership of the IRG should be put to the September Board meeting.

Action: Alan Harvey

Any Other Business

57. There were no other business items raised.

Date of next meeting

58. The next scheduled open meeting would be held in London on 15 September 2005.