

BSE/10 (30)

Ref: Exprt133

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Date: 13 March 1990Copy: Dr Purves MB5A  
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## EXPORT OF BRITISH BIOLOGICAL PHARMACEUTICALS

1. Please see the attached note of a recent meeting in Brussels. For Dr Purford should read Dr Purves (I think). If the Germans get their way, and it looks as if they might, because of worries about BSE we could end up with a ban on certain bovine materials being exported from the UK for pharmaceutical manufacture. These materials include cell cultures of bovine origin (? and also any cultures which have been fed bovine nutrient material), bovine serum and fetal calf serum.
2. Whilst export of these raw materials may be very limited, it is only a small step to include in this export ban any finished product made from such materials. This would include virtually all biologicals and vaccines. This could have very serious effects on the export trade of British manufacturers of biologicals because even where they source their bovine ingredients outside the UK it might be impossible or at least very difficult to bypass any export ban.
3. Our own line is that we have not used regulations to restrict the use of British bovine material for non-food use, although certain offals cannot be used for human consumption. The MCA looks at the details of every biological product and makes its own assessment of risk and benefit and any changes thought necessary are being incorporated on a licence basis. We would not expect British companies to export material found unsatisfactory for domestic use. The CPMP is the appropriate body, not the SVC, to discuss pharmaceuticals and they are well aware of the theoretical problem concerning BSE.
4. However, since the MCA do not have the industry sponsorship role I thought it right to bring this to your attention. But I am not clear what, if anything, we can do at this stage. The MAFF representatives are arguing hard at SVC along lines we would support, but they appear to be being overruled.

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