

BSE AND SHEEP CONTINGENCY POLICY

Executive Summary

1. This paper asks the Board to agree, for purposes of contingency planning, a possible approach to a graduated strengthening of measures to protect consumers in response to one or more findings of BSE in the current UK sheep flock.
2. The paper also notes the high level of uncertainty around estimates of the possible risk from BSE in sheep and that, if BSE were ever found in a UK sheep, the estimate of the risk to consumers would depend on the accumulated results of surveillance for BSE in sheep up to that time. It therefore recommends that the policy be kept under review and that any policy agreed now on a contingency basis should urgently be reconfirmed taking into account the circumstances at the time of any finding of BSE in a UK sheep.
3. The Board is invited to:
 - **note** that, in the event of confirmation of BSE in a sheep, targeted testing of animals in the affected flock or flocks would be carried out to assist in determining the potential spread of the disease and whether it may have entered the food supply (paragraph 9).
 - **agree** that an expert group be set up to advise on what additional surveillance should be put in place, if BSE were to be found in a UK sheep, to improve estimates of prevalence of BSE in UK sheep (paragraph 13).
 - **agree** that, on current knowledge, it would advise the following graduated response to one or more findings of BSE in the current UK sheep flock:
 - one finding of BSE in sheep - remove additional SRM;
 - two findings of BSE in unrelated flocks - exclude sheep aged over 12 months from the food supply and remove the additional SRM from the remaining sheep;
 - three findings of BSE in unrelated flocks - allow into the food supply only sheep that were either genetically resistant to BSE or semi-resistant and aged under 12 months and remove the additional SRM from those sheep (paragraph 20).

- **agree** that its contingency policy for a finding of BSE in sheep should be kept under review and be urgently reconfirmed should BSE actually be found in a UK sheep (paragraph 22).
- **comment** on the outline handling plan at Annex F and the strategy for the external communication that would be needed (paragraph 30).

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BSE AND SHEEP CONTINGENCY POLICY

Issue

1. The advice to consumers that the Agency would give and the further measures to protect consumers that the Agency would recommend if BSE were found in the UK sheep flock.

Strategic Aims

2. This work links to the Agency's aims to ensure that BSE controls in the food chain are based on the latest scientific knowledge and to protect consumers by implementing and enforcing proportionate and effective BSE controls.

Background

3. Sheep were exposed to BSE-contaminated feed and are known to be infected experimentally by BSE. It is therefore not impossible that BSE entered the UK flock. As scrapie, an endogenous transmissible spongiform encephalopathy (TSE) in sheep, which is not considered to be harmful to humans, has similar clinical signs in sheep to BSE, it was possible that BSE in UK sheep was masked by scrapie. However, a significant programme of testing, which has been in progress for a number of years, has not, to date, found BSE in the UK sheep flock.
4. Defra have published a contingency plan setting out the UK Government's strategy for responding to a finding of BSE in sheep. The plan takes into account the Agency's probable advice on the actions needed to protect public health were such a finding to be made.
5. The Board considered the approach the Agency would take if BSE were found in sheep (or goats) in the UK most recently in April 2006 (Board paper FSA 06/04/03). Until April 2006, the Agency's policy in the event of such a finding in sheep was that only sheep that were either genetically resistant to BSE or semi-resistant and aged under 12 months would be allowed to enter the food supply. At its April 2006 meeting, the Board agreed that, if only a single UK sheep with BSE were found, the above genotype-based restrictions, which could in a worst case involve the loss of almost the entire lamb crop for that year, would not apply. The Board however agreed that, in that case, intensive and targeted surveillance should be carried out to (i) determine whether the case was an isolated one and (ii) estimate what the prevalence of BSE might be in the UK sheep flock.

6. The Board also at its April 2006 meeting:

- requested a paper in June that should contain recommendations on actions to be taken were BSE ever to be found in larger numbers of sheep;
- agreed that the Agency's advice on eating sheep and lamb had not changed, but that the June paper should consider what the advice might be if BSE were ever to be found in the UK sheep flock; and
- asked that the June Board paper also address research into quicker and cheaper testing regimes, and the issues of sheep identification and determining the age of sheep.

This paper responds to the above points.

Possible Additional Surveillance in the Event of Finding a Single BSE Case in UK Sheep

7. Currently, under EU legislation, all sheep that are suspected of being infected by a TSE must be tested. In addition, there is a requirement for continual surveillance for TSE under which a sample¹ of healthy sheep slaughtered for human consumption and of sheep that are killed or die for other reasons ("fallen sheep") must also be tested. Any samples that test positive for TSE are then subjected to further discriminatory testing to determine whether or not the presence of BSE can be excluded².
8. The action that would be required to be taken under EU rules if BSE were confirmed in a sheep or goat is set out at Annex A. That action would be the responsibility of Defra and the territorial rural affairs departments. It includes the targeted testing of animals in flocks which have, following an inquiry to find the possible origin of the disease and other holdings on which there are animals which may have been infected, been identified as potentially infected and culled. That testing would, in conjunction with the veterinary investigation that would be carried out, seek to answer the questions of when and how BSE may have entered the flock; whether it had spread within the flock or to other flocks; and if it may have been dispersed to further flocks or into the food supply.

Recommendation

9. The Board is invited to **note** that, **in the event of confirmation of BSE** in a sheep, **targeted testing of animals in the affected flock or flocks** would be

¹ the current minimum annual sample sizes for the UK are 10,000 healthy slaughtered sheep aged over 18 months and 10,000 fallen sheep. These sample sizes are about to be increased (see footnote 4)

² similar rules requiring testing of suspects, ongoing surveillance and discriminatory testing of TSE-positive samples also apply to goats

carried out **to assist in determining the potential spread** of the disease and whether it may have entered the food supply.

10. The ability to take the required action on the affected flock or flocks depends on being able to trace the index case back to the flock in which it could have been exposed to the disease and having adequate information on the movements of animals into and out of the flock concerned. The rules on sheep identification and tracing have been progressively tightened over recent years. The current system of batch tracing of animal movements should have improved significantly the likelihood of movement tracing being successful. However, movements before 2001 will remain difficult to trace. EU requirements for electronic identification and tracing of individual sheep and goats are due to take effect on 1 January 2008.
11. As to wider surveillance to estimate the prevalence of BSE in UK sheep if it were found to exist, the approach that has been taken up to now has been the testing of all sheep TSE cases using discriminatory tests for BSE. The rationale for this approach is that the prevalence of BSE may be highest in sheep diagnosed with a TSE, making it easier to detect in those sheep if it were present. One option for intensifying surveillance for BSE in sheep would be to see if a way could be found of increasing the number of sheep TSE cases notified³.
12. An alternative would be to carry out a random survey of slaughtered sheep. However the accumulated results from the discriminatory testing of sheep TSE cases carried out to date indicate that, if present, prevalence of BSE in sheep screened at random would be likely to be extremely low. A survey that would be capable of refining current estimates of the possible prevalence of BSE in sheep would therefore need to be very large. Further consideration of the best approach to improving estimates of prevalence of BSE in sheep is needed, with expert epidemiological input and taking into account costs and practicalities, before a clear recommendation can be given.

Recommendation

13. The Board is invited to **agree that an expert group be set up** to advise on **what additional surveillance** should be put in place, **if BSE were to be found in a UK sheep**, to improve estimates of prevalence of BSE in UK sheep.
14. It may be expected that, if BSE were found in a sheep, the European Commission would propose an increase in the scale of surveillance across the EU⁴. The development of advice on additional surveillance in the UK, as

³ scrapie has been a notifiable disease since 1993. Any animal suspected of having scrapie must by law be notified to the local animal health office. Although scrapie is a notifiable disease, experts suspect that the true incidence is under-reported.

⁴ as it did in 2004 when BSE was found in a French goat. A European Commission proposal to increase surveillance in sheep following the recent findings of unusual TSE cases in sheep in France and Cyprus has recently been adopted. This will require the UK to test 44,000 slaughtered sheep and 20,000 fallen sheep in the period July – December 2006.

recommended, would provide a useful basis for consideration of any such proposal by the Commission.

Risk to Consumers if BSE were found in UK Sheep

15. As the Board is aware, there are many uncertainties in relation to the risk that BSE in sheep might pose, if it were present. Modelling work carried out by Professor Angela McLean's team at Oxford indicates that the possible annual exposure from BSE in sheep would at most be a small fraction of the total human exposure from BSE in cattle since 1980. On the other hand, as the human exposure risk from BSE in cattle is now at a very low level, annual exposure to BSE in sheep would be much larger than current exposure from cattle⁵.
16. These risk estimates are based on a current estimate that BSE might be present undetected in up to 3 flocks in the UK. As explained in Annex C, if the number of TSE-infected flocks tested without finding BSE continues to rise, the estimate of the number of potentially BSE-affected flocks, and hence the risk estimates, would gradually reduce over time. If, on the other hand, BSE were actually found in one or more UK flocks, the risk estimates would increase. In the case of a single finding of BSE in sheep, statistically the most likely estimate of the number of affected flocks would be one, but the upper estimate⁶ of the number of flocks that could potentially be affected would increase from 3 to 4 flocks. BSE in sheep would also have become a real rather than just a possible risk. The risk would remain low relative to total human exposure to BSE since 1980, but could be much higher than the current very low risk from BSE in cattle.
17. As also explained in Annex C, given the estimate that BSE might currently be present undetected in up to 3 UK flocks, a single finding of BSE in sheep would not necessarily mean that the underlying risk from BSE in sheep had changed. However a finding of two outbreaks of BSE in sheep within a relatively short period with no apparent connection with each other could be an indication that the risk from BSE in sheep had increased. Finding three or more unconnected outbreaks within a similar period would cause real concern that such an increase had actually occurred. In either case the uncertainty around estimates of the possible number of affected flocks would also be increased. Findings of two or three (or more) apparently unconnected outbreaks of BSE in sheep would therefore progressively raise concern not only that the risk from BSE in sheep was increasing but also that the assumptions which underlie the current estimates of the possible scale of the problem were no longer valid.

⁵ the modelling indicates that, if a strategy which gave a 70% reduction in risk were adopted, the possible annual exposure from BSE in sheep could be up to values that range from 1/1,000th to 1/100,000th of the total human exposure from BSE in cattle since 1980. That level of annual exposure to BSE in sheep would be in the range of 500 to 50,000 times greater than recent (2001) exposure from cattle.

⁶ i.e. upper 95% confidence limit

Possible Additional Measures to Protect Consumers if BSE were found in UK Sheep

18. Given the high level of uncertainty, there is no firm basis on which to judge whether additional risk reduction measures would be needed if BSE were found in sheep and, if so, how precautionary they should be. A range of risk reduction policies, together with estimated costs and some of the practical implications, is at Annex D. The most effective policies are:

- removing more specified risk material (SRM), which would produce a risk reduction of around 70% at an annual cost of up to £50 million;
- excluding sheep aged over 12 months from the food supply and removing more SRM from the remaining sheep. This would achieve over 90% risk reduction, at an annual cost of around £113 million;
- allowing into the food supply only sheep that were either genetically resistant to BSE or semi-resistant and aged under 12 months. Such a policy would reduce risk by around 99% at an annual cost of around £435 million⁷⁸.

19. As noted in paragraph 4, the Board has agreed that, in the event of finding BSE in a single sheep in the current flock⁹, a policy of allowing into the food supply only sheep that were either genetically resistant to BSE, or semi-resistant and aged under 12 months (i.e. policy (c) above), would not be justified. The Board may nevertheless consider that additional measures to reduce risk in the event of a single finding of BSE in sheep should be recommended. The Board will note that either of the policies at (a) or (b) in paragraph 17 would provide a significant risk reduction. If the Board agrees that policy (a) (additional SRM) should be recommended in the event of a single outbreak of BSE in sheep, then policies (b) and (c) would provide a graduated response to increasing risk should BSE be found in a larger number of flocks. The Board will also note that, for the reasons outlined in paragraph 16, findings of BSE in two or three unconnected UK sheep flocks could provide appropriate trigger points for increasing the level of protection.

Recommendation

20. The Board is invited to **agree** that, on **current knowledge**, it would advise the following **graduated response** to one or more **findings of BSE** in the current UK sheep flock:

⁷ this would be an average annual cost over a period of seven years by which time it is assumed that the flock would have become fully resistant, thus removing the BSE risk. In principle the costs of the other options might continue indefinitely since they would have no effect on the level of BSE in the flock.

⁸ or £458 million if the additional SRM is removed from the animals allowed into the food supply (option 6 in Annex C)

⁹ i.e. not in a historical sample

- **one** finding of BSE in sheep - remove additional SRM;
- **two** findings of BSE in unrelated flocks - exclude sheep aged over 12 months from the food supply and remove the additional SRM from the remaining sheep;
- **three** findings of BSE in unrelated flocks - allow into the food supply only sheep that were either genetically resistant to BSE or semi-resistant and aged under 12 months and remove the additional SRM from those sheep¹⁰.

21. Decisions taken now on contingencies that may happen at some future time cannot of course remain fixed but must be kept under review in the light of changing circumstances. For example the genotype-based policy would not be viable if atypical scrapie were found to be a human health risk¹¹. The policy the Board now adopts would therefore need urgently to be confirmed should BSE ever be found in sheep. Any opportunity should also be taken, following a first finding of BSE in sheep, to look again, on the basis of the knowledge then available, at contingency action in the event that further positives are found.

Recommendation

22. The Board is invited to **agree** that its **contingency policy for a finding of BSE in sheep should be kept under review** and be **urgently reconfirmed** should BSE actually be found in a UK sheep.

Scope for Quicker and Cheaper Testing Regimes

23. Eight rapid tests are currently approved by the EU for testing for TSE in sheep and goats. Competition between tests is likely to drive unit test costs down. However, given the estimated cost differential between testing and removal of additional SRM, which provides a greater risk reduction (see Annex D), testing would need to become significantly cheaper before a risk-reduction policy based on testing would provide a cost-benefit comparable to additional SRM removal.

24. On the speed of testing, laboratories are able to provide test results early in the day following that on which the sample was taken. There is little scope for making the overall testing process any quicker while samples have to be transported to a

¹⁰ the genotype-based policy the Agency currently advises does not require the additional SRM to be removed. However a genotype-based policy plus removal of the additional SRM would be consistent with the graduated response to one or more findings of BSE in sheep recommended. Such an approach would increase the protection provided by a genotype-based strategy if it were established that there were some risk from “resistant” sheep. There is some though inconclusive evidence that this may be the case.

¹¹ because atypical scrapie shows a higher prevalence in those animals carrying the gene associated with BSE resistance. The genotype-based strategy considered to provide a high level of protection in respect of BSE in sheep would therefore make the UK flock more susceptible to atypical scrapie.

laboratory for testing. Even with a quicker test - and progress is being made in developing commercial TSE tests that are quicker and simpler to use - the time required for transfer of samples to the laboratory would delay the return of test results into the following day.

25. The development of “same day” testing would require a test that could be used at the abattoir. Such a test should ideally be capable of “real-time” testing on the slaughter line, in order to avoid the need for batch processing and retention of carcasses and other body parts of the tested animals pending test results¹². No test with that capability exists at present.

Stakeholder Views

26. The outcome of a stakeholder workshop held in June 2005 to consider risk reduction options has been reported to the Board previously (Board paper INT 05/11/01). A summary is at Annex E. Stakeholders’ overall conclusion was that there needed to be a thoughtful escalation of the response graduated on the number of BSE cases and whether they were indicative of a wider spread of the disease.

Handling Plan for a finding of a BSE Case in UK Sheep

27. A handling plan for a possible finding of BSE in a UK sheep is outlined in Annex F. The plan is intended to enable the Agency, having consulted SEAC, to provide advice to Government on the measures needed to protect consumers as soon as such a finding has been confirmed.

Advice to Consumers if BSE were found in UK Sheep

28. External communication on a finding of BSE in a UK sheep would need to be integrated with the handling plan. As outlined in Annex F, there would be three broad stages in the process of confirming and reacting to a finding of BSE in a UK sheep:
- Stage 1 – from notification of a possible finding of BSE up to confirmation, by multi-laboratory “ring trial”, that BSE had been found. During this stage the FSA would consider what its advice to Government would be if BSE were confirmed;
 - Stage 2 – following confirmation of BSE in sheep, the Agency would issue its advice to Government and the UK Government position would be established;

¹² which would in turn require systems for maintaining a linkage between the retained parts of tested animals and the test results and ensuring that only those from animals that test negative are released into the food supply.

- Stage 3 – it is likely that, following a finding of BSE in sheep, the European Commission would put measures in place to manage the risk to consumers on an EU-wide basis. The European Commission would play a key role during this phase, in consultation with the UK, other member states and the European Food Safety Authority, in agreeing a harmonised response. Legislation to implement the agreed policy would then be introduced.

29. The detail of the Agency's advice to consumers would depend on the context in which the advice was being given and the circumstances at the time. However, throughout the process, it will be crucial for communication to be clear, open, pro-active and timely to ensure that there is a measured and informed response to what could potentially be a serious situation.

Recommendation

30. The Board is invited to **comment** on the **outline handling plan** at Annex F and the **strategy for the external communications** that would be needed.

Board Action Required

31. The Board is invited to:

- **note** that, in the event of confirmation of BSE in a sheep, targeted testing of animals in the affected flock or flocks would be carried out to assist in determining the potential spread of the disease and whether it may have entered the food supply (paragraph 9).
- **agree** that an expert group be set up to advise on what additional surveillance should be put in place, if BSE were to be found in a UK sheep, to improve estimates of prevalence of BSE in UK sheep (paragraph 13).
- **agree** that, on current knowledge, it would advise the following graduated response to one or more findings of BSE in the current UK sheep flock:
 - one finding of BSE in sheep - remove additional SRM;
 - two findings of BSE in unrelated flocks - exclude sheep aged over 12 months from the food supply and remove the additional SRM from the remaining sheep;
 - three findings of BSE in unrelated flocks - allow into the food supply only sheep that were either genetically resistant to BSE or semi-resistant and aged under 12 months and remove the additional SRM from those sheep (paragraph 20).

- **agree** that its contingency policy for a finding of BSE in sheep should be kept under review and be urgently reconfirmed should BSE actually be found in a UK sheep (paragraph 22).
- **comment** on the outline handling plan at Annex F and the strategy for the external communication that would be needed (paragraph 30).

THE CONSEQUENCES OF DIAGNOSING BSE IN SHEEP

Statutory Requirements

- The EU TSE Regulation (999/2001) as amended sets out detailed provisions for control and eradication of TSE in sheep. The Transmissible Spongiform Encephalopathies (England) Regulations 2006 (and equivalent legislation in Scotland, Wales and N. Ireland) provide for the enforcement and administration of this legislation in the UK.
- When a TSE is suspected in a small ruminant, all other small ruminants on the holding or holdings concerned¹³ must be placed under movement restriction. Potentially infected animals are thereby prevented from moving into the food supply or to other flocks until subsequent action is completed.
- If TSE is confirmed, an inquiry must be carried out to identify:
 - all other small ruminants on the holding (including embryos, ova and last progeny of a female animal with the disease);
 - the possible origin of the disease and other holdings on which there are animals which may have been infected or exposed to the same feed or contamination source; and
 - movement of potentially contaminated feedingstuffs or other material that may have transmitted the TSE agent.
- If BSE is confirmed on the basis of molecular tests (this would precede final confirmation by mouse bioassay by 1-2 years), all the animals, embryos and ova identified by the inquiry must be killed and destroyed (as the animals will be under restriction, this need not be done immediately but can be phased e.g. if significant numbers require TSE testing).

Investigating the Source and Potential Spread of Disease

- The inquiry carried out when a TSE is confirmed requires an epidemiological investigation to be conducted. Such an investigation involves study of farm records and histories to attempt to identify how infection entered the flock. Possible scenarios would include purchase of infected sheep or, in the case of BSE, that feed had been contaminated.

¹³ which may be the holding on which the animal was present when TSE was suspected or, if that is not likely to be the holding where it could have been exposed, the holding of exposure, or both

- Should BSE be diagnosed, it will be important to attempt to identify the scale of infection within the affected flock, and whether or not it came from, or spread to, other flocks.
- The action required to do so will be dependent on individual circumstances such as:
 - the size of the affected flock;
 - whether the positive sheep was purchased or born in the flock;
 - if purchased, how long it had been in the flock, and the age at which it was purchased;
 - the genotype distribution of sheep within the flock;
 - whether sheep, especially those born at about the same time as the affected animal, and its parents and siblings, had been moved to other flocks, and were available for testing;
 - the history of the flock, e.g. whether sheep had been on a holding with cattle or likely to have been exposed to concentrate feed.
- Having investigated the chain of association to determine whether the focus should be on the affected flock, or flocks from which infection may have originated, and flocks to which it may have moved, animals will be culled, and, by law, a proportion would be tested.
- The purpose of the testing, which would be dependent on the epidemiological investigation and probable examination of genotype, would be:
 - (a) to determine when BSE may have entered the flock - depending on the age (birth group) of positive animals that were identified;
 - (b) possibly as a result of a) and the epidemiological investigation, identify how it entered the flock;
 - (c) determine whether it has spread within the flock, and/or to other flocks, again depending on genotype and management practices of the farmer;
 - (d) provide information on which an assessment of the likelihood of dispersal to further flocks or into the food chain may be based.

SUMMARY OF REQUIREMENTS FOR SHEEP IDENTIFICATION AND TRACING

1. Before 1 January 2001, sheep and goats did not need to be identified.
2. Between 1 January 2001 and February 2003, sheep and goats were required to be identified with a UK mark (eartag or tattoo) made up of the letters 'UK' followed by the flock mark (a 6-digit number that identifies the holding where the flock is kept), but no individual number.
3. From March 2003 to 9 July 2005, sheep and goats were required to be identified with a UK mark, made up of the letters 'UK' followed by the flock mark and an individual number, within 12 months of birth or before the animal was moved off its holding of birth, whichever happened first.
4. Sheep and goats born after 9 July 2005 must be identified with a single UK eartag (showing the flock mark and individual identification number) within six months of birth for intensively-reared animals or nine months of birth for extensively reared animals or before the animal is moved off its holding of birth, whichever happens first.
5. With effect from 9 July 2005, sheep and goats born before March 2003 that do not have an identification mark that complies with the current rules must be marked with a tag carrying an individual identification number before being moved off the holding where they are being kept.
6. Sheep and goats being moved from a holding which is not the holding of birth must be marked with another tag carrying the flock mark of the holding from which they are being moved. Alternatively the full identification number of the animal must be recorded on the movement document and holding register.
7. A movement document must be completed for all movements of sheep and goats between holdings. Sheep and goat keepers must keep a register that records all movements of such animals off or onto their holdings, which must include their flock marks (that most recently applied in the case of animals moved onto the holding) but in most circumstances not the individual number. Flock records must be retained for at least 6 years and movement documents for three years by the recipient keeper.
8. Movements of batches of sheep have had to be reported to the local authority since September 2001. Details are entered onto a database, the Animal Movements Licensing System. No details are available of sheep movements prior to September 2001.

RATIONALE FOR THE PROPOSED POINTS FOR ESCALATING THE RESPONSE IF BSE WERE FOUND IN ONE OR MORE UK SHEEP FLOCKS

1. As the Board is aware, the current estimate from the modelling work carried out by Professor Angela McLean's team is that BSE could be present undetected in up to 3 flocks in the UK. This estimate is on the basis that some 2483 TSE cases from 605 flocks from 1998 onwards have been analysed and none has yielded a BSE-like result. It assumes that the underlying level of BSE in sheep has not changed over the period 1998 – 2005. If BSE is not found, the estimate of the number of potentially BSE-affected flocks would slowly reduce over time as the number of flocks tested increases.
2. However, a consequence of finding BSE in sheep would be that the estimate for the maximum number of flocks that could be affected would increase. If one BSE case were found, the most likely estimate of the number of BSE-affected flocks would be 1 flock, but the estimate of the maximum number of flocks that could be harbouring BSE would rise, at present, on a conservative estimate, to around 4 flocks.
3. The corresponding estimates for the maximum number of flocks that could be harbouring BSE if cases were found in two or three flocks would at present, on a similar conservative basis, be around 6 flocks and 7 flocks respectively.
4. These figures continue to assume that BSE prevalence has remained unchanged since 1998. A finding of BSE in a single flock would be consistent with the current estimate that BSE could be present undetected in a small number of flocks in the UK. Such a finding could, as a result of the subsequent veterinary investigation, lead to a finding of cases of BSE in one or more additional flocks. However, if it was established that the cases found were a manifestation of a single outbreak of BSE in sheep then the fact that BSE had been found in more than one flock would not be an indication that the underlying prevalence of BSE in sheep had changed.
5. Finding BSE in two unrelated flocks within a relatively short period (i.e. say less than 6 months) would also not be inconsistent with an assumption that the underlying prevalence of BSE in sheep had not changed since 1998. However, given the large number of sheep with observable TSE tested up to now with a negative result, such a finding could indicate that incidence of BSE in sheep had started to rise at some time in the past. If that were the case, then the position could be that the potential risk to consumers that BSE in sheep might pose had increased. As, in that case, the assumption that the prevalence of BSE in sheep has remained unchanged would no longer be valid, the level of uncertainty

around estimates of the total number of flocks that could be affected would also substantially increase¹⁴.

6. For a similar reason, a finding of three or more separate outbreaks within a relatively short period would cause significant concern that BSE incidence in sheep had started to rise. In that case, it would be more likely that the actual level of risk was increasing and the uncertainty on the number of affected flocks would be further increased.

¹⁴ this is because, if the assumption that the underlying prevalence of BSE in sheep was unchanged over the period since 1998 were considered no longer valid, it would not be appropriate to use the number of flocks tested since 1998 as the basis for estimates of BSE prevalence. If for example it were considered that it would be more appropriate to use the annual number of flocks tested as the sample, that would be a much smaller number and the upper confidence limit for any estimate based on that sample would be higher.

ANNEX D

RISK REDUCTION STRATEGY	ESTIMATED AVERAGE ANNUAL COST	% RISK REDUCTION (approximate)	PRACTICALITIES
1. Exclude sheep aged over 12 months from the food supply <ul style="list-style-type: none"> • Current SRM applies 	£67m	60%	Ageing of sheep based on a dentition check which would be approximate. Impact on availability of mutton.
2. Remove more SRM <ul style="list-style-type: none"> • Current SRM applied to all animals • Add to SRM all thoracic viscera excluding the heart; all abdominal viscera; stomach contents; pre-crural fat; and all accessible lymph nodes 	Up to £50m	70%	Practical difficulties of removing all lymph nodes would be considerable (this option assumes 30% of lymph nodes are removed). However the intestine, which is practical to remove, is the biggest contributor. Would require increase in time and resources at cutting premises.
3. Test all sheep over 12 months <ul style="list-style-type: none"> • Test negative animals allowed into food supply 	£100m	60%	Ageing of sheep based on a dentition check which would be approximate. Would require considerable adjustment and add major burden to those abattoirs handling older sheep.
4. Exclude sheep aged over 12 months from the food supply <ul style="list-style-type: none"> • Remove the additional SRM from animals allowed into food supply 	£113m	91%	Combines option 1 with option 2. Practicalities of age cut-off as for option 1. Practicalities of SRM removal as for option 2.

5.	Allow into the food supply <ul style="list-style-type: none"> • Resistant sheep of all ages • Semi-resistant sheep under 12 months • Current SRM applies 	£435m	99%	Problems associated with lack of reliable system which could readily identify the sheep. There is no such universal system yet in place as there is with cattle. In the absence of that, there would be no alternative but to stop all sheep from entering the food supply, if this option were followed.
6.	Allow into the food supply <ul style="list-style-type: none"> • Resistant sheep of all ages • Semi-resistant sheep under 12 months • Remove the additional SRM from animals allowed into food chain 	£458	99%	Combines option 5 with option 2. Slightly greater risk reduction than option 2, at an additional cost of £23million per year.

Notes: Costs are provisional estimates only.
Costs for all options are equivalent annual economic costs.

SRM Controls

The following tissues are currently designated as SRM for sheep and goats and must be removed and destroyed:

- skull, including brain, eyes and tonsils, and spinal cord of animals over 12 months;
- spleen and ileum of animals of all ages.

These requirements apply to all member states and to all imports into the EU from other countries (with the exception of sheep or goats born, reared and slaughtered in 17 countries considered free of BSE).

Ageing of Sheep

In the absence of any system for individual registration and identification of sheep, measures that apply a cut-off at age 12 months depend on the use of dentition to determine the age of the animal. The timing of the eruption of the first permanent incisor provides an approximate means of determining whether or not an animal is over that age. According to the literature, the mean ages of earliest and latest eruption of the first permanent incisor in sheep are 11.5 months and 16.75 months respectively (median 14 months).

STAKEHOLDER WORKSHOP

1. At a workshop in June 2005, stakeholders were invited to contribute to the review of the Agency's current genotype based policy, its proportionality and consideration of the other risk management options considered by the Board in December 2004. The event was advertised on the FSA's website and over 90 stakeholders were individually invited. The 28 stakeholders who attended the workshop represented a wide range of interests including consumers, industry (farming and breeding interests), processing and retail. In order to inform discussions on proportionality, presentations were given on risk reduction, costs and practicalities of the options considered by the Board.
2. The consensus of those who attended the workshop was that:
 - In the event of a single finding of BSE in sheep, the affected flock should be culled and surveillance testing increased across the country to determine if the case were an isolated one. One stakeholder (the Human BSE Foundation) considered that a single case was enough to trigger the introduction of additional specified risk material controls. Other Stakeholders considered that, even in the event of a single finding, the Agency needed to communicate the risks clearly and that this would have an impact on what further controls were necessary.
 - A handful of cases would trigger the consideration of further measures such as additional specified risk material (SRM) controls and that the geographical and temporal spread of cases would be important factors in determining what further actions would be required.
 - That the options of TSE testing animals over 12 months or the removal of animals over 12 months from the food supply were not sufficiently effective in terms of risk reduction and so should be discounted.
 - That overall there needed to be a thoughtful escalation of the response graduated on the number of BSE cases and whether they were indicative of a wider spread of the disease.

HANDLING PLAN FOR A FINDING OF A BSE CASE IN UK SHEEP***Timescale for Identifying a Possible Finding of BSE in Sheep***

1. Laboratory testing for confirming the presence of TSE and investigating the possible presence of BSE in sheep and goats is carried out within a framework of EU rules, which are specified in detail in EU legislation.
2. Under these rules, samples from animals that are suspected of having a TSE or have received a positive result from a rapid test must undergo confirmatory testing. Where the confirmatory test is positive, the animal is regarded as a positive scrapie case and the sample must be subject to further examination using discriminatory tests. The discriminatory testing potentially comprises three phases:
 - (a) primary molecular testing – for a UK sample this would be carried out by the Veterinary Laboratories Agency (VLA);
 - (b) samples in which the presence of BSE cannot be excluded by the primary molecular testing must then be forwarded to three laboratories (one of which is the VLA, the other two being French) where they must be submitted to a “ring trial” using at least three further molecular tests. The results must be interpreted by the Community Reference Laboratory (the VLA) assisted by an expert group;
 - (c) samples must then be further analysed by a mouse bioassay for final confirmation (whether the results of the ring trial were indicative for BSE or inconclusive).
3. Prior warning of a possible finding of BSE in a UK sheep would be given at the first stage of discriminatory testing (phase (a) above) in a case where BSE could not be excluded by the primary molecular test. At that point the VLA would formally seek clearance from UK Government to put the sample into the ring trial. There would then be a period of up to two weeks while the ring trial is undertaken and the expert group reaches a conclusion on the results. The European Commission must formally be informed immediately of the group’s interpretation but, for a UK case, UK Government would be informed at the same time.

Action while the Ring Trial is taking Place

4. As noted above, following notification by VLA of a possible case of BSE in sheep there would be a short intervening period until the expert group’s interpretation of the outcome of the ring trial is communicated. Such a period would provide an opportunity for the Board to consider what its advice on the measures necessary to protect health would be should the panel conclude that the result is indicative

for BSE. The Agency would then be in a position to advise Government as soon as the outcome of the ring trial is known.

5. In order to achieve this, as soon as possible following a notification by VLA of a possible BSE case, a meeting of SEAC would be convened to advise, on the basis of the knowledge then available, on the possible significance of the result and the potential risk to consumers were the results of the ring trial be indicative of BSE. At the same time, arrangements would be made for a meeting of the FSA Board, to take place shortly after the SEAC meeting. At that meeting, the Board would consider the advice from SEAC and decide what its advice to Government would be in those circumstances.

Action Following the Announcement of the Result of the Ring Trial

6. The action that would follow would depend on the expert group's interpretation of the results of the ring trial. If the group were to conclude that the sample could conclusively be classified as BSE in sheep, then the Agency would be in a position immediately to advise Government as to its advice to consumers on the safety of sheepmeat and sheep products and what further measures were needed to protect consumers. In those circumstances, the European Commission could be expected urgently to consult the European Food Safety Authority (EFSA) and, depending on EFSA's advice, to propose action to manage the risk at EU level. In that case, the Agency's advice would shape the UK Government's position in the discussions on the Commission's proposals that would follow. Any additional measures needed to protect consumers as a result of a finding of BSE in sheep would require EU legislation.
7. The expert group might however advise that the sample could not conclusively be classified as BSE in sheep and that further investigation by bioassay was warranted. In that event the question of whether additional risk-management measures should be taken on a precautionary basis pending the results from the bioassay would need to be considered. In those circumstances SEAC would need urgently to be reconvened to provide expert advice on how far the results of the ring trial had increased the likelihood that BSE might be present in sheep. The expert group's interpretation of how closely those results matched expectations for a BSE-like result would be a key element in SEAC's consideration.