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17 February 1989

En En.

Following our Ministers meeting with Sir Richard Southwood on 14 February, at which the CMO and Dr Hilary Pickles were present, I have prepared the attached draft note for MISC 138, together with a Q&A brief. I should be very grateful for your comments by lunchtime Monday 20 February if possible. I know that Hilary Pickles is already working on the section of the Q&A brief relating to medicines. We are separately seeking Sir Richard Southwood's clearance for the references to him in the papers, and for several of the individual Q&As.

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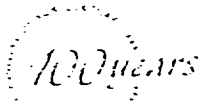
I am copying this to George Thomson, DAFS, Roger ~~BOILINGTON~~ WOAD and Rutherford Armstrong, DANI. I should be very grateful if all recipients would bear in mind Ministers' concern that publication of the report should be handled in an orderly way; could circulation of copies of this material therefore be limited strictly to those who have a clear and immediate need to see them.

Yours sincerely,

A R Cruickshank

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P.S. I understand Hilary Pickles has some comments on the Q&A brief. He has some suggestions for improvement. I shall incorporate these in the final version.



89/02.17/5.1

CONFIDENTIAL

SOUTHWOOD REPORT ON BOVINE SPONGIFORM ENCEPHALOPATHY (BSE)

NOTE FOR MISC 138

BACKGROUND

1. BSE is a recently identified neurological disorder of cattle, which is ultimately fatal. It is one of a group of degenerative diseases of the central nervous system, which includes scrapie in sheep and Creutzfeldt Jakob Disease (CJD) in humans.

2. In April 1988 the Government announced the establishment of a Working Party, chaired by Sir Richard Southwood, Professor of Zoology at Oxford University, to examine the implications of BSE in relation to both animal health and any possibly human health hazards and to advise on any necessary measures. The final text of the Report was presented to the Minister of Agriculture, Fisheries and Food and the Secretary of State for Health on 9 February.

FEED BAN

3. Research studies show that the most likely cause of the disease was the feeding to calves of animal protein (meat meal and bone meal) derived from ruminants, including scrapie affected sheep. This practice was therefore banned from 18 July 1988. The Working Party has welcomed this action.

INTERIM RECOMMENDATIONS AND GOVERNMENT RESPONSE

4. The Government has acted on four interim recommendations:
- (a) that affected cattle should be compulsorily slaughtered and destroyed as a precautionary measure;
 - (b) that a Consultative Committee on research should be established to oversee and advise on R & D in relation to BSE and the other encephalopathies;

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(c) that milk from cattle with suspected BSE should be destroyed as a further precautionary measure;

(d) that the feed ban (which was originally time limited) should be extended indefinitely. It has been extended to the end of this year and will continue beyond that unless safe processing methods, which will destroy the agent, are found.

SOUTHWOOD'S MAIN CONCLUSIONS

5. The Working Party concludes that from present evidence it is likely that cattle will prove to be a 'dead-end host' for the disease agent and most unlikely that BSE will have any implications for human health. They comment that they believe the disease developed because of feeding practices associated with modern agriculture and that consideration should be given to changes in present methods. As a result of the feed ban imposed last July, the disease could be extinct in about nine years (taking account of the long incubation period). The Working Party welcome the Government's speedy action to implement their interim recommendations and also the animal feed and farming industry's response in ensuring the effectiveness of the regulations.

6. Despite their general conclusion, the Working Party make a number of recommendations aimed at minimising any possible risk to human health.

BABY FOODS

7. The Working Party consider that manufacturers of baby foods should, as a precautionary measure, avoid the use of ruminant offal and thymus. Sir Richard Southwood has told the Minister of Agriculture, Fisheries and Food that the likelihood of problems arising through the use of these products in baby food is very low indeed and that this suggestion is counsel of "extreme prudence". In practice thymus is not used in the preparation of baby foods. Kidneys and liver are because of their nutritional value. Official

will contact manufacturers urgently to seek their reaction to the suggestion.

MEDICINAL PRODUCTS

3. The Working Party have considered the potential for transmission of BSE between cattle and other species, including man, through the use of medicinal products prepared from bovine tissues. They recommend that the attention of those involved in the licensing of medicines should be drawn to the emergence of BSE. This has already been done. Guidelines drawn up by DoH and MAFF are in fact to be issued shortly to all manufacturers of medicinal products, and a list is being drawn up of all medicines manufactured from bovine material. The information will be reviewed to determine what, if anything, further is required to safeguard human and animal health.

HEALTH AND SAFETY

9. The Working Party recommend that the Health and Safety Executive (HSE) be alerted to the potential problems for occupational groups who could conceivably be exposed to the BSE agent. This has already been done. Although the Working Party have not suggested any specific guidance they have emphasised the need to adhere to recommended procedures for handling animals and animal products. HSE's views are being sought on whether any further measures are necessary.

SURVEILLANCE

10. DoH officials will be contacting the medical profession and the Office of Population Censuses and Surveys to ask them to monitor CU cases so that they can report atypical cases or changing patterns in the incidence of disease, which might indicate the presence of BSE in humans.

RESEARCH

11. The Working Party recommend that the Consultative Committee on research (see para 4 above) should consider and advise the

Government on a number of areas of R & D. These include studies which they believe could lead to complete reassurance about the lack of risk to human health. The research programme will be reviewed in the light of the Consultative Committee's advice.

PROPOSED ANIMAL PROTEIN

12. The Working Party have considered the implications of the use of processed animal protein (meat meal and bone meal) in animal feed. They believe that "the risks from inadequately sterilised animal products are such that this method of disposing animal waste should be changed so as to eliminate these novel pathways for pathogens".

13. The rendering industry is an essential adjunct to the meat industry, disposing of over one million tonnes of slaughterhouse waste each year. A total ban on the use of animal protein for feeding livestock would lead to serious problems for the renderers, since the alternative outlets for their product are unlikely to be economically viable or indeed practicable. The result could be an impairment of the rendering industry's capacity to dispose of slaughterhouse waste, which in turn could give rise to public health problems as well as having significant economic implications for the meat industry.

14. Sir Richard Southwood has made it clear that his Committee takes the view that recycled animal protein should be properly sterilised before use, but he is not advocating a ban on the use of all animal protein as feed for pigs or poultry. A ban on the feeding of ruminant protein to ruminants is already in place (see para 3 above) arising from the earlier recommendation from the Committee. Poultry are highly unlikely to be affected by sub-viral agents because their physiology is totally different from ruminants and also because of their very short life which makes it highly improbable that they could develop clinical symptoms of any encephalopathy. Pigs on the other hand are omnivores and for that reason are at greater risk. However the feeding of swill to pigs has taken place for very many years without the development of any

encephalopathy and a pig's life is also so short that it is highly unlikely that even breeding pigs would have time to develop clinical symptoms. Nevertheless, bearing in mind the concerns expressed by Professor Southwood, transmission experiments in pigs have already commenced to determine whether they will succumb to the disease when challenged experimentally. In the meantime it is not proposed to ban the feeding of recycled animal protein to pigs.

15. On the broader issue of sterilisation of animal protein, steps have been taken to tighten the controls on the production of animal protein under the Protein Processing legislation. These include intensification of the amount of monitoring of the end product and the introduction of powers to ensure that the product of unsuitable plants is not used for animal feed without further treatment. All plants covered by the Protein Processing Order are able to destroy all pathogens with the exception of the sub-viral agents which require extreme temperatures for their destruction far in excess of the operating temperatures of modern continuous production systems.

GOVERNMENT ANNOUNCEMENT ABOUT THE REPORT

16. It is planned to publish the Report next week. A draft announcement is attached, together with a brief on the many questions which will inevitably arise.

Ministry of Agriculture, Fisheries and Food
17 February 1989

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CONFIDENTIAL

BOVINE SPONGIFORM ENCEPHALOPATHY: SOUTHWOOD REPORT
QUESTION AND ANSWER BRIEF

HUMAN HEALTH RISKS

Q.1 Are there any?

A.1 Working Party conclude that from present evidence it is most unlikely that BSE will have any implications for human health. However, they add that if their assessment proves incorrect, the implications would be extremely serious. They therefore welcome the speed with which MAFF has implemented their interim recommendations (slaughter and disposal of suspected BSE cattle, prohibition on sale or use of milk, extension of feed ban).

Q.2 Further research into human health risks?

A.2 The Working Party have recommended that the recently established Consultative Committee on research (the Tyrrell Committee) should consider a number of areas of possible research, such as transmission experiments in muscle and milk, which may lead to complete reassurance about the lack of risk to human health.

BABY FOODS

Q.3 Why does Southwood suggest baby food manufacturers should avoid the use of ruminant offal and thymus?

A.3 Sir Richard has said that the likelihood of problems arising through the use of these products in baby food is very low indeed, and the suggestion (it is not a recommendation) is counsel of extreme prudence.

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Q.4 Will Government act on this?

A.4 Yes - thymus is not used in preparation of baby foods but we are contacting all manufacturers to seek their reaction on use of kidneys and liver from ruminants. Will consider any necessary measures in the light of their response.

MEDICINES

Q.5 Can medicines spread BSE from bovine material to humans and to other animal species?

A.5 The Report describes any risks as remote.

Q.6 How can risks be avoided?

A.6 A DoH/MAFF Working Group has been examining guidelines for the pharmaceutical industry which will be issued shortly.

Q.7 What will guidelines say?

A.7 In essence they call for non-bovine sources to be used if possible, including synthetic material of biotechnological origin. Where this is not possible the industry should look for sources which are free of BSE and which are collected in a manner which avoids risk of contamination by the BSE agent.

Q.8 Is this approach practical?

A.8 The guidelines will be tough and may pose problems for some sectors of industry. Time may show if we are being over-cautious. But health not an area where we can afford to take risks.

Q.9 What medicines are involved?

A.9 Bovine source material is used in a number of vaccines and other medicines.

Q.10 How many medicines are involved?

A.10 Computer records show that about 300 of the 3,950 veterinary medicines licensed in the UK are manufactured directly from bovine source material. However, other medicines may be produced from bovine sources and a letter is going to all licence holders so that a comprehensive list can be drawn up. (Data on human medicines to be provided by DoH.)

HEALTH AND SAFETY

Q.11 Is there a risk to people working with cattle?

A.11 The Health and Safety Executive have already been alerted to emergence of BSE. Working Party think no specific guidance appropriate at this time - but they emphasise the importance of adhering to recommended procedures for handling animals and animal products.

Q.12 Further measures?

A.12 Will contact HSE again in the light of Report to see if they recommend any further advice - for example, in relation to those involved in calving and lambing.

RESEARCH

Q.13 Has Government acted on recommendations to set up Consultative Committee?

A.13 Yes - as announced on [] a Consultative Committee has been established under Dr David Tyrrell to oversee and advise on research into BSE and the other transmissible encephalopathies. It will hold its first meeting in March.

Q.14 What about areas of research which Working Party considers should be undertaken?

A.14 Some are already under way such as the epidemiological survey, transmission, genetic and molecular biological studies. The other areas will be considered by the Tyrrell Committee who will then advise the Government.

USE OF PROCESSED ANIMAL PROTEIN IN ANIMAL FEEDS

Q.15 Is the Working Party recommending a total ban on the feeding of re-cycled animal waste to livestock? (Ban already applies to feeding of ruminant-based material to ruminants.)

A.15 No - they conclude that if animal waste is to continue to be re-cycled as animal protein feed it must be properly sterilised to eliminate the risk of disease transmission.

Q.16 Government attitude on this?

A.16 Accept the principles expressed by the Working Party and measures already taken or planned to confirm this.

Q.17 What are they?

A.17 From 18 July last year the Government banned feeding of ruminant-based protein rations to ruminants, since this is the most likely cause of the disease. This ban will remain in place unless possible to establish processing methods sufficient to kill the BSE agent. MAFF also has research project under way.

Q.18 What is "unnatural" feeding?

A.18 The word "unnatural" is used in the Report in the technical zoological sense, to refer to the feeding of material which the animals in the wild state would not eat - in particular the feeding of protein derived from animals to herbivores. It does not mean the food is not nutritious.

Q.19 What is the Government's view on this?

A.19 Processed animal protein (meat meal and bone meal) is a nutritious feed and provided adequate precautions are taken should not be a means of disease transmission.

Q.20 Although ruminant-based protein is banned in feed for ruminants, what about pigs and poultry?

A.20 Can still be fed to pigs and poultry.

Q.21 Is there a risk of transmitting BSE to poultry?

A.21 The Report concludes that the risks are so small that action is not appropriate at this stage.

Q.22 What about pigs?

A.22 The Report suggests that transmission experiments might be undertaken in pigs. In fact, the Government has already acted on this and has begun transmission experiments.

Q.23 What is reaction to recommendation Government should address problem of animal waste disposal "as part of the adjustment of the framework of the agricultural policy of the EC in coming years?"

A.23 There is some likelihood that proposals may be tabled soon for rules on the disposal of waste material in the Community. This would be an appropriate forum in which to consider this issue.

BAN ON FEEDING RUMINANT-BASED MATERIAL TO RUMINANTS

Q.24 Why not extend ban indefinitely as Southwood recommends?

A.24 This will be done unless we can identify conditions under which ruminant protein can be heat-treated so as to destroy the BSE agent.

Q.25 Control on imports of feed material?

A.25 Legislative provisions ensure that all feed which is a potential risk is not fed to ruminants.

Q.26 Why are imports a risk if no BSE elsewhere?

A.26 Has recently been reported in the Republic of Ireland. Do not know for certain that material from other countries is safe even though BSE may not have been reported. Other countries may have the same combination of critical factors which has led to the emergence of disease in this country.

Q.27 Exports of feed material containing animal protein materials?

A.27 If exports take place most used in pig and poultry feed. Importing countries well aware of the occurrence of BSE in this country. Up to them to decide whether to import and under what conditions.

Q.28 What are time/temperature combinations required to make product safe from BSE?

A.28 This is something we intend to establish precisely in consultation with the Neuropathogenesis Unit in Edinburgh since no definite information is available on the survival of the agent under conditions of processing currently applied in GB.

Q.29 Research?

A.29 Part of the continuing epidemiological study is to look at the relationship between the use of meat meal and bonemeal and the occurrence of BSE.

MILK PROHIBITION

Q.30 Why prohibition on milk from suspect BSE animals?

A.30 Government accepted the Working Party's interim recommendation that although in their view the transmission of BSE via milk very unlikely, it would be prudent, as a precautionary measure, to prohibit its use for human or animal consumption.

Q.31 Why not ban milk from the whole herd?

A.31 Absolutely no reason to ban use of milk from the whole herd, particularly since there is no evidence whatsoever of animal to animal spread. Furthermore, the Report confirms that milk has never been shown to be able to transmit any of the other spongiform encephalopathies. Also worth pointing out that in about 80% of cases only one animal in that herd has been affected.

Q.32 Why allow feeding to cow's own calf?

A.32 Unless someone present at birth, it is impossible to prevent sucking taking place; if there was a risk of maternal transmission it is likely to be from the placenta and not the milk. Could also be animal welfare problems if attempt made to prevent sucking.

Q.33 Research?

A.33 This is one of the areas which the Report recommends should be considered by the Tyrrell Committee, in essence to repeat earlier experiments which showed that milk was not a vehicle for scrapie transmission to any species.

- Q.34 What about milk from cattle with pre-clinical BSE?
- A.34 Measures in relation to clinically affected cattle only being taken as a precautionary measure on the advice of the Working Party. There is no scientific evidence that transmission is possible via milk. In addition, it has never been shown capable of transmitting any other of the spongiform encephalopathies.

GENERAL

- Q.35 Number of cases of BSE?
- A.35 At 10 February 2,823 cases had been confirmed on 2,069 farms.

- Q.36 What is geographical distribution?
- A.36 Cases have occurred in most parts of the country, but with well over half in the South, particularly the South West.

- Q.37 Why more in South?
- A.37 Not clear, but studies continuing to try to determine why.

- Q.38 Number of new cases each week?
- A.38 In recent weeks it has been running at a little over 100 confirmed cases a week.

- Q.39 How long will current incidence continue?
- A.39 Long incubation period means that might be four years before current incidence begins to fall off significantly.

- Q.40 Problems for exports?
- A.40 No major difficulties but a number of countries have chosen either to ban imports of cattle, semen and embryos or to impose health conditions in relation to the importation of cattle.

- Q.41 Which countries have imposed a ban or additional certification on imports of cattle from Great Britain?
- A.41 Australia, Israel and Sweden have imposed an embargo for the time being. Canada, Denmark, Finland, The Netherlands, New Zealand, the Republic of Ireland, South Africa and the US require additional certification prior to exports taking place.

Q.42 What about semen and embryos?

A.42 Australia's embargo covers semen and embryos as well as cattle. New Zealand and USA require certification for semen and embryos. The Republic of Ireland requires certification for embryos.

Q.43 BSE spreading?

A.43 No evidence of cattle to cattle spread - the cause is most likely to have been feeding of protein derived from ruminants (including sheep affected by scrapie) when the animals were calves. This now banned.

Q.44 Is compensation at 50% of value sufficient?

A.44 Yes, in view of fact that animal has terminal illness and is therefore of low value - but is valued for compensation purposes as if free from BSE.

Q.45 Are farmers evading requirement to notify cases of BSE?

A.45 No evidence from the numbers being reported.