7. Exports of MBM and compound feed, gelatine, tallow and medicines

7.1 In this chapter we examine the impact of BSE on exports from the UK of MBM and animal feed containing MBM, gelatine, tallow and medicines. Chapter 6 of vol. 3: The Early Years, 1986–89 includes our discussion of the consideration given to UK exports of MBM in the early years of BSE.

MBM and compound feed

Introduction

7.2 The evidence received by the Inquiry about the export from the UK of MBM and animal feed containing MBM suggests that the market for such products was small in the period before the emergence of BSE. Although exports of MBM to EU countries were rising steadily in the period from 1979 to 1988, total exports of MBM in 1988 were still less than 15,000 tonnes.244 This represented less than 4 per cent of the UK production of MBM in that year, based on MAFF estimates that annual production of MBM in the UK was about 400,000 tonnes.245

7.3 The Inquiry sought evidence from witnesses representing the feed industry about the extent of exports of MBM and compound feeds containing MBM. Mr Robert Peck of the Grain and Feed Trade Association (GAFTA) told the Inquiry . . . Prosper De Mulder had the lion’s share of UK produced meat and bonemeal exports, being the biggest producer. We, at rare times, exported cargos or truckloads of meat and bonemeal. By and large there was a deficit in the UK of meat and bonemeal. It was only on rare occasions that there was sufficient to warrant the additional cost to make it attractive to a third country outside of the UK.246

7.4 Mr Paul Foxcroft, on behalf of Prosper De Mulder Ltd, the largest rendering company in the UK, said the following in one of his statements:

PDM did export MBM to Europe and other countries (mainly Indonesia, Thailand and Sri Lanka) after the emergence of BSE.

The MBM was for use in poultry or pig feeds and post-September 1990 was produced from non-SBO raw materials.

244 See Figure 7.1 below
245 YB90/12.18/3.5
246 T61 pp. 55–6
The quantities exported represented a small proportion of PDM’s total MBM sales (approx. 5%) and were at prices compatible with those on the home market.247

7.5 Mr David Goldwater of GAFTA explained that MBM exports ‘would primarily go to manufacturers of concentrates who would use the meat and bonemeal in that particular end ration, and most of those concentrates would then be re-exported from either Belgium, Holland or France to the Middle East or North Africa’.

7.6 As regards the export of compound feed, Dr Brian Cooke, a nutritionist employed by Dalgety Agriculture Ltd told the Inquiry: ‘There is really very little export of compound feeds, if any. In the ruminants area any export is usually in the specialist broiler area or something like that, not in cattle feed.’248

7.7 Mr David Goldwater, when asked about trade in compound feedstuffs containing animal protein, told the Inquiry: ‘There would be the odd container load of finished feed that might go to one of the African countries or to the Middle East but absolutely no quantity at all. It would be minuscule in the context of the total feed trade.’249

Export to EU Member States

7.8 In Chapter 3 we discuss the impact of the introduction of the ruminant feed ban on the domestic rendering and feed manufacturing industries. The ruminant feed ban prohibited the inclusion of ruminant protein in ruminant rations. The practical effect of the ban was to exclude the use of any MBM in ruminant rations, since renderers were generally unable to guarantee that MBM produced by them was completely free of ruminant protein.

7.9 As already mentioned, MAFF estimated that UK production of MBM was approximately 400,000 tonnes per annum. Of this it was estimated that about 12 per cent of the domestically produced MBM had gone into ruminant feed before the introduction of the ban.250 After the imposition of the ban renderers would therefore have needed to find new markets for a significant proportion of their production. In evidence Mr James Reed, Director-General of the UK Agricultural Supply Trade Association (UKASTA), was asked if any companies might have continued to produce ruminant feed containing MBM for the export market. He stated:

I do not think it would have been worthwhile to any company to do that, because the export trade simply was not big enough in any compound feedingstuff.251

7.10 Dr Cooke’s and Mr Goldwater’s comments have been noted above.

7.11 Although it appears that MBM would not have been included in compound feed for ruminants for the export market, there was a marked increase in exports of
MBM from the UK in 1989. In July 1989 Mr Lawrence, from the Animal Health Division of MAFF, wrote:

The rendering industry has survived the July 1988 prohibition [the ruminant feed ban], in part because they have been able to fill the gap in the market through exports. In 1988 exports to other Member States were worth £2.2 million. In the first quarter of 1989 it was £1.9 million . . .

7.12 In spring 1989 concern about UK exports of MBM began to be expressed within the EU. Nevertheless the Commission at that stage saw no need for direct intervention and no justification for restrictive trade measures.

7.13 On 22 June 1989 Mr G Legras, Director-General of the Agriculture Directorate (DG VI) of the European Commission, sent a telex to the UK Government requesting an assurance that ruminant products would not be used in ruminant feed for either domestic use or export. A reply approved by MAFF on 6 July stating that:

Since BSE was first identified in this country additional health guarantees have been agreed for exports to a number of Member States. It would not have been appropriate to ban exports of such material as its use continues to be permitted in pig and poultry feed.

7.14 Mr Lawrence attended the Standing Veterinary Committee in Brussels on 18–19 July. In a minute to Mr Robert Lowson, Head of Animal Health Division at MAFF, he reported that the Commission was expecting the UK to take action to ban the export of MBM containing ruminant material. He pointed out that if the UK did impose a ban on the export of MBM containing ruminant material, the measure would effectively end MBM exports as virtually all rendering plants used ruminant waste.

7.15 On 21 July Mr Lowson updated the MAFF Minister, Mr John MacGregor, on the developments at the Standing Veterinary Committee including the calls for a ban on export of ruminant MBM from the UK. He said there was a possibility of individual Member States imposing unilateral import bans of ruminant-based MBM, and reported that Germany had already imposed such a ban. He advised that ‘. . . there is no advantage to us in cutting off all our export opportunities’.

7.16 On 23 July 1989 Mr John Gummer took over from Mr MacGregor as Minister for Agriculture, Fisheries and Food. He received a briefing from Mr Lowson on 25 July which included an update on the issue of export of MBM. Mr Lowson told Mr Gummer:

There has been criticism about the fact we continue to permit the export of meat and bone meal even though it is banned from use in ruminants in this country. However it has been emphasised that importing countries have been made fully aware about BSE and its probable cause and it is, therefore, up to them to decide whether to import and under what conditions.
7.17 He added that ‘the material can still be used for feeding to pigs and poultry in this country and exports may be going for the same use’.\(^{258}\) Mr Gummer told the Inquiry that he felt an export ban should be opposed and a Community-wide arrangement banning the feeding of ruminant protein to ruminants be sought.\(^{259}\)

7.18 On 1 August the Netherlands banned the feeding of ruminant protein to ruminants. France banned the feeding of ruminant protein to cattle on 13 August.

7.19 The European Commission proposed a ruminant feed ban in September 1989,\(^{260}\) which was supported by the UK, the Netherlands and France but opposed by other Member States. Germany and Denmark felt that they should not have to adopt such measures as they did not have scrapie or BSE.\(^{261}\)

7.20 As a consequence, UK exports of MBM to EU states continued to be permitted and no ban on the feeding of such material to ruminants was imposed by the EU. However, the introduction of unilateral bans by individual Member States, together with the effect of the raised profile of the issue within the EU, inevitably had a strong influence on UK exports of MBM in 1990. By 1991, exports to the EU had fallen to almost negligible levels.\(^{262}\)

7.21 In December 1990 MAFF described recent developments in the market for material processed from animal waste as follows:

- there is no market at all for material derived from specified [bovine] offal;
- demand is slack for all animal protein because of caution over the implications of BSE, particularly material derived from fallen animals (following advice from UKASTA that their members should avoid its use);
- the international market for both tallow and meat and bone meal is depressed.\(^{263}\)

7.22 MAFF estimated that since 1988 the price of MBM had fallen from over £200 per tonne to about £120 per tonne of material with no bovine or fallen animal content, and £90 per tonne for material containing no specified offal.

\(^{258}\) YB89/07.25/5.5  
\(^{259}\) S311 Gummer para. 33  
\(^{260}\) YB89/9.6/9.1  
\(^{261}\) YB89/09.19/7.3  
\(^{262}\) See Figure 7.1 below  
\(^{263}\) YB90/12.18/3.5
As Figure 7.1 above demonstrates, the loss of EU markets for MBM after 1991 was compensated for by increased exports to non-EU countries. The extent to which the UK Government made efforts to ensure that all importing countries were aware of the potential for MBM from the UK to contain the BSE agent, is discussed in vol. 3: The Early Years, 1986–88.

Exports of gelatine

In February 1992 the EU’s Scientific Veterinary Committee Sub-Group on BSE assessed gelatine and concluded that the risk from trading it for ‘consumption or for use in cosmetics’ was negligible, regardless of the tissue source. This conclusion was accepted by the EU. However, when Commission Decision 94/381/EC was adopted on 27 June 1994, prohibiting the feeding of protein derived from mammalian tissues to ruminant species, one of its effects was to ban the inclusion of gelatine in ruminant rations, since gelatine would contain protein.

The Scientific Veterinary Committee reviewed the situation late in 1994 and concluded once again that the risk from trading gelatine was negligible. It therefore recommended that gelatine be excluded from the prohibition on feeding mammalian protein to ruminants. This advice was accepted by the EU, and Commission Decision 95/60 excepted gelatine from the general prohibition.

Figure 7.2 below shows that, in the period from 1986 to 1996, exports of gelatine from the UK rose considerably. It thus appears that any impact BSE may have had on such exports was minimal.

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264 SEAC19 tab 1 Appendix 3; YB92/1.17/6.11
265 L4 tab 1
266 YB95/03.15/4.4
267 LAA tab 5
268 The data contained within this chapter was collected by HM Customs and Excise. The commodity codes used to record the quantities of exports of gelatine and related products over this period changed. As a result we can not be entirely confident that the figures given in each year are absolutely consistent with those of the previous year.
During November 1991 the French authorities imposed restrictions on imports of tallow from the UK because of their concern that the protein contained in tallow represented a risk of carrying the BSE agent. However, by 28 November the restrictions were withdrawn pending further scientific consideration, and they were not subsequently reinstated.  

There is no evidence to suggest that other importing countries raised concerns, in the period prior to March 1996, about the safety of tallow derived from bovine carcasses. Although Figure 7.3 below shows some fluctuation in the export figures for tallow, it is difficult to draw any firm conclusions from the data.
Medicines

7.29 In 1989 guidelines were introduced in the UK to address the potential for BSE to be transmitted to humans via medicines. The guidelines recommended that all products licensed under the Medicines Act 1968 for human or veterinary use, which were administered parenterally or to the eye or to open wounds, should in general conform with the guidance if they contained material from a bovine source, or if bovine material had been used during their manufacture. Most significantly, the guidelines provided for the following:

Tissues excluded

No brain or neural tissue, spleen, thymus and other lymphoid tissue, placental tissue or cell cultures of bovine origin should be used in manufacture.

Cattle source for all other tissues

Bovine material should come from animals, taken from a closed herd in the female line since 1980, in which no animal has been clinically suspected of having BSE, and which has not been fed rations containing ruminant derived protein during that period.270

7.30 At a Scientific Veterinary Committee Meeting held on 13 March 1990 it was agreed that a Commission Decision would be passed which would ban the export from the UK of certain tissues and organs derived from bovine animals born before 18 July 1988 ‘for uses other than human consumption’.271 In a minute of 29 March, discussing the implementation of the Decision, Mr Lowson explained that:

The reference to ‘uses other than human consumption’ may look rather odd. In fact it was the closest we could get to making it clear that this relates to materials for pharmaceutical use.272

7.31 On 15 March 1990, in a memorandum concerning the SVC meeting two days earlier, Mr Lawrence discussed the issue of implementation of the proposed Decision. He said:

Presumably, in the short term at least, it will have to be done by administrative means, ie an instruction to OVS/EHOs . . . We can stop issuing veterinary certificates under the Meat Hygiene Export Order but that may not be sufficient. One possibility might be an Order under Section 11 of the Animal Health Act. On the face of it this seems to be appropriate. Perhaps Mr Yavash will be good enough to advise on this.273

7.32 This led to considerable debate within MAFF about the best way to implement the Commission Decision in UK law.

270 YB89/2.23/6.7
271 YB90/03.15/4.1
272 YB90/3.29/14.2
273 YB90/3.15/4.1–4.2
7.33 On 19 March 1990 all Divisional Veterinary Officers were telexed by MAFF with instructions to withdraw certain export certificates relating to the export of bovine material for pharmaceutical use, as a way of implementing the Decision.274

7.34 The Commission Decision (90/200/EEC) was adopted formally on 9 April 1990. Ms Bronwen Jones of MAFF’s Meat Hygiene Division minuted Mrs Elizabeth Attridge, Head of the Animal Health and Veterinary Group, on 6 August about UK implementation of the Commission’s Decision, saying:

The amendment of the Bovine Offal (Prohibition) Regulations would certainly provide an opportunity to do so . . . the fact that the export ban in the Decision of 9 April goes beyond offal for human consumption means that we would have to prohibit its export for pharmaceutical uses etc. This could give rise to criticism that we were not taking the same precautions in relation to pharmaceutical products in the UK. Moreover a ban on pharmaceutical uses may not be able to be effected in legislation made under the Food Act and separate Regulations would, it seems to me, raise the profile of the issue considerably . . .

Given these difficult issues and the fact that as far as I am aware, neither the Commission nor any importing Member State has complained, I would recommend that we continue with administrative measures which we have in place, rather than attempt to put them in Regulations. Although there are some aspects of the two Decisions on which we could legislate with no difficulties, I think that to be selective in what we include in Regulations would only arouse suspicion and provoke criticisms.275

7.35 However, a year later, with the introduction of the Export of Goods (Control) (Amendment) (No. 7) Order 1991, which came into effect on 10 July, implementation of the Decision no longer remained purely administrative. The 1991 Order required that all exports of SBO and protein derived from it be under a specified licence issued by the Department of Trade and Industry. This gave legal force to the measures already in place.276

7.36 In 1992 the EU Committee for Proprietary Medicinal Products (CPMP) adopted guidelines for ‘minimising the risk of transmitting agents causing spongiform encephalopathy via medicinal products’.277 The CPMP guidelines applied to:

. . . all [human] medicinal products which contain active ingredients and/or excipients derived from bovines, as well as medicinal products for which the production process involves bovine materials.

7.37 They also covered:

. . . the use of such materials in procedures which are indirectly associated with the manufacturing process, for example, in test media used in the validation of plant and equipment to avoid cross-contamination.278

274 YB90/3.19/1.1
275 YB90/8.6/1.1
276 YB91/7.22/1.1; L2 tab 6
277 DH01 tab 6 p. 13
278 YB91/12.11/3.4
7.38 All products were to be considered on a case-by-case basis taking into account: the selection and processing of source materials; the age and geographic origin of the individual source animal; the intended use of the product; its stipulated dose and route of administration; the production process; and quality control.279

7.39 The main focus of the guidelines was the sourcing of bovine material used in manufacture. Sourcing was allowed from countries ‘which have not reported cases of BSE, if they have an effective veterinary service capable of detecting a low incidence of disease and if BSE is reportable’. Additionally, it was recommended that the risk of BSE infection arising from factors including the feeding of SBO material to the animals in question should be avoided.280 Materials could also be sourced from countries with a ‘low incidence’ of BSE if a number of precautionary measures were taken, including destroying all affected carcasses, and not using any progeny of affected animals.281

7.40 Manufacturers throughout the EU were required to comply with the new provisions. However, Dr John Purves, of the Medicines Control Agency, told the Inquiry that the practical assessment of licence applications went on as before because ‘the [CPMP] guidelines incorporated the principles of the CSM/VPC guidelines’.282 Corresponding guidelines for veterinary medicines were introduced by the Committee for Veterinary Medicinal Products (CVMP) in May 1993.283 It is unlikely, therefore, that the CPMP and CVMP guidelines caused any further disruption to UK medicines manufacturers who were already complying with the CSM/VPC guidelines.

7.41 On 28 February 1994 the German Federal Health Office (BGA) issued safety standards for human and animal medicinal products to minimise the risk of BSE/scrapie transmission.284 Dr Purves told the Inquiry that the ‘new German safety standards had been issued unilaterally without prior discussion at the CPMP and appeared to go further than the existing European Guidelines’.285

7.42 In a minute to Mr John Sloggem of the Medicines Control Agency (MCA) and Mr Thomas Eddy at MAFF on 18 May 1994, Mr Charles Lister of DH’s Health Aspects of Environment and Food Division, interpreting the German guidelines, noted that they did not accept any UK-sourced bovine material. This was in contrast to the current European guidelines, which said that materials could be sourced from animals under six months old and from established and monitored herds whose feeding and breeding history was documented.286

7.43 In September 1994 a CPMP meeting was held at which the German guidelines were discussed extensively. Dr David Jefferys of the MCA, who attended the meeting, reported that:

The German delegates sought to present this as supplementary, national advice and clarification to the existing CPMP Guideline. The Commission was not prepared to accept this explanation and argued that if clarification or additions were required to agreed guidelines then these should be discussed

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279 YB92/1.09/3.4
280 YB91/12.11/3.5
281 YB91/12.11/3.5
282 SS35 Purves para. 193. CSM = Committee on Safety of Medicines; VPC = Veterinary Products Committee (both UK bodies)
283 M74 tab 4B
284 YB94/5.23/3.1–3.2
285 SS35 Purves para. 208
286 YB94/5.18/6.1–6.2
within the CPMG and its Working Parties after which a revised Guideline could be issued. They did not accept that a Member State could issue its own supplementary Guideline . . . The Germans appeared to back off . . . saying that they had only made minor additions to the existing Guideline. They reluctantly agreed that their concerns should be discussed with the relevant CPMP Working Parties and would regard their documents as only being a provisional view from the Federal Republic in carrying forward the debate.287

7.44 The German guidelines continued to be discussed at CPMP meetings in December 1994. Although no agreement was reached between the UK and Germany on the issue of revising the European guideline, the CPMP confirmed that the current guideline would remain in force until such time as it was modified through the ongoing discussions.288

7.45 In January 1995 Germany was still refusing to change its position on its guidelines. Dr Purves told the Inquiry:

The effect of that was that in practice pharmaceutical companies in the UK chose to attempt to comply with the German guidelines by changing the source of materials to avoid all UK bovine material, even that certified as being from BSE free herds. 289

7.46 Mr Sloggem agreed that ‘the German guidelines remained a barrier to trade because in practice companies in the UK chose to attempt to comply with them by changing their sourcing arrangements to avoid UK sourcing’.290

7.47 On 29 September 1995 Mrs Isabelle Izzard of DH’s Pharmaceutical Industry branch minuted colleagues and Dr Purves and Mr Sloggem at the MCA. She reported that there had been no further developments on the question of the German guidelines since the matter had been referred to the CPMP. Mrs Izzard also reported that she had attended a recent meeting with the European Oleochemicals and Allied Products Group (APAG) at which APAG had reported that their member companies were encountering problems because of the German guidelines. Purchasers were requiring assurances that products did not contain any material derived from UK cattle. Mrs Izzard sought comments on three options that she outlined:

. . . for the UK representatives on CPMP to raise the matter with the Committee again; for the DoH to approach the Commission again through UKREP; for the DoH to take the matter up with the German Health Ministry.291

7.48 Mr Lister replied on 4 October 1995 indicating that the matter would be pursued further at the European level:

Now that the APAG have alerted us to the commercial disadvantage caused to their UK members by the German guidelines, there is good justification for pursuing this issue further on the grounds that:

287 YB94/09.19/3.1–3.2
288 YB92/12.21/8.1
289 S535 Purves para. 241
290 S454 Sloggem para. 107
291 YB95/9.29/16.1
– the German guidelines are a substantive restriction on trade;

– there is no public health justification for rules which go further than the CPMP guidelines.

I have discussed with MAFF colleagues the options outlined in your minute for taking this issue forward. I think it is clear that the matter should be raised again within the CPMP. Subject to Mr Brown’s view, we would also be happy for DH to approach the Commission once more through UKREP. However, we would not support a direct approach to the German health Ministry for bilateral discussions. It would be more appropriate to keep the issue on an EU basis, as with previous approaches, eg on beef. This is an issue on which MAFF feel strongly.

7.49 On 17 January 1996 Mr Sloggem sent a minute to Dr Purves about the revision of the CPMP guidelines and the still outstanding position of Germany’s compliance. Dr Purves replied in a handwritten note on 20 January to indicate that it was Mrs Izzard from the Pharmaceutical Industry branch who was to take the matter forward and advise the German authorities that their position was a restraint of trade to be taken up with the European Commission. However, these efforts were overtaken by the announcement in March 1996 of a connection between BSE and vCJD.

7.50 Although the UK pharmaceutical industry was clearly inconvenienced by this long-running disagreement with Germany, the general economic impact on the sector up to March 1996, as we say in Chapter 4, was limited. Volume 7: Medicines and Cosmetics gives a full account of how the UK addressed the risk of the BSE agent being transmissible to humans via these potential pathways of infection.