ADVISORY COMMITTEE ON ANIMAL FEEDINGSTUFFS

43rd ACAF Meeting 24th September 2008

HERBAL ADDITIVES

DISCUSSION PAPER

Action required: The Committee is invited to consider the recommendations made for the assessment of herbal feed additives by EFSA. The Committee is asked to consider these proposals and their possible impact on animal nutrition and the animal feed industry.

Secretariat
August 2008

HERBAL ADDITIVES

Purpose

1. The aim of this paper is to inform the Committee of recommendations made by EFSA for the assessment of herbal additives. The Committee is invited to consider their impact on animal nutrition and the animal feed industry and to help identify any aspects that may require further discussion.

Background

2. Herbal additives were first raised as a topic for ACAF to consider at its meeting of 24 Sept 1999. ACAF has since discussed this subject area in subsequent meetings and this subject has been included in the forward work programmes for 2005-2006, 2006-2007 and 2007-2008.

3. Currently, some herbs are used by the feed industry as flavouring compounds; they are a type of sensory additive. However, there is some evidence that certain herbal additives might have zootechnical properties; that they can be used to favourably affect the performance of animals in good health or used to favourably affect the environment. Under the feed additives Regulation (EC) No 1831/2003, if an additive has any zootechnical claims a dossier must be submitted to be assessed, and the additive approved before use. Therefore, herbs approved as sensory additives cannot be used as growth promoters or as additives to favourably affect the environment.

4. There is an overlap of responsibility for herbal and homeopathic products between ACAF and the Veterinary Products Committee (VPC). This was discussed at the ACAF meeting of 1 December 1999 (point 10-12, Annex I). A paper was provided by the Secretariat on this subject (ACAF/99/13 - Annex II).

   The VPC provides advice to the VMD for products claiming to treat or prevent disease, or capable of restoring, correcting or modifying physiological function in food producing animals. ACAF provides advice in respect of herbal products which are present in pet food and horse food, and herbal additives and feed ingredients in food producing animals.

5. At the meeting of 1 December 1999, ACAF expressed concern about the potential for herbal additives to be used and informally marketed for their therapeutic or prophylactic abilities. The Committee noted that the expense involved in obtaining approval for a veterinary medicine product could encourage making ‘off label’ claims (i.e. where therapeutic claims do not appear on the label but may be promoted by the salesperson or by other means).

6. A presentation was given to the Committee by Mr Anderson of the VMD on legislation affecting homeopathic and herbal products at the meeting of 4 May 2000 (point 26, Annex III). A paper was presented by the Secretariat on the procedures for authorising herbal substances as veterinary medicinal products (ACAF/00/18 – Annex IV) and on the procedures for marketing herbal and homeopathic products in food for human consumption (ACAF/00/12 – Annex V).

7. At the meeting of 8 February 2005, the Chairman noted that a self-task group had been set up by EFSA to look at herbal additives in animal feed. At the meeting of 20 Sept 2005, the Chairman expressed interest in being kept informed of developments.

EFSA report on herbal additives

8. Under Article 10 of Regulation No 1831/2003, authorised herbal additives will be re-evaluated after November 2010, provided that a dossier has been submitted for reauthorisation. The EFSA panel felt that the current assessment of herbal additives lacks sufficient information on quality control, efficacy and safety. In order to address these potential gaps in knowledge, EFSA has assessed 42 herbs with regard to:

    - background experience with the plant;
    - historical use;
    - systematic description;
    - occurrence;
    - plant description;
    - use of plant parts and products;
    - phytochemical constituents (including chemistry, variation and analysis);
    - pharmacology (*in vitro* and *in vivo* studies);
    - anti-microbial effects;
    - efficacy / quality of the animal product; and
    - toxicology / safety.

    A copy of the introduction and background to the EFSA report can be found at Annex VI.

9. Using these evaluations, EFSA recommended areas that would need to be addressed in future assessment, these are:

    - identification of the starting material;
    - natural variation of the plant material (genetic, developmental and morphological variation);
    - agricultural and harvesting practices;
    - contamination (agrochemical or microbiological);
    - identification of the active substance;
    - product consistency and stability;
    - hazard identification and characterisation; and
    - risk characterisation.

    Not all of these points would need to be included for each assessment. Therefore, EFSA has produced a decision tree to identify the areas that need evaluation. A copy of EFSA's full conclusion, including the decision tree can be found at Annex VII.

10. The recommendations from this report have since been applied in Regulation (EC) No 429/2008, which lays down rules for the preparation and the presentation of applications and the assessment and authorisation of additives.

Future developments

11. We anticipate further developments in this area before November 2010. The Secretariat will keep the Committee informed of developments.

Action required

12. The Committee is invited to read the attached recommendations from the EFSA panel at Annex VII. It is asked to consider these recommendations and their impact on animal nutrition and the animal feed industry.