ANNEX III

SPECIFIC REQUIREMENTS TO BE SATISFIED BY THE DOSSIER PROVIDED FOR IN ARTICLE 3 WITH RESPECT TO CERTAIN CATEGORIES OF ADDITIVES OR CERTAIN PART ICULAR SITUATIONS, AS PROVIDED FOR IN ARTICLE 7(5) OF REGULATION (EC) No 1831/2003

9. MODIFICATION OF THE AUTHORISATIONS

Since reliance can be placed on the evaluation of the data supplied for previous authorisations, a dossier prepared for an application under Article 13(3) of Regulation (EC) No 1831/2003 needs to comply only with the requirements listed below.

An application for modification of the terms included in an existing authorisation Regulation, such as the identification, the characterisation or the conditions of use of the additive, shall demonstrate that the modification does not have any harmful effect on the target species, the consumer, the user or the environment. An additive can be considered as identical for this purpose if the active substance(s) or agent(s) and the conditions of use are the same, its purity is essentially similar and no new components of concern have been introduced. For such products an abridged application may be submitted as it will normally not be necessary to repeat studies to demonstrate the safety for the target species, the consumer and the environment and efficacy.

The application shall address the following requirements:

1. the whole of Annex I applies — this includes details of the modification requested;

2. the whole of Section II of Annex II applies;

3. data must be provided indicating that the, chemical or biological characteristics of the additive are essentially the same to those of the established product;

4. where appropriate, evidence for bioequivalence shall be provided either by specification, or by published literature or from specific studies. Where bioequivalence is not fully demonstrated, conformity of the withdrawal period with the MRL has to be demonstrated;

5. evidence shall be presented that in the light of current scientific knowledge that the additive remains safe under the approved conditions for target species, consumers, workers and the environment;

6. a report on the results of the post-market monitoring, if such monitoring requirements are included in the authorisation, shall be provided; and

7. the specific data supporting the request for change must be submitted in compliance with the relevant parts of Sections III, IV and V of Annex II.