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

10. RENEWAL OF AUTHORISATIONS

Applications for renewal of authorisation under Article 14 of Regulation (EC) No.1831/2003 shall comply with the following requirements:

10.1. Section I: summary of the dossier

The whole of Section I of Annex II applies. A copy of the original Community authorisation for placing the feed additive on the market, or the last renewal of authorisation, shall be provided. An updated dossier shall be prepared according to the most up-to-date requirements and a list providing all variations since the original authorisation, or the last renewal of authorisation shall be submitted. The applicant has to provide a summary of the dossier, detailing the scope of the application, and any new information that has become available since the previous authorisation/ renewal in terms of identity and safety.

10.2. Section II: identity, characterisation and conditions of use of the additive; methods of analysis

The Section II of Annex II applies as following:

— for additives subject to a specific holder of the authorisation, the whole of the Section II applies,

— for other additives the paragraphs 2.1.2, 2.1.3, 2.1.4, 2.1.4.2, 2.2, 2.3.1, 2.3.2, 2.4.1, 2.4.2, 2.4.4, 2.5, 2.6 apply.

Evidence shall be presented to show that the additive has not been significantly changed or altered in composition, purity or activity in respect of the additive that was authorised. Any change in the manufacturing process shall be reported.

10.3. Section III: studies concerning the safety of the additives

Evidence shall be presented that in the light of the current knowledge the additive remains safe under the approved conditions for target species, consumers, workers and the environment. A safety update for the period since the original authorisation, or the last renewal of authorisation with information on the following items shall be presented:

— reports on adverse effects including accidents (previously unknown effects, severe effects of any type, increased incidence of known effects) for target animals, consumers, users and the environment. The report on adverse effects shall include the nature of the effect, number of affected individuals/organisms, outcome, conditions of use, and causality assessment,

— reports on previously unknown interactions and cross-contaminations,

— data from residue monitoring, where appropriate,

— data from epidemiologic and/or toxicological studies,

— any other information concerning the safety of the additive and risks of the additive to animals, humans, and environment.

If no further information is provided on any of these issues, the reasons for this shall be clearly identified.

A report on the results of the post-market monitoring program shall be provided, if such a monitoring requirement is included in the previous authorisation.

Where, as provided for in Article 14(2)(d) of Regulation (EC) No 1831/2003, the application for renewal of the authorisation includes a proposal for amending or supplementing the conditions of the original authorisation, *inter alia,* the conditions concerning future monitoring, the specific data supporting the proposal for amendment must be submitted in compliance with the relevant parts of Sections III, IV and V of Annex II.