SCIENTIFIC OPINION

Guidance on the renewal of the authorisation of feed additives[1]

EFSA Panel on Additives and Products or Substances used in Animal Feed (FEEDAP)[2,3]

European Food Safety Authority (EFSA), Parma, Italy

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This guidance document follows the structure and definitions of Regulation (EC) No 1831/2003 and its implementing rules (Regulation (EC) No 429/2008). It is intended to assist the applicant in the preparation and the presentation of its application, as foreseen in Article 7.6 of Regulation (EC) No 1831/2003. This document does not substitute for the obligation of an applicant to comply with the requirements of Regulation (EC) No 1831/2003 and its implementing rules.

[1] On request from EFSA, Question No EFSA-Q-2012-00962, adopted on DD Month YYYY.

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BACKGROUND AS PROVIDED BY EFSA

Regulation (EC) No 1831/2003 establishes the rules governing the Community authorisation of additives for use in animal nutrition. According to Article 9 of this Regulation, the authorisation for a given feed additive is valid for ten years and it can be renewed for ten year periods following the provisions of Article 14.

During the last years, the FEEDAP Panel has developed several guidance documents to assist applicants in the preparation and presentation of dossiers for the authorisation of feed additives. These guidance documents have been prepared mainly to help applicants in the preparation of technical dossiers for the authorisation of new feed additives/new uses of a feed additive (Article 4), the re-evaluation of feed additives already authorised (Article 10) or the modification of terms of an authorisation (Article 13). However, no guidance has been developed so far to help applicants in the preparation of dossiers for the renewal of the authorisation (Article 14).

TERMS OF REFERENCE AS PROVIDED BY EFSA

The FEEDAP Panel is requested to produce a guidance document to help the applicants in the preparation and submission of technical dossiers for the renewal of the authorisation of additives for use in animal nutrition.

THE TECHNICAL DOSSIER – GENERAL ASPECTS

The dossiers must enable an assessment to be made of additives based on the current state of knowledge and permit verification of the compliance of these additives with the fundamental principles for the renewal of the authorisation, which are laid down in Article 14 of Regulation (EC) No 1831/2003.

The information to be submitted and the extent of it will depend on the additive nature, the functional group, the substance itself, the target animals and the conditions of use. The applicant should refer to Regulation (EC) No 429/2008 in order to evaluate which information should be submitted with the application. Reasons must be given for the omission from the dossier of any data prescribed there.

The dossier shall be structured in accordance with the numbering system proposed in the Regulation (EC) No 429/2008. The dossier shall include references and copies of all published scientific data mentioned and the copies of any other relevant opinions which have already been produced by any recognised scientific body. Where these studies have already been evaluated by a European scientific body following the legislation in force in the European Union, a reference to the outcome of the evaluation should be sufficient and a copy should be provided. Data from studies that have been conducted and published previously or coming from peer review shall clearly refer to the same additive as the one subject to the application for renewal of the authorisation.

When preparing the application for the renewal of feed additives, the applicant should consider the most up-to-date scientific knowledge, the current scientific/methodological approaches and should follow the most updated guidance documents of EFSA and any other relevant guidance documents.

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 and any new information that has become available since the previous authorisation/renewal in terms of identity and safety, and when appropriate on efficacy. Any proposal for amending or supplementing the conditions of the original authorisation should be detailed. All the changes introduced since the last evaluation should be detailed and their consequences in terms of identity and safety (and efficacy when relevant) considered. The summary should not contain any confidential information.

1.2 Scientific summary of the dossier

A scientific summary including details of each part of the documents submitted to support the application shall be provided. This summary should detail the scope of the application, and include any new information that has become available since the previous authorisation/renewal in terms of identity and safety (and when appropriate on efficacy). Any proposal for amending or supplementing the conditions of the original authorisation should be detailed. The consequences of these new elements in terms of identity and safety (and efficacy when relevant) should be carefully considered.

The summary must follow the order of Annex II of Regulation (EC) No 429/2008 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 should be added.

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

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

1.5 Information on the previous authorisation and use of the additive

A copy of the original Community authorisation for placing the feed additive on the market, or the last renewal of authorisation, should be provided. Reference to previous assessments made by EFSA should also be provided. Information of use of the feed additive in the European Union (e.g., volume, geographical distribution and time) should be provided.

2 SECTION II: IDENTITY, CHARACTERISATION AND CONDITIONS OF USE OF THE ADDITIVE; METHODS OF ANALYSIS

A complete Section II should be provided for each dossier following the guidance document for the relevant category(ies): technological additives, sensory additives, nutritional additives, zootechnical additives or coccidiostats and histomonostats.

Evidence should be presented to show that the additive has not been changed or altered in composition, purity or activity with respect to the additive that was authorised. Any changes in the manufacturing process, composition, purity or activity should be properly described and documented. Their implications for the assessment of the feed additive should be considered. Recent (not older than one year from the date of submission of the application) analytical data from at least five batches for the composition of the additive and at least three for the purity should be provided. If the changes introduced may have an impact on the physico-chemical properties, additional data on the physical properties (e.g., particle size, dusting potential), stability or homogeneity should be provided, as appropriate.

For microorganisms used as additives or as production strains, the name and taxonomic classification of each micro-organism should be confirmed according to the latest published information in the International Codes of Nomenclature. Compliance with the most recent guidance documents regarding antibiotic resistance and virulence factors should be ensured (see guidance on the assessment of bacterial antimicrobial susceptibility, guidance on *Bacillus*, guidance on the assessment of *Enterococcus faecium*).

Any incompatibilities or interactions of the additive in feed with feed materials, carriers, other approved additives, or medicinal products not previously described should be reported and documented.

Any proposal for the modifications of the conditions of use of the additive should be properly described.

3 SECTION III: STUDIES CONCERNING THE SAFETY OF THE ADDITIVE

Evidence shall be presented that in the light of the current knowledge the additive remains safe under the approved conditions for target species, consumers, users/workers and the environment. An update on the safety for the period since the original authorisation, or the last renewal of authorisation should be presented including:

- 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 should include the nature of the effect, number of affected individuals/organisms, outcome, conditions of use, and causality assessment and should consider the use in water for drinking when it is authorised.
- reports on previously unknown interactions and incompatibilities.
- data from residue monitoring, where appropriate.
- data from epidemiologic and/or toxicological studies, where available.
- any other information concerning the safety of the additive to animals, humans, and environment.

This safety update should be prepared taking into consideration the new scientific developments and updated regulatory requirements. If no further information is provided on any of these issues, appropriate justification should be provided.

As a tool to provide information on the safety of the feed additive under the conditions of authorisation, structured database searches may be used. Relevant scientific databases (including e.g. agricultural/aquacultural, toxicological and medical/veterinary databases) should be searched in a structured manner. The databases examined, search terms used, total and relevant hit rate and any restrictions used should be stated. The database search should cover at least the period since the last assessment of the additive. Copies of the relevant papers should be provided. In order to place the results of database searches into context, where possible, information on use of the generic product (e.g., volume, geographical distribution and time) should be provided.

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

When the applicant includes a proposal for amending or supplementing the conditions of the original authorisation that may have an impact on the safety of the additive (e.g., an increase in the maximum recommended dose, increased bioavailability of the active substance), additional safety studies may be required. In that case, the relevant guidance documents should be followed.

4 SECTION IV: STUDIES CONCERNING THE EFFICACY OF THE ADDITIVE

In general, efficacy studies are not required for applications for the renewal of authorisation unless the applicant includes a proposal for amending or supplementing the conditions of the original authorisation. In that case, if the proposal may have an impact on the efficacy of the additive (e.g., a reduction of the minimum recommended dose), additional efficacy studies may be required. When efficacy studies are required the guidance for the relevant category(ies) of feed additive should be followed.

In the case of coccidiostats and histomonostats, evidence of the maintained susceptibility of *Eimeria* spp. and *Histomonas meleagridis* to the coccidiostat and histomonostat, respectively, should be provided in the form of sensitivity studies. These studies should be done not earlier than one year before the submission of the application. For more information, see the guidance on coccidiostats and histomonostats.

5 SECTION V: POST-MARKET MONITORING PLAN

When a post-market monitoring plan was undertaken as a result of the original authorisation or the last renewal of authorisation, the results of this plan should be reported under Section III. If the applicant includes a proposal for amending or supplementing the conditions of the original authorisation regarding the conditions concerning future monitoring, this should be clearly described. In that case, the guidance for the relevant category(ies) of feed additive should be followed.