

Open Government Status: Fully Open

INTERDEPARTMENTAL LIAISON GROUP ON RISK ASSESSMENT

LESSONS TO BE LEARNED FROM THE REPORT OF THE BSE INQUIRY

A Paper by the Food Standards Agency

Executive Summary

1. The attached paper summarises the main findings of the BSE Inquiry chaired by Lord Phillips and discusses the lessons to be learned from it. It was presented to the FSA Board of the Agency at their meeting on 8 February 2001. The Government is responding formally in two stages, and the Agency is contributing to that process. The creation of the Food Standards Agency is itself a very important demonstration of what had already been learned from the BSE story. We have already made changes to the way we work which are consistent with the lessons highlighted by the Phillips report. These are only first steps. Under the pressure of events it is all too easy to forget new ways of working; the best way of improving is to learn from our mistakes as well as from what has gone well.

2. Key themes in the Phillips report are:

- openness (para 8)
- communication (para 11)
- effective enforcement (para 16)
- risk management and the precautionary approach (para 19)
- contingency planning (para 22)
- advisory committees (para 25)
- research (para 29).

3. There is much activity on these issues within Whitehall – see Appendix 1 attached in draft form (assembled by Cabinet Office) - and elsewhere. ILGRA is already progressing the development of policy on the precautionary principle. In addition, separate papers for consideration at this ILGRA meeting address collaboration in contingency planning where risks span more than one Department (ILGRA/MAY01/05) and various administrative measures to improve joined up working between Departments on risk issues (ILGRA/MAY01/08).

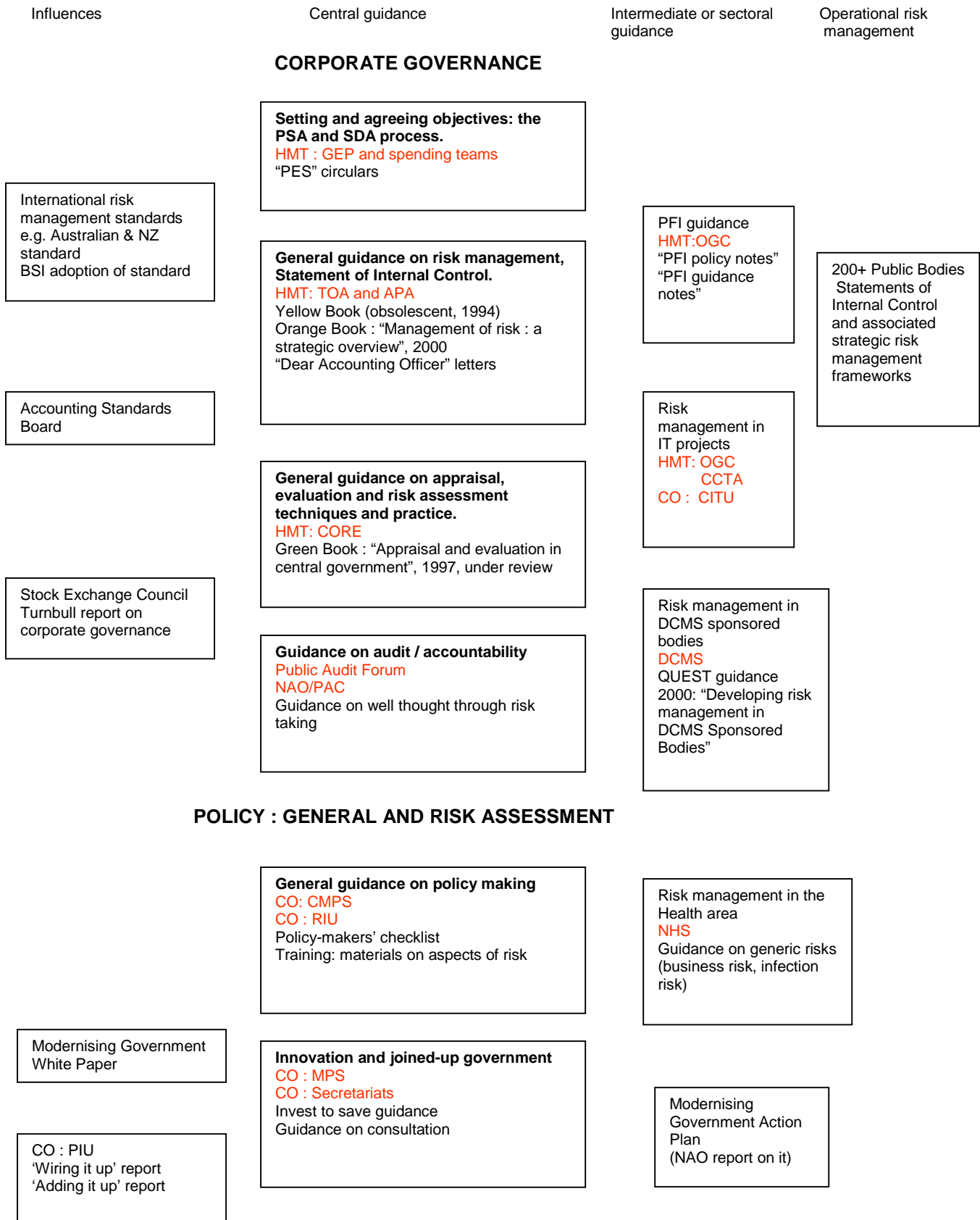
ACTION

4. ILGRA members are invited to consider the issues in para 2 above, and:

- identify those to which ILGRA could best add value without duplicating existing initiatives; and
- suggest what role ILGRA might take in developing policy.

Appendix 1

DRAFT MAP OF GOVERNMENT RISK RESPONSIBILITIES AND GUIDANCE



Influences

Central guidance

Intermediate or sectoral guidance

International and treaty obligations. EU Directives etc.

Civil contingencies : risk assessment and management
 Home Office
 CO : EDS

Overseas contingencies : risk assessment and management
 CO : DOAS
 CO : JIC

Co-ordination of information, risk communication
 No10 Press Office
 GICS

EU Communications e.g on precautionary principle

General guidance on regulation (including risk aspects)
 CO : RIU
 'Good Policy Making A Guide to Regulatory Impact Assessment'
 'Guide to Better European Regulation'

Central Government departments and agencies published risk frameworks on risks affecting the public (where these are significant)

POLICY MAKING - SCIENTIFIC UNCERTAINTY

Research (some commissioned by government) e.g. ESRC risk and human behaviour programme

General advice on risk assessment techniques and policy development
 ILGRA
 "Risk communication, a guide to regulatory practice", 1998

Guidance on clinical health issues
 NICE,....

Local authority fora?

Land use planning H&S in offices and shops
 Local Authorities

Building Regulations
 DETR

Oversight and co-ordination of scientific advice
 Chief Scientific Adviser/OST
 Guidelines 2000
 Guidelines on scientific advisory committees
 Guidance on commercial exploitation of government research (Baker report)
Co-ordination of scientific advice with devolved administrations

Scientific Advisory Committees

H&S in factories etc
 HSE (including railways inspectorate, nuclear safety inspectorate)

Guidance on Environmental risk management
 DETR/EA/IEH
 "Guidelines for Environmental Risk Assessment and Management"

Fire services

ISSUE

1. To consider the lessons to be learned from the report of the BSE Inquiry and note the steps already taken and planned for the future in the light of these lessons.

BACKGROUND

2. The BSE Inquiry was set up by the Government on 12 January 1998. Its membership and terms of reference are given in Annex 1.
3. The Inquiry held all its proceedings in public and published full transcripts daily on the Internet. It took written and oral evidence from a very large number of people, including some who are now on the staff of the Agency. The report of the Inquiry was given to the Government in October 2000. It was published in 16 volumes, with a total of some 4000 pages. All the essential findings are presented in Vol. 1, "Findings and Conclusions". Chapter 14 of this volume, entitled "Lessons to be learned" is included at Annex 2 to this paper.
4. The report's findings are based on the events surrounding the discovery of BSE and the actions taken in the subsequent years, up to 20 March 1996. Many of the issues covered relate specifically to issues of food safety, but other issues are also addressed, including medicines, consumer products (such as cosmetics) and the safety of bovine material used in school science lessons. Many of the report's conclusions are relevant to the whole of Government, across the UK. The Government's response will be in two stages, an interim response for consultation followed by a final response taking into account the views expressed. Agency officials are involved in the process and it is likely that the work of the Agency will figure significantly in the responses. At the time of writing, it was expected that the interim response would be published on or near to the date of this meeting, and the final response in the summer.

5. The purpose of this paper is to identify the key findings of the report that relate to the work of the Agency as whole. It is important to recognise that the report addresses fundamental issues regarding all aspects of the Agency's work – while there is much in the report which is specific to the nature of BSE and the handling of zoonoses, it has much wider implications. Work is already in hand to ensure that all Agency staff are aware of this; the Chief Executive has written to all staff and held two seminars with staff to discuss the findings of the report. Some of the key lessons from the report will also feature in the tailored management development programme for FSA staff on which we are now working.

6. In many ways the creation of the Food Standards Agency was in itself the result of the Government's recognition of the need for change in the wake of the BSE story. The nature and role of the Agency, and many of its statutory provisions, follow from the lessons learned from the events of the previous two decades.

7. Major themes to emerge from the report of direct relevance to the Agency are: openness, communication across the UK, effective enforcement, risk management and the precautionary approach, contingency planning, the use of advisory committees and research.

Openness

8. Key conclusions of the report were:
 - There was too much secrecy
 - There was too much unjustified reassurance
 - The Government needs to be more open with the public
 - It is important to acknowledge and deal with uncertainty

9. The Agency is already committed to openness; it is one of our core values. We have published a draft Code of Practice for public consultation and are putting this commitment into practice in a variety of ways, including for example the holding of Board meetings in public and the publication of

advice to Ministers. We have also made a point of being open and honest about uncertainty, telling people what we do not know as well as what we do. The BSE controls review provides a good example of the benefits of carrying out deliberations in public and giving all concerned the opportunity both to observe and to participate in the discussions. The web-site specifically established for this review has received over half a million hits.

10. Openness is widely regarded as one of the great strengths of the Agency and we have been widely praised for the progress made. The report makes the point that the public will respond rationally to openness (a conclusion supported by a body of research) and this accords with our experience so far. Future developments will follow the communications audit, currently underway. The Board discussed a preliminary paper on the Agency's communications strategy in October and will have a further opportunity to discuss priorities in due course. Other developments currently in hand include an interactive website. The staff training and development programme that is being drawn up will ensure that the core values, including openness, become embedded in everyday work.

Communication across the UK

11. The report raised a number of concerns about communication between Government Departments and across the different parts of the UK. Key conclusions include:

- Actions across the UK should be better co-ordinated
- It is essential to share resources and information
- A structure for consultation and joint decision-making is needed

12. The fact that the Agency is a UK body advising all 4 governments will ensure consistency of risk assessments. For those decisions where the responsibility rests with the Agency, we should have little difficulty ensuring internal consistency. We have access to expertise from across the UK and the Advisory Committees will help to ensure that that expertise feeds into Agency analyses. Both the membership of the Board and

internal management structures should help to ensure that the views and needs of all parts of the UK are properly considered.

13. However, it is important to recognise that devolution allows devolved administrations to make different choices of risk management options. Where Ministerial decisions are needed, the information we have will be available to all four governments of the UK. While it is essential that we are consistent in the presentation of risk assessments, we must also ensure that options for risk management are correctly analysed in terms of local conditions and considerations so that each government is able to make the best possible decision for the population affected. To take a current example, it is quite feasible for different governments in the UK to take different views of the balance between safety and consumer choice in respect of unpasteurised milk.

14. This is an area where the creation of the Agency provides a clear mechanism for improvement. Effective internal communications are crucial and these should remain under constant review. We are developing clear links between officials dealing with related policy issues in the FSA's offices in across the UK, and are working on short-term shadowing and secondment arrangements.

15. Communications with other Westminster departments are also very important. Concordats with the main relevant departments and agencies have been agreed or are near to agreement. We have generally established good working relationships, but we are both new and unusual as a government department and it will take time for everyone to become accustomed to the new ways of working. It will be important to maintain and develop good communications.

Enforcement

16. The report concludes that ineffective enforcement of the control measures was a significant weakness in the Government's response to BSE. Key comments in the report include:

- Policy makers and legislators should consult enforcers before making new regulations
- Regulations must be based on understanding what actually happens in the real world
- Regulations must be enforceable
- There should be effective communications with enforcers

17. There have been several major changes since the period covered by the report. The Agency's first Director of Enforcement has been appointed. The Meat Hygiene Service (MHS) was created in 1995 to address many of the issues which the Phillips report now raises with respect to slaughterhouses etc, and the report praises the MHS. The MHS is now part of the Agency and is, as a matter of routine, included in decision-making processes. Arrangements are different in Northern Ireland, but the Agency has entered into a close relationship with the Department of Agriculture and Rural Development in relation to the enforcement of meat hygiene legislation. The Food Standards Act gave the Agency a new statutory role in relation to Local Authorities, giving us powers to set standards and monitor and audit the performance of LAs. We have a Framework Agreement with LAs, developed in close consultation with the enforcers, and working relations with their representative bodies are generally very good. The Agency also provides the opportunity to deliver a single, consistent message on food safety to enforcers.

18. This is an area where we have made considerable progress but more remains to be done. The Framework Agreement with LAs provides the opportunity for better communication and consultation, but these still need to be put into practice. Internal procedures are currently under discussion to ensure that all proposals for regulation and Regulatory Impact Assessments include consideration of enforceability.

Risk Management and the Precautionary Approach

19. The report says “At the heart of the BSE story lie questions of how to handle hazard...”. Risk management is central to the work of the Agency and the report makes a number of key points:

- It is not the job of government to eliminate risk
- Precautionary measures should be implemented urgently and rigorously
- Absence of evidence is not evidence of absence
- Actions taken in uncertain situations should be reviewed regularly
- Applicability of the ALARP principle (as low as reasonably practical)
- To protect the public, urgent action may be needed
- Delays were caused by too much refinement “The best is the enemy of the good”
- Immediate steps can be reconsidered with more in-depth analysis

20. We have published our statement of policy on risk management. We are committed to taking a precautionary approach. The Food Standards Act requires us protect the interests of consumers, but also to take account of costs and benefits. We have the essential components of policy in place, but difficulties inevitably arise when it comes to putting the principles into practice in individual cases.

21. A couple of recent examples illustrate what can be done. In its discussions on pesticides and veterinary medicines, the Board asked PSD to review its licences routinely in the light of new information and agreed a policy statement on pesticides and veterinary medicines saying that exposures should be ALARP. However, when urgent issues arise, it can be more difficult and in situations of great uncertainty it is hard not only to take a decision but also to know when to take it and when and how to make it public. For example, in the case of the GM-contaminated seed, earlier in 2000, it was probably a mistake not to make public straight away our risk assessment. Board Members will want to bear in mind the lessons of BSE when difficult issues of this kind arise.

Contingency planning

22. Key conclusions of the report were:

- The Government should have foreseen the possibility that BSE might be a cause of vCJD
- There was no sensible planning for what to do if so
- Measures to protect public health were not prepared in advance
- No communications strategy was prepared

23. In a narrow sense, contingency planning is a key aspect of our emergency and incident handling plans. More broadly, our policy development should generally include consideration of the “what if?” aspects. Good examples include the Board’s considerations of the possibility of BSE being found in sheep and the handling of French BSE issues.

24. We shall be holding a stakeholder workshop in March to review the way we handle hazards. We are also committed to post-hoc reviews of the way we have handled incidents, with the help of stakeholders, so that we can continue to learn the lessons from major events.

Advisory committees

25. The comments in the report fall into two categories:

(a) what advisory committees should do:

- Make clear the uncertainties in their conclusions
- Make clear what evidence they have reviewed and what they are merely quoting
- Be conscious of conflicts of interest (real or apparent)

(b) what the Government should do

- Not ask ACs to deal with issues beyond their competence
- Not ask ACs to make risk management decisions
- Not put issues to ACs as a way of avoiding urgent action
- Not be selective in quoting their advice

26. Considerable progress has been made in the way advisory committees operate since the period covered by the report. Members are now appointed through open competition, declarations of interest are the norm and committees generally publish their agendas, minutes and non-confidential papers. Last year the then Chief Scientific Advisor, Sir Robert May, assisted by the Chairman and the CMO, reviewed the approach taken by advisory committees dealing with food safety. Their conclusions were published in July 2000 and were very similar to those in the Phillips report (Annex 3). The Chairman and the CMO have written to the advisory committees to ask them to consider the conclusions of the May review and report back. SEAC has already published its conclusions on the lessons learned from the Phillips report.

27. We shall be carrying out a review of our advisory committees later in the year, and this will take into account both the Phillips report and the May review.

28. In relation to both advisory committees and research, the report also makes the point that government departments need to have sufficient scientific expertise in house to commission work, to understand what is produced and interpret it if necessary for policy- and decision-makers. About 40% of the Agency's staff have specific scientific, medical, environmental health or veterinary expertise. It will be important to maintain the level of expertise and to ensure that we have the right skills, in the right places, to deal with existing and future issues.

Research

29. The report makes a number of points about scientific research:

- Co-ordination of research effort is desirable
- Progress of research and implications of developments should be kept under review
- There may be a role for an independent research "supremo"

- There are benefits in issuing an open call for proposals

30. Some of the criticisms made in this report do not apply to our research. The Agency's programmes are managed under the ROAME system (Rationale, Objectives, Assessment, Monitoring, Evaluation), as recommended by the Office of Science and Technology. Most of the programmes are managed with the assistance of external programme advisers and every project has a project officer in the Agency to monitor developments. Programmes are subject to regular peer review evaluation involving national and often international experts. All projects are subject to open competition, and calls for proposals are now issued quarterly. There is some co-ordination with research councils and/or OGDs in areas where there are common interests. There is scope for improvement in our co-ordination with other research funders and this is being addressed currently as part of a wide-ranging review of the way the Agency's R&D programme is managed and prioritised. (It should be noted that TSE research is already well co-ordinated across Government.)

31. The review of the Agency's R&D programme will be discussed by the Board in 2 – 3 months' time.

Conclusions

32. We have made a real start in addressing the issues raised in the Phillips report. Our statutory powers and duties reflect many of the key conclusions, as do our core values. We have taken many steps to put these into practice. However, there is more that can and should be done. Perhaps the single most important lesson implicit in the report is how easy it is to get drawn further and further down an incorrect line, even if everyone is doing their best to meet what they believe to be their responsibilities. We must always be open minded, accept and consider criticism and alternative views and be ready to reconsider our position in the light of new evidence. Those involved should remain constantly aware of the impact or potential impact of their decisions in the real world. The

Board will want to be vigilant in its oversight of all the Agency's activities to ensure that the lessons are put into practice.

BOARD ACTION REQUIRED

The Board is asked

- to **note** the key issues raised by the Phillips report
- to **note** what we have done so far to learn the lessons of the BSE story
- to **note** the other relevant developments planned
- to **agree** that the Board should monitor developments to ensure that the lessons of this report are properly taken into account

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Annex 1 MEMBERSHIP AND TERMS OF REFERENCE OF THE BSE INQUIRY

Members

Lord Phillips of Worth Matravers

Mrs June Bridgeman

Professor Malcolm Ferguson-Smith

Terms of Reference

To establish and review the history of the emergence and identification of BSE and new variant CJD in the United Kingdom, and of the action taken in response to it up to 20 March 1996; to reach conclusions on the adequacy of that response, taking into account the state of knowledge at the time; and to report on these matters to the Minister of Agriculture, Fisheries and Food, the Secretary of State for Health and the Secretaries of State for Scotland, Wales and Northern Ireland.