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

5. COCCIDIOSTATS AND HISTOMONOSTATS

5.1. Section I: summary of the dossier

The whole of Section I of Annex II applies

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

The whole of Section II of Annex II applies

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

5.3.1. Studies concerning the safety of use of the additive for target animals

The whole of the subsection 3.1 of Annex II applies

5.3.2. Studies concerning the safety of use of the additive for consumer

The whole of the subsection 3.2 of Annex II applies

5.3.3. Studies concerning the safety of use of the additive for users/workers

The whole of the subsection 3.3 of Annex II applies

5.3.4. Studies concerning the safety of use of the additive for environment

The whole of the subsection 3.4 of Annex II applies

5.4. Section IV: studies concerning the efficacy of the additive

These additives protect the animals from the results of an invasion of *Eimeria* spp. or *Histomonas meleagridis*. Importance shall be attached to evidence of the specific effects of the additive (e.g. species controlled) and its prophylactic properties (e.g. reduction in morbidity, mortality, oocyst count and lesion score). Information on the effect on growth and feed conversion (fattening birds, replacement layers and rabbits), effects on hatchability (breeding birds) shall be provided, as appropriate.

The required efficacy data shall derive from three types of target animal experiments:

— artificial single and mixed infections
— natural/artificial infection to simulate use conditions
— actual use conditions in field trials

Experiments with artificial single and mixed infections (e.g. battery cages for poultry) are intended to demonstrate the relative effectiveness against the parasites and do not require replication. Three significant results are required for studies simulating use conditions (e.g. floor pen studies with poultry, battery cage studies with rabbits). Three field studies in which a degree of natural infection is present are also required.

5.5. Section V: post-market monitoring plan

This section of Annex II shall apply under provision of Article 7(3)(g) of Regulation (EC) No 1831/2003.