ANNEX II

GENERAL REQUIREMENTS TO BE SATISFIED BY THE DOSSIER PROVIDED FOR IN ARTICLE 3

1. SECTION I: SUMMARY OF THE DOSSIER

1.1. Public summary according to Article 7(3)(h) of Regulation (EC) No 1831/2003

The applicant shall submit a summary indicating the main features of the additive concerned. The summary shall not contain any confidential information and shall be structured as follows:

1.1.1. Contents

(a) name of the applicant(s);

(b) identification of the additive;

(c) method of production and method of analysis;

(d) studies on safety and efficacy of the additive;

(e) proposed conditions for use; and

(f) proposal for post-market monitoring.

1.1.2. Description

(a) name and address of the applicant(s)

This information shall be provided in all cases, independent of the type of feed additive authorisation (holder-specific or non-holder specific). When a dossier is submitted by a group of applicants, the name of each of them shall be indicated.

(b) identification of the additive

The identification of the additive shall contain a summary of the information required according to Annex II or III, depending on the type of the feed additive authorisation. In particular: name of the additive, proposed classification by category and functional group, target species/animal categories and doses.

(c) method of production and method of analysis

The manufacturing process shall be described.

The general procedures of the analytical methods to be used for the analysis for the official controls of the additive as such, in premixtures, and in feedingstuffs, as required in this Annex and Annex III shall be described. If appropriate, on the basis of the information submitted in this Annex and Annex III, the procedure of the method(s) to be used for the analysis for the official controls of the additives or its metabolites in food of animal origin shall be included.

(d) studies on safety and efficacy of the additive

The conclusion regarding the safety and efficacy of the additive based on the different studies performed shall be given. The results of the studies may be included in a tabular form to support the conclusion of the applicant(s). Only studies required according to Annex III shall be indicated in the summary.

(e) proposed conditions for use

The proposal for conditions of use shall be provided by the applicant(s). In particular the applicant shall describe the level of use in water or feed, together with the detailed conditions of use in complementary feedingstuffs. Information is also required where other methods of administration or incorporation in feed or water are used. Any specific conditions for use (e.g. incompatibilities), specific labelling requirements and animal species for which the additive is intended shall be described.

(f) proposal for post-market monitoring

This part shall only relates to additives, which according to point (g) of Article 7(3) of Regulation (EC) No 1831/2003, do not belong to categories shown as (a) or (b) in Article 6(1) of the same Regulation and to additives falling within the scope of Community legislation relating to the marketing of products consisting of, containing or produced from GMOs.

1.2. Scientific summary of the dossier

A scientific summary including details of each part of the documents submitted to support the application, according to this Annex and Annex III shall be submitted. This summary shall include the conclusions made by the applicant(s).

The summary must follow the order of this Annex and address all the different parts with reference to the relevant pages of the dossier.

1.3. List of documents and other particulars

The applicant must identify the number and titles of volumes of documentation submitted in support of the application. A detailed index with reference to volumes and pages shall be added.

1.4. List of parts of the dossier requested to be treated as confidential, where necessary

The list shall make reference to the relevant volumes and pages of the dossier.