FSA 04/12/04 **AGENDA ITEM 6, 9 DECEMBER 2004**

BSE AND SHEEP CONTINGENCY POLICY

Executive summary

1. This report considers the approach the Agency would take to a finding of BSE in UK sheep or goats, with present knowledge. A number of possible risk management options are explored ranging from the current FSA policy of allowing only resistant and semi-resistant sheep under 12 months into the food chain, removing all sheep above a certain age, extending the list of specified risk material and introducing testing in abattoirs. Provisional costs and an indication of risk reduction are presented for these risk management options.

2. The Board is invited to **agree**:

   - That it remains the FSA's policy, in the event of a finding of BSE in UK sheep, and with current SRM controls continuing to apply, and subject to any overarching EU measures being introduced, to recommend that only resistant and semi-resistant sheep under 12 months could enter the food chain.
   - That in the event of a finding of BSE in a UK goat, we would follow the approach being taken at EU level in relation to a possible finding of BSE in a French goat.
   - That a stakeholder process be initiated with the aim of seeking views on the current contingency plans and other alternatives, in relation to sheep and goats.
   - That the outcome of the consultation process be fed back to the Board with the aim of completing the current contingency planning policy review by autumn 2005.

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BSE AND SHEEP CONTINGENCY POLICY

Issue

1. To consider the current FSA policy on action necessary in the event of a finding of BSE in sheep in the UK flock.

Strategic aim

2. Links to the Agency's aims to ensure BSE controls are based on latest scientific knowledge and are effectively enforced

Background

Scrapie and BSE in sheep and goats

3. Scrapie is one of a group of diseases known as transmissible spongiform encephalopathies (TSEs) which also includes BSE and CJD. Scrapie is known to have been present in UK sheep for at least 250 years and is not considered to be a risk to human health.

4. BSE was spread to many cattle through the practice of including meat and bone meal (MBM), prepared from rendered carcasses, in cattle feed. The expert view is that the consumption of BSE infected meat or meat products is the cause of vCJD from which 146 people have died to date in the UK.

5. The same MBM was included in sheep and goat feed and therefore there is a risk that some UK sheep and goats may have been infected with BSE. We do not know if BSE has got into the UK sheep or goat populations, but if so, only a small number of sheep and goats could be affected (see paragraph 23).

6. No cases of BSE in sheep or goats have been found to date in the UK. However the European Commission have reported a possible case of BSE in a French goat slaughtered in October 2002 (see paragraphs 19 and 20). Sheep and goats have been experimentally infected with BSE, which has demonstrated similarities between scrapie and BSE, including that the two diseases cannot be distinguished by their symptoms. Therefore a differential diagnosis of scrapie or BSE has to rely on laboratory tests.

7. The risk to consumers from any cattle infected with BSE is reduced to very low levels, in particular through the removal and destruction of specified risk material (SRM). SRM includes all those tissues that have been shown by experimental analysis to carry BSE infectivity in cattle. Because these tissues are limited, it is practical for them to be removed whilst still leaving the main carcass available for consumption. It has been estimated that in cattle over 99% of infectivity in an infected animal will be removed as SRM.

8. By contrast, in experimentally infected sheep, BSE infectivity is found in many different tissues as the disease progresses. SRM are currently removed from sheep and goats as a precautionary measure against the possibility of BSE being present. However it would not be proportionate to remove all potentially infected tissues as a precautionary measure. Under the current controls it has been estimated that the infectivity that could enter the food chain from a single sheep of the most susceptible genotype with clinical BSE, could be over a thousand times that from a cow with clinical BSE. The FSA has concluded that should BSE be found in the sheep flock, additional measures beyond the current SRM controls would be necessary.

June 2002 Board Conclusions

9. In 2002, a core stakeholder group, together with scientific experts, discussed the action that would need to be taken if BSE were found in the UK flock. The current policy is based on the situation in 2002 as defined in paper FSA 02/06/02. This essentially restricts sheep and goat meat and dairy products entering the food chain to those from animals with a genetic resistance to TSEs. For sheep this has been interpreted as meaning fully resistant animals of any age and semi-resistant animals under 12 months. To date no resistant genotype has been found in goats and therefore all goat meat and milk would need to be kept out of the food chain under this policy. It was also recognised that, at that time, almost no UK sheep could reliably be identified as being of the appropriate genotype.

Testing for scrapie and BSE

10. Currently, under EU legislation, all sheep or goats that are suspected of having scrapie must be reported and their brains tested to see if they have a TSE. In addition a minimum number of animals must be tested to provide data on scrapie

prevalence. A positive test result demonstrates that the animal is suffering from a TSE. However the basic tests used do not distinguish between scrapie and BSE.

11. A number of laboratories have now developed rapid tests that are capable of distinguishing between the BSE samples obtained from experimentally infected sheep and known scrapie samples. One of these has been applied to all available TSE positive GB sheep samples from 1998 onwards, and is applied to all new positive samples. BSE has never been demonstrated in the UK sheep flock, but the results of this testing have been used to estimate the possible hypothetical maximum level (see paragraph 23). More detail on testing is given in Annex A.

12. At their meeting in September SEAC 'acknowledged that the testing to distinguish BSE from scrapie is becoming more robust'. However there is still some uncertainty surrounding these tests as none has been shown beyond all doubt to differentiate BSE from scrapie, but work is on going.

13. Increasing the testing of sheep and goats is one possible risk management option that is considered below (see paragraph 30).

Genotyping and the NSP

14. For a number of years it has been clearly recognised that sheep vary in their susceptibility to scrapie. In the UK, the National Scrapie Plan (NSP and NISP in NI) developed by rural affairs Departments has been working towards an increase in the level of the resistant genotypes in the national flock whilst decreasing the level of those most susceptible to scrapie. To date over 1 million sheep have been genotyped, mainly in the flocks at the top of the breeding pyramid. The ultimate objective is to eliminate TSEs from the flock, which would benefit both animal health and protect the consumer, should BSE be in sheep. Defra are working to reduce scrapie incidence by 40% by 2010, but total elimination may take 20 years or more. A voluntary scheme has been in place for over 4 years but will be replaced with a compulsory EU scheme from 1 April 2005.

15. Restricting sheep that may enter the food supply based on their genotype and age is one possible risk management option that is considered below (see paragraph 27). Further details on genotyping are given in Annex B.

SRM controls

16. In the UK SRM controls have been applied to sheep and goats as a precaution against the possibility that they may be infected with BSE since 1996. However, as noted in paragraph 8, these do not remove all the tissues that have been shown to carry infectivity. One risk management option that is considered (see paragraph 29 below) is to increase the number of tissues that are included as SRM and/or the age at which the controls are applied.

EU Position

EU law

17. TSEs are not exclusively a UK problem. Scrapie is endemic in many EU countries and, with the exception of Sweden and 4 accession states, all member states have experienced at least one case of BSE in cattle. The EC has enacted legislation directly applicable in all member states (EC999/2001 and amendments) to regulate the handling and surveillance of cattle, sheep and goats with regard to BSE and scrapie. However this does not yet include any action to be taken outside the source farm, in the event of a possible finding of BSE in sheep or goats. A first phase, which is currently under negotiation, will cover the process to be followed to identify a case of BSE. Any TSE sample from a sheep or goat, in any member state, that has any similarities to BSE will be subjected to all the tests in the ring trial (see Annex A), with an expert panel organised by the Community Reference Laboratory meeting to agree the result.

18. The action to be taken following a result that is determined to be 'BSE-like' has not yet been agreed. Commission officials in bilateral discussions have indicated their concern about any member state taking unilateral action either for a sheep or goat with BSE in their country, or against another member state with such a case. The FSA legal view is that unilateral action under the EU 'safeguard' procedures could only be taken if there were considered to be an immediate risk not contemplated by the current rules.

French goat with possible BSE

19. The EC have recently reported that a French goat slaughtered in 2002 might have BSE. An expert group considered the results of a number of tests that have been carried out on samples from this animal. On November 26 2004 the

Commission reported that further work was necessary before the group could come to a conclusion as to whether the test results were indicative of BSE. This work is expected to take approximately two months. Some 140,000 goats have been TSE tested since April 2002 in the EU with 111 found positive for TSE infection by screening test. No other goats have been reported as possibly having BSE.

20. An Opinion from the European Food Safety Authority (EFSA) in November 2004 has concluded that, while there is a paucity of experimental data, the milk and cheese from goats are unlikely to pose a TSE risk if taken from an animal without clinical BSE infection. In the meantime member states will be meeting with the Commission to consider possible risk management options should this goat eventually be confirmed as probable BSE. The FSA is consulting stakeholders on this point.

Contingency planning

21. Defra have published an overarching contingency plan covering the action that would need to be taken in the UK if BSE was found in sheep. It is based on the current FSA policy of allowing only known genetically resistant or semi-resistant sheep with an age cut -off into the food supply. The EU requires that each member state draw up such a plan based on similar worst case planning assumptions. This advice is likely to be considered further by EFSA perhaps leading to an EU contingency plan being drawn up. It is stressed in the opening section of the Defra plan that it is a "living document" which will be subject to changes in the light of developments and emerging science.

Developments Since 2002

Estimate of possible BSE prevalence

22. VLA have now applied their molecular test to differentiate BSE from scrapie to a total of 2147 samples from sheep TSE cases which have come from 450 different flocks. None has given a BSE-like result. This work was presented to SEAC in September 2004[3] who cautioned that the absence of a BSE-like result cannot be considered to be the final word. This is because of the limitations on the test

[3] See attached SEAC notes at Annex D

methodology and the relatively small number of samples.

23. These results – if taken to demonstrate an absence of BSE - can be used to estimate the maximum proportion of sheep TSE cases that could be BSE. Based on SEAC recommendations the estimate is based on the number of flocks, not the number of sheep where a TSE case has tested negative for BSE. The resulting estimate is that the proportion of TSE cases that could possibly be BSE is in the range 0 - 0.66% (95% confidence interval). With over 77,000 flocks in GB in 2003 a maximum estimate of 0.66% translates into some 4 to 5 flocks with possible BSE cases. From this it can also be estimated that if BSE were in the GB sheep flock the maximum number of sheep that might be infected with BSE (as distinct from BSE cases), would be over 700 in a flock of some 33 million sheep and lambs. In 2002 an estimate of a range of between 0 and 2% for the proportion of sheep TSE cases that could be BSE was obtained, based on the negative results for the mouse bioassay of approximately 200 TSE positive samples.

24. Modelling work, based on these 2004 calculations, has been carried out by Dr. Angela McLean's team at Oxford to estimate the effect of a number of potential risk management measures. The results are summarised in Annex C. There are limited data to underpin this study. However SEAC[3] noted that 'the estimate of infectivity entering the food chain from a sheep with clinical BSE suggested this could present a significantly greater risk than a cow with clinical BSE'. They also agreed that, 'although there was no evidence of a large, self-sustaining epidemic of BSE in sheep, the model suggests that the presence of small epidemics in a few flocks cannot yet be ruled out'. A summary of SEAC deliberations on this subject is at Annex D.

25. As part the contingency planning exercise the FSA's Economics team have calculated the financial costs of implementing various risk management options based on Defra cost estimates. These are also given in Annex C.

Options

26. As can be seen from Annex C, the possibilities for action in the event of a finding of BSE in sheep include allowing only resistant and semi-resistant animals under

12 months into the foodchain, removing all sheep above a certain age, extending the list of SRM and introducing testing at abattoirs.

27. The most effective risk management option in terms of risk reduction is to allow only resistant and semi-resistant sheep into the foodchain, in line with the current FSA policy endorsed by the Board in 2002 and the EU guidelines for contingency planning.

28. Unlike cattle, sheep do not have a universal tracking system in place, such as ear tagging and passports, which would allow for individual identification. However a flock register scheme is due to be introduced in 2005 . In addition, there is an EU plan for the introduction of compulsory electronic identification from 2008 for all sheep over 12 months of age but this is some way off, and in any case will not apply to the majority of sheep entering the food chain which are under 12 months of age.

29. Additional across-the-board SRM controls are a possibility but the practical difficulties of removing all lymph nodes, which are distributed through out the carcase, would be considerable. Extension of the SRM controls to other tissues arguably would not add sufficiently to the risk benefit to be worthwhile, except perhaps if intestine were to be singled out.

30. Testing animals over 12 months would also not appear to reduce risk sufficiently and would be dependent on the acceptability of the current screening tests, which have yet to be fully validated for sheep and goats.

31. The most straightforward practical step, though draconian in its immediate implications, remains that of stopping UK sheep from entry into the food chain unless demonstrably of the resistant or semi-resistant genotype. In the event of a BSE finding, and based on earlier FSA advice, Defra currently envisage that in a worst case scenario the entire lamb crop for one breeding season could be lost. Only fully resistant rams would then be used in breeding to confer semi resistant status on the lambs that would be produced in the following year's crop. A whole raft of enforcement issues would then arise, associated with implementing a workable manifestation of this policy, which we understand Defra are currently scoping.

32. In the future, should a larger sample of animals on testing be found negative for BSE, the Agency could then determine that prevalence and risk was low enough at that time for voluntary options to be considered. These could include advising that there is now a demonstrable small risk of BSE associated with eating sheep meat, such that consumers could, in effect, decide for themselves

33. The Agency's approach needs to be proportionate as knowledge in this area develops. Although there are increasing numbers of TSE positive sheep testing negative for BSE, there is still the possibility of a small number of BSE infected sheep flocks where the infectious load entering the food chain from just one clinical BSE infected sheep, as mentioned earlier, would be over a thousand times that of a similar cow.

34. In order to seek wider views, it is proposed that a stakeholder process be initiated. The aim would be to seek their views on the current FSA contingency planning policy and strategies given in Annex C, as well as possible combinations of options generated by the modelling work on potential risk management measures (see paragraph 24). Stakeholder views on the possible interventions and their proportionality would inform the Agency's assessment of future risk management options which would be reported back to the Board in 2005. In the meantime it is recommended that the Agency's contingency policy remain based on genotype and age cut-off.

35 The Board is invited to **agree**:

- That it remains the FSA's policy, in the event of a finding of BSE in UK sheep, and with current SRM controls continuing to apply, and subject to any overarching EU measures being introduced, to recommend that only resistant and semi-resistant sheep under 12 months could enter the food chain.
- That in the event of a finding of BSE in a UK goat, we would follow the approach being taken at EU level in relation to a possible finding of BSE in a French goat.
- That a stakeholder process be initiated with the aim of seeking views on the current contingency plans and other alternatives, in relation to sheep and goats.
- That the outcome of the consultation process be fed back to the Board with the aim of completing the current contingency planning policy review by Autumn 2005.

ANNEX A

TSE Testing Of Sheep And Goats

1. Under EU law all sheep or goats that are suspected of having scrapie must be reported. These are required to be slaughtered and their brains tested to see if they have a TSE. In addition a minimum number of animals over 18 months of age must be tested to provide data on scrapie prevalence. In the UK the required sample size has varied, but is currently set at 10,000 sheep slaughtered for human consumption and 10,000 sheep and 500 goats that are fallen stock (found dead on farm) per annum. The results for 2003 and 2004 to date are shown in the Table below.

2. A positive test result demonstrates that the animal is suffering from a TSE as the basic tests used do not distinguish between scrapie and BSE.

Testing for BSE

3. A number of laboratories have now developed rapid tests that are capable of distinguishing between the BSE samples obtained from experimentally infected sheep and known scrapie samples. The BSE samples include sheep that have been infected directly from cattle brain, and those that have been secondarily infected with brain from these first sheep. This is an experimental model simulating the fact that if BSE were to be found in the flock now, it would have to have been passed on (in the same way that scrapie is passed on) to the sheep alive today from those that ate the contaminated MBM before 1996, when a reinforced feed ban was introduced.

4. In the UK two different tests which distinguish between BSE and scrapie have been developed by staff at the Veterinary Laboratories Agency (VLA). One of these has been applied to all available TSE positive GB sheep samples from 1998 onwards, and is applied to all new positive samples. The results of this testing have been used to calculate the possible maximum level of BSE in the GB flock. (see paragraph 23 in the main text) In Northern Ireland differential testing for BSE and scrapie has been carried out on all TSE positive samples since 2001.

Ring trial

5. As well as the UK developed tests there have also been three similar molecular tests developed in France. These five tests have been evaluated in a ring trial process – where designated laboratories all test the same samples and compare

their results thus providing assurance on their reliability. All of the tests were found to correctly identify the same scrapie and BSE samples. Work is in progress to include a further test, which is based on a different principle (the conformation-dependent immunoassay, developed in the US). The Government's TSE advisory committee (SEAC) have recently stressed the importance of the inclusion of this further test in the ring trial as it does not rely on a process common to the other tests.

Atypical scrapie

6. As previously reported (April 2004) the UK recently identified two sheep samples that initially showed BSE-like properties. The conclusion was that, whilst these were not typical of 'normal' scrapie, neither did they resemble BSE in sheep, at least as the profile is understood from experimental work.

Anomalous test results

7. Another testing anomaly that has been reported by several member states, including the UK, are the samples that are positive by the rapid test used for surveillance, but which were initially negative by the further tests used to confirm the result. Further testing has shown that these animals do have some form of abnormal prion[1] in their brains and are therefore now confirmed positive. Active research into these samples is continuing.

Mouse bioassay

8. Prior to the development of molecular test methods BSE could only be differentiated from scrapie by inoculating the material into mice and looking at the pattern of disease in their brains and the susceptibility of specific mouse strains. This is still regarded as a robust method for identifying BSE. However this process takes several years. Genetically altered mice that come down with disease more rapidly are now available, but testing still takes many months. Work is underway in preparation for putting the atypical samples (paragraph 6 above) into mouse bioassay.

[1] The prion is the protein in the brain that is changed when an animal is suffering from a TSE

Results for scrapie testing the UK for 2003 and 2004

	Tested in 2003	Confirmed Positive	Tested in 2004	Confirmed Positive
Scrapie suspects - sheep	553	440	3,789[a]	239
Abattoir survey - sheep	72,518	46	10,278	6
Fallen stock survey - sheep	5,126	13	4,432	5
Abattoir survey - goats	191	1	12[b]	0
Fallen stock survey - goats	54	0	42	0

[a] In 2004 this total includes the additional animals culled and tested under the voluntary scrapie affected flocks scheme.
[b] Currently not a legal requirement

ANNEX B

Genotyping and the NSP

Genetic resistance to TSEs

1. For a number of years it has been clearly recognised that sheep vary in their susceptibility to scrapie. It is now known that the most resistant genotype may not be fully resistant to all types of TSE. To date 3 of 19 experimental animals of the most resistant type have come down with BSE when it was injected into their brains, but none of 8 fed BSE have shown any signs of disease. In addition some of the 'anomalous' sheep (Annex A, paragraph 7) are of this genotype.

The NSP

2. In the UK the National Scrapie Plan (NSP and NISP in NI) developed by rural affairs Departments has been working towards an increase in the level of the resistant genotypes in the national flock, whilst decreasing the level of those most susceptible to scrapie. Given the results above, the validity of selecting for the resistant genotypes, has been considered by the EFSA experts. They concluded 'that increasing genetic resistance may decrease the incidence of clinical disease. However it is possible that a 'carrier state' may exist in these sheep'[2]. To date over 1 million sheep have been genotyped, mainly in the flocks at the top of the breeding pyramid. The ultimate objective is to eliminate TSEs from the flock, which would benefit both animal health, and protect the consumer should BSE be in sheep. Defra are working to reduce scrapie incidence by 40% by 2010, but total elimination may take 20 years or more. The effect on BSE, should it be present, will depend on the uptake and the rate at which the most BSE susceptible genotype can be decreased. A voluntary scheme has been in place for over 4 years but will be replaced with a compulsory EU scheme from 1 April 2005.

3. The genotyping program has progressed such that some 30% of genotyped rams are now of the resistant genotype, which can be used to sire lambs that are at least semi-resistant (currently estimated to be 74% of lambs entering the food chain). But if BSE were found in sheep these would not be eligible to enter the food chain under current FSA advice unless they could be positively identified, either on an individual basis (as for cattle) or as belonging to a particular flock.

[2] The EFSA Journal, 2003

4. A voluntary flock register scheme to recognise their TSE resistance has been proposed by the EU. This will recognise flocks where rams (and possibly ewes) have been genotyped under the NSP, and is due to be launched in 2005.

Compulsory Scrapie flocks scheme

5. EU legislation has recently introduced the requirement to cull or genotype herds confirmed to have scrapie so as to retain the most resistant genotypes. However this can only be applied for known scrapie cases and where the flock can be identified.

ANNEX C

STRATEGIES	EST. AVERAGE ANNUAL COST £	RISK REDUCTION	PRACTICALITIES
1. To allow into the food chain: • resistant sheep of all ages •semi resistant sheep of under 12 months •Current SRM applies	£480m	Very High	This is the FSA's stated favoured policy from 2002. The problem here is one of having a reliable system in place which could readily identify the sheep. There is no such universal system yet in place, such as ear tagging and passports for individual animals, as with cattle. In the absence of that, there would be no alternative but to stop all sheep from entering the food chain, if this option were followed.
2. Remove all sheep over 12 months • Current SRM applies	£90m (ewes only)	Low	More straightforward (though ageing a sheep can only ever be approximate).
3. Remove more SRM • Current SRM applied to all animals • Max. option add intestine, lymph nodes, liver, stomach and thymus to SRM	£20m - £60m	High	Practical difficulties of removing lymph nodes would be considerable. However the intestine, which is practical to remove, is the biggest contributor. Would require increase in time and resources at cutting premises.
4. Test all sheep over 12 months • -ve allowed into food chain	£100m (cull ewes)	Low	More straightforward (though ageing a sheep can only ever be approximate). Would require considerable adjustment and add major burden to those abattoir handling older sheep.

Notes: Costs are provisional estimates only.
Risk reduction categories: Very High: 100-91%, High: 90 – 76%, Medium 75 – 41%, Low below 40%
Costs for Options 1, 2 & 4 are equivalent annual economic costs. The cost for option 3 is an annual cost.

Dairy products

Unlike cattle, in sheep the lymph nodes of susceptible sheep carry BSE infectivity and lymphocytes are found in milk. However some experiments injecting milk from infected sheep/goats into mice have been done and not shown infectivity, but the data are limited. Given this uncertainty, sheep and goat milk and dairy products are included in the current FSA advice on a precautionary basis.

They are not included in the table above, but in 2002 the value of this industry was estimated to be over £16 million. However, the full economic impact will be limited as the cheese industry is likely to be able to find alternative inputs or import supplies to continue production. Furthermore, substitute products will gain (such as cow's milk and soya milk as well as imports), thus producing an offsetting benefit.

SRM controls

The following tissues are currently designated as SRM for sheep and goats and must be removed and destroyed:
The skull, including brain, eyes and tonsils, and the spinal cord of animals over 12 months;
The 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).

ANNEX D

Summary of SEAC discussion on BSE & sheep: the FSA contingency policy

The Spongiform Encephalopathy Advisory Committee (SEAC) was provided with background information on the analytical techniques used to detect and discriminate BSE and scrapie in sheep samples, and the preliminary results from an on-going ring-trial comparing the analytical methods used by different research groups.

SEAC was also presented with the findings from two studies modelling the:

- maximum number of sheep that could potentially be infected with BSE in the GB sheep flock based on testing results from retrospective and prospective surveillance of TSEs in sheep (Simon Gubbins; VLA);

- Potential BSE infectivity in sheep together with strategies to reduce the risk of BSE infectivity entering the food chain based on a) the relative susceptibilities of sheep genotypes to BSE infection, b) removal of specified risk materials or c) TSE testing (Angela McClean, Oxford).

TSE test methods

SEAC noted that the analytical methods used to detect TSEs in sheep, and distinguish BSE from scrapie, were becoming more robust. A combination of tests now provides a reasonably rigorous, although not completely unambiguous, approach to distinguishing conventional scrapie from conventional BSE in sheep. The results from the on-going ring-trial will be important to assess more fully the robustness of the methods. It was considered important to analyse final data from the conformation-dependent immunoassay (CDI) method in the ring-trial because, unlike all the other methods used, it does not rely on differential enzyme (Proteinase K) digestion of the prion protein (PrP). Thus, it could be an important and possibly powerful additional discriminatory test.

SEAC considered that, using the currently available tests, the vast majority of the TSE's detected in sheep in prospective and retrospective surveys were likely to be scrapie and not BSE. Furthermore, no unambiguous case of BSE in sheep has yet

been detected. Nevertheless, because of limitations in methodology and the number of samples tested this conclusion cannot be considered certain.

SEAC noted that two surveillance samples had given atypical test results that were inconsistent with the criteria used to define either BSE in sheep or scrapie infection. It was considered possible that these two atypical TSE test results could indicate the presence of a variant form of scrapie, a variant form of BSE, another as yet uncharacterised TSE, or reflect a modifying effect of a particular sheep genotype. It was noted that tests of orally transmitted and passaged BSE in all sheep genotypes had not yet been conducted. The committee agreed it was very important to conduct more research to try to establish the nature of these samples and particular urgency should be given to in vivo infectivity studies.

Possible prevalence of BSE in sheep

SEAC generally accepted the approach used to model the possible prevalence of BSE in sheep. However, it was noted that the model depended on the ability of the tests used to effectively detect and discriminate between scrapie and BSE and current tests were not yet 100% reliable (see above).

Perhaps more significantly, SEAC considered that, because many of the samples included in the surveillance had come from farms with a large number of scrapie cases, which may be more likely to report scrapie cases, the data may have been influenced by a selective ascertainment bias. It was agreed that basing the calculation of the prevalence of BSE in sheep on TSE affected flocks, rather TSE cases, was preferable. Nevertheless, even if only flocks are considered, the effect of non-random sampling may have led to an underestimation of the number of potential BSE cases. It was suggested that that if the modelling was restricted to the results obtained from active surveillance the bias could be minimised, although such an analysis would significantly reduce the data that could be included in the model. Additionally, it was suggested that data from a 2002 scrapie postal survey, relating to the distribution of cases on scrapie affected farms, could be compared with the passive surveillance data in order to assess the possible effect of the sample bias.

Impact of risk reduction strategies

SEAC generally accepted the modelling approach used and acknowledged that it was extremely difficult to estimate the potential BSE infectivity entering the food

chain from tissues of infected sheep. The committee noted that the model of BSE infectivity in sheep was based on a large number of assumptions. For example, the model assumed that the pathogenesis of BSE and scrapie in sheep may be similar, yet this is still largely unknown. In addition, although ARR homozygous sheep appear to be the most resistant PrP genotype, sheep of this genotype could not now be considered to be completely resistant to TSE infection. SEAC noted that, in contrast to the assumptions made in the modelling, sheep breeds were heterogeneous and methods of husbandry differed considerably between farms. Also, it may not be appropriate to generalise about the prevalence and distribution of PrP genotypes in sheep because PrP genotype can extremely variable between different sheep breeds.

It was noted that estimates used for the quantity of sheep tissues entering the food chain differed from values used by other research groups. In addition, the effective removal of lymph nodes was considered unrealistic.

Bearing in mind these assumptions and caveats, SEAC noted that:

- the model of BSE infectivity in sheep tissues suggested that a single BSE infected sheep entering the food chain could present a significantly greater risk to public health compared with the current risk associated from a single infected cow;

- although there was no evidence of a large self-sustaining epidemic of BSE in sheep, the model suggests that the presence of small epidemics in a few flocks cannot yet be ruled out;

- the models suggest that strategies based on control of specified risk material or TSE testing are currently unlikely to be very effective in minimising risk of human infection. The committee considered that should the sensitivity of TSE tests be improved they may be effective in the future.

- the model suggests that strategies based on the PrP genotype of sheep would be the most effective in reducing risk of human infection. However, the committee stressed that the magnitude of the relative reductions in risk between the various strategies modelled could not be regarded as absolute.

SEAC Secretariat 11 October 2004