

MANAGEMENT IN CONFIDENCE

CERTIFIED BSE-FREE HERDS FOR SOURCE OF MATERIAL FOR BIOLOGICAL PRODUCTS

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INTRODUCTION

Biological products for both humans and animals may require the use of materials from cattle in their preparation. Such materials may contain or become contaminated with BSE agent during or after collection if steps are not taken to control the source, the technical procedures used for collection of the source material and subsequent processing. Sheep or goat material would have similar risks since both species may be infected with scrapie agent which can certainly be transmitted to ruminant species and specifically to sheep through contaminated vaccines. We have no evidence for transmission of these agents to man but there is a potential risk with BSE that must be recognised, eliminated or reduced to an acceptable level. Quite apart from the potential for actual transmission, fear could reduce the use of important childhood vaccines with disastrous consequences for the nations health.

Officially BSE occurs only in the British Isles. Suggestions have been made to secure bovine source material needed for biologicals production from abroad on the basis BSE does not occur there. There are several reasons for doubting the validity of this assumption. Also it can never be guaranteed that it would not occur at a future date. The four main reasons for doubt relate to:

- a) TME occurrence in the USA from bovine/equine origin material. TME also has occurred in mainland Europe.
- b) UK calves are exported to Europe and adult cattle semen and embryos elsewhere.
- c) Meat and bone meal containing ruminant protein is exported and we have no control of its use.
- d) The quality of animal disease surveillance abroad compared with the high standards in the UK.

If, despite this, biologicals manufacturers went abroad for their source material it may have an adverse effect on this specialist trade in the UK. Also our animal stock may be at increased risk from infection introduced by biologicals prepared with foreign ingredients not to mention human health hazards. In this context obtaining materials from controlled sources in the UK may be more safely based on 'better the devil you know than the devil you don't'.

MAFF are in a strong position to utilise the knowledge they have for the benefit of the UK biologicals industry. MAFF could raise income by charging for certification of BSE-free herds and control of methods of collection of materials from cattle and their subsequent use in biologicals manufacture. Other health concerns relate to the occurrence of Bovine visna virus (BVV) in bovine source materials (due to possible relationships with AIDS virus) quite apart from common agents causing disease in man or animals.

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1. The Ministry sets up a BSE-free Certified Herd Scheme for payment. To qualify a herd should be closed in the female line since 1980, have had no BSE case, used no semen from a BSE confirmed bull and must not have been fed any food containing ruminant-derived protein in the period. The basic scheme would assist exporters of cattle, semen and embryos.

A fee would be levied and an annual inspection undertaken to ensure compliance. This could be extended to various tests to satisfy the safety needs of biologicals manufacture.

The owner should agree that the herd can be identified on request from for example importers, export agencies and companies preparing biologicals.

2. Companies wishing to prepare or distribute biologicals should be licenced and conform to recommendations governing their preparation with particular regard to the source, collection and subsequent use of materials obtained from ruminants.
3. There are a number of options for MAFF involvement in this item which relates to the premises used for specimen collection, the method of collection, storage and transport to the site of biologicals production. For example two would be:

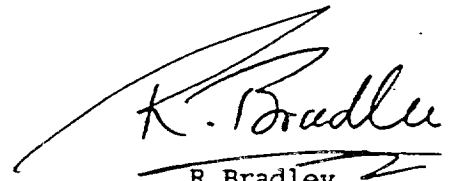
- a) The SVS could set up 1 or more 'laboratories' which would be licenced only to deal with preparation of bovine materials for biologicals manufacture on a commercial basis and the necessary test procedures to ensure absence of specified infectious agents. In essence the laboratory would either directly or via the Biologicals Company purchase/obtain or breed and rear animals for collection of source material (fetal calf serum, albumen, pancreas, bone chips etc). Staff would collect, prepare and despatch material to the Biologicals Company according to strict protocols and certifying its purity on a commercial basis.
- b) Private laboratories (including the Biologicals Companies themselves) could undertake all or some of the procedures in a) but with licencing, training and supervision for a fee by MAFF. MAFF could offer testing facilities for a fee.

There could well be a demand for the services from abroad - either the products themselves or advice on setting up laboratories.

ACTION REQUIRED

The above proposals which are incomplete and preliminary have been stimulated by recent events in the BSE saga in relation to biologicals production and other recent or long standing concerns such as with BVV, for man and F & M virus for animals. they have not been discussed outside of CVL.

1. Initial reaction to the proposals and whether or not they should be pursued as they are or in modified form.
2. How the herd certification proposals could correlate with existing or proposed health schemes controlled by HQ.
3. What could be the role for CVL?
4. We will need to know costs, benefits and the size of the UK market. How can this be done?



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