ADVISORY COMMITTEE ON ANIMAL FEEDINGSTUFFS

22nd Meeting of ACAF on 25 November 2003 – Agenda Item 3

THE FUTURE ARRANGEMENTS FOR THE ENFORCEMENT OF LEGISLATION RELATING TO MEDICATED FEEDINGSTUFFS AND ZOO TECHNICAL FEED ADDITIVES

Action: The Committee is invited to note and discuss the contents of this paper and the annexed views of the Animal Medicines Inspectorate.

Secretariat November 2003
THE FUTURE ARRANGEMENTS FOR THE ENFORCEMENT OF LEGISLATION RELATING TO MEDICATED FEEDINGSTUFFS AND ZOOTECHNICAL FEED ADDITIVES

Background

1. At its 20th meeting on 25 June 2003, ACAF considered a paper (ACAF/03/27) summarising and elaborating upon a presentation on the role of the Animal Medicines Inspectorate (AMI) of the Royal Pharmaceutical Society of Great Britain (RPSGB) in feed law enforcement given at the nineteenth meeting of ACAF by John Millward of the RPSGB. Members were informed that the AMI had also submitted views on its future but that, as Defra’s Veterinary Medicines Directive (VMD) was currently conducting a review of the AMI, these would be put before the Committee for discussion at a later meeting.

2. Whilst considering the review of the AMI, the VMD has since decided that it would be preferable to take a wider view of the future of enforcement and instead review enforcement arrangements, including the AMI, as part of that review along with other options.

Purpose

3. This paper updates the Committee on the VMD’s intentions regarding the arrangements for future enforcement of the feed legislation and encloses the AMI’s own views on this subject, particularly on the future of the AMI.

VMD’s Review of Future Arrangements for Enforcement of Feed Legislation.

4. The VMD has recently prepared a paper for Defra Ministers outlining options for the future arrangements for enforcement of various aspects of veterinary medicines including the legislation relating to medicated feedingstuffs and zootechnical feed additives. The VMD will update members on the recommendations and the Ministerial response at the meeting.

The Views of the AMI

5. The views of the AMI on its future and its proposals for improved feed law enforcement, particularly in relation to medicated feedingstuffs and zootechnical feed additives, are set out in the Annex. The Committee may be particularly interested in a number of points raised by the AMI which echo, to some extent, concerns or views expressed by members during the Committee’s review. For example, paragraph 2 of the Annex refers to the consolidation of feedingstuffs legislation to improve the efficiency and
effectiveness of enforcement. Similar views are put forward in the discussion paper on the Barriers to Good and Consistent Enforcement (ACAF/03/43). The AMI draws attention, at paragraph 3 of the Annex, to the number of different enforcement bodies and overlap of their activities. This point has already been made by some members of the Committee and is put forward for its further consideration in the “Next Steps” paper (ACAF/03/44). The AMI proposes, at paragraph 3 of the Annex, a single enforcement agency to undertake all approval work. Members may wish to weigh this option against those suggested at paragraph 12 of ACAF/03/44. At paragraph 8 of the Annex, the AMI suggests a consolidated “official” Code of Practice for businesses operating in the feed sector, whilst the Barriers to Good and Consistent Enforcement paper refers to mandatory codes of practice. The AMI also has concerns about the checks on imported animal feed (paragraph 10 of the Annex refers), a subject that the Committee is being asked to consider further in the “Next Steps” paper.

Action

6. The Committee is invited to note the contents of this paper and discuss the views of the AMI at Annex I.

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Food Standards Agency
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The AMI’s Views on its Future

1. The AMI believes that the decline in the number of businesses approved by the AMI will continue. The banning of all remaining antibiotic growth promoters (AGPs) as from 1 January 2006 will mean that some 500 zootechnical compound feed manufacturers will no longer require approval. Other in-feed medicinal/zootechnical substances will undoubtedly also be banned/withdrawn. Whilst the decrease in the number of approved businesses means that fewer inspections would need to be carried out, in practice the requirement uniformly to enforce the relevant regulations throughout Great Britain, means that logistical problems would be encountered if the size of the Inspectorate was reduced further. Therefore, to offset the resulting reduction in income from a reduced premise base whilst maintaining full coverage of Great Britain, annual approval fees will need to be increased, which will inevitably lead to a further decline in the number of premises and perpetuate the cycle. It is therefore highly likely that without additional income the AMI will become financially unviable within 12-24 months.

2. The AMI is well respected for its expertise, efficiency and uniform enforcement throughout Great Britain, not only by Government agencies and industry bodies, but also by approved businesses. At a time when there appears to be an increase in animal medicines and feedingstuffs legislation being proposed by the European Commission it would seem ironic to lose this expertise. The Inspectorate is currently in discussion with the Veterinary Medicines Directorate in an attempt to identify any additional work that the AMI could undertake, possibly by consolidation of a number of enforcement activities and/or whether direct funding from Government could be obtained. The Inspectorate also believes that it could play a part in the consolidation of enforcement of feedingstuffs legislation with the ultimate aim of improving the efficiency and effectiveness of enforcement.

Further Points for Consideration:

3. Further to the above, a major complaint within the feedingstuffs industry relates to “red tape” and the number of different enforcement and inspection bodies that visit such businesses, the activities of whom often overlap.

Proposal: Means of consolidating feedingstuffs enforcement activities should be considered, possibly based on the terminology introduced in Directive 95/69/EC on the approval and registration of establishments and intermediaries. Activities requiring approval are the primary step in feedingstuffs manufacture and are deemed to be of higher risk than those requiring registration. They require a far greater level of inspection than registration activities and consist of a relatively small amount of specialist
work. Currently there are three bodies carrying out approval work – the AMI, the Medicines and Healthcare Products Regulatory Agency (MHRA) and local authorities. One means of consolidating enforcement activities would be for a single, specialised enforcement body, such as the AMI, to undertake all approval work. The larger amount of registration work could remain with local authorities and the two bodies could work closely together in areas such as training, sampling and information transfer.

4. There are currently at least four different samples taken separately from feed manufacturers under (i) Medicated/Zootechnical Regulations, (ii) Feeding Stuffs Regulations, (iii) Establishments/Intermediaries Regulations and (iv) Mammalian Meat and Bone Meal Legislation (MMBM). In the case of manufacturers approved under the Medicated Feedingstuffs/Zootechnical Products Regulations, there is no provision in the fees for sampling for banned medicinal/zootechnical substances nor is there provision for sampling products at intermediaries/distributors.

Proposal: The approval and registration enforcement bodies, either independently or working in co-operation, should take samples and have them officially tested for several substances, e.g. permitted medicines/additives, banned substances, dioxins and MMBM.

5. Checks on those manufacturers producing medicated/zootechnical feedingstuffs for feeding to their own livestock (home-mixers) include checks on the storage and usage of such feeds. However, there are no such checks on storage/usage of purchased compound medicated/ zootechnical feedingstuffs.

Proposal: Consideration should be given to inspections being carried out of medicated/zootechnical compound feedingstuffs users.

6. Unlike the strict controls on the distribution of medicated feedingstuffs (some of which have a zero withdrawal period), there are no controls on the sale/supply of compound zootechnical feedingstuffs, many of which contain additives with a withdrawal period of up to 5 days. Such feeds were controlled when zootechnical additives were classified as Schedule 2 PML medicines.

Proposal: Compound zootechnical feeds should only be sold by approved intermediaries.

7. Whilst the use of zootechnical supplementary mineral feedingstuffs is regulated, their supply is not (as they are compound feedingstuffs and not premixtures). This effectively breaks the traceability chain and could lead to the feeding of zootechnical feedingstuffs to species for which the additive is
not authorised, particularly where there is a medicinal version which can only be acquired on a medicated feedingstuffs prescription.

**Proposal:** Such feeds should only be sold by approved intermediaries.

8. The introduction of the Medicated Feedingstuffs Regulations 1988 as amended, saw the publication of MAFF Codes of Practice for Category A and Category B manufacturers and Category 2 Agricultural Merchants. These Codes were withdrawn and were not replaced when the Medicated Feedingstuffs Regulations 1998 and the Feedingstuffs (Zootechnical Products) Regulations 1998 were introduced. Equally, no code of practice exists for manufacturers/suppliers approved/registered under the Establishments and Intermediaries Regulations. This has led to a number of guidance notes and codes being introduced by both enforcement bodies and trade associations, which whilst similar, are not the same. In the case of Codes introduced by trade associations, it has also led to the growth in commercial audits in addition to official inspections.

**Proposal:** Consideration could be given to the production of a consolidated official code of practice for businesses operating in the feed sector, which could be used by all enforcement and trade organisations conducting inspections.

9. Co-operation between enforcement agencies within the UK and between UK agencies and those of other Member States needs to be improved.

**Proposal:** Means of improving co-operation and transfer of information between agencies within the UK and with other Member States should be considered.

10. There appear to be few checks carried out on imported animal feeds and feed ingredients, particularly medicated/zootchnical products and feedingstuffs.

**Proposal:** Means of monitoring and checking such imported products should be considered.