ADVISORY COMMITTEE ON ANIMAL FEEDINGSTUFFS

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Information Paper

EC REVIEW OF FEED ADDITIVES UNDER EC REGULATION 1831/2003

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Purpose

1. The purpose of this paper is to provide the Committee with information on how feed additives currently authorised will be re-assessed and re-authorised under the provisions of in European Council and Parliament Regulation 1831/2203 (*Official Journal of the European Union*, 18.10.2003, L268/29).

Assessment and authorisation prior to Regulation 1831/2003

2. Before Regulation 1831/2003 took effect (i.e. before 18 October 2004) the procedures in place for assessment and authorisation were laid down in Council Directive 70/524/EEC. The most recent major amendment to this was Council Directive 96/51/EC (*Official Journal of the European Communities*, 17.9.1996, L235/39). The provisions of the Directive were implemented in domestic legislation *via* The Feeding Stuffs Regulations 2000 and 2005.

3. Essentially, the system for assessment and authorisation required an applicant to ask a Member State to act as rapporteur for its dossier. It then provided its draft application to its rapporteur for initial assessment. Once the applicant had addressed any shortcomings identified by the rapporteur, the dossier was formally submitted to the European Commission and to all Member States for consideration. There then followed a cycle of questions from Member States (and possibly from the Commission's Scientific Committee for Animal Nutrition) and answers from the applicant until all significant issues concerning safety, efficacy and quality had been addressed. At this stage, the Commission would have prepared a draft Regulation for a vote at Standing Committee. Authorisation could be either be without time limit, for ten years (for coccidiostats and antibiotics only) or for four years (a provisional authorisation where efficacy had not been fully established). Additives with a provisional authorisation could be granted a full authorisation on receipt and assessment of further satisfactory efficacy data.

4. Directive 96/51/EEC set a time limit for the assessment procedure (320 days), which could be extended and the applicant asked to provide additional data. Hence, the assessment process was frequently protracted.

Assessment and authorisation under Regulation 1831/2003

5. Articles 4 – 9 of the Regulation set out a system that provides an effective separation of the risk assessment and risk management activities for new feed additive applications. The management of risk remains the preserve of the Commission and Member States. However, the main risk assessment is now the responsibility of the European Food Safety Authority (EFSA).

6. Regulation 1831/2003 sets limits for the assessment and authorisation processes; EFSA has six months in which to undertake its assessment and the Commission has three months after a favourable EFSA Opinion in which to prepare authorising legislation. Authorisations made under Regulation 1831/2003 last for up to ten years. Article 14 permits authorisations for a further ten year period. For zootechnical additives the initial ten year authorisation is made on a product-specific basis, in order to give some commercial protection to such applicants.

Guidelines

7. To assist both the compilation and assessment of applications, guidelines were agreed in the form of Council Directive 87/153/EEC – the most recent amendment to this is Commission Directive 2001/79/EC (*Official Journal of the European Communities*, 06.10.2001, L267/1). However, it was considered that this was in need of an update or replacement, and revised guidelines received a vote in favour at Standing Committee in late 2007 and will be published shortly in the *Official Journal* as a new Commission Regulation. The text will provide for a lighter assessment for certain types of additives (e.g. those already used in food and pet food additives). In addition to the new guidelines, there is now additional advice available to applicants on the EFSA and Commission websites:

http://www.efsa.europa.eu/EFSA/ScientificPanels/FEEDAP/efsa_locale-1178620753812_feedap_guidance.htm

http://ec.europa.eu/food/food/animalnutrition/feedadditives/index_en.htm

Products authorised under Directive 70/524

8. Article 10 of Regulation 1831/2003 deals with feed additives authorised under Directive 70/524 and a few authorised previously under the Bioproteins Directive (Directive 82/471). They need to be re-assessed and then authorised under Regulation 1831/2003. Firstly, such additives needed to be notified to both the Commission and EFSA, and such notifications recorded in the Commission's Register of authorised additives. The Register is updated by the Commission on a regular basis to take account of products that have been granted new or revised authorisation, and those whose authorisation has expired. Secondly, applications (i.e. dossiers) need to be submitted before November 2010; and comply with the new guidelines. For many generic feed additives, the new guidelines provide for a fast-track system that focuses on the essential safety issues. However, zootechnical additives (e.g. enzymes and micro-organisms) need to be backed by a full dossier.

9. The feed additive industry has responded to the demand for a large number of existing additives (potentially ca. 3,000) that would need to be re-authorised by forming industry consortia to compile dossiers for generic feed additives. However, the task facing the sector is still immense, and likely to be

mirrored by the amount of work to be faced post-2010 by both risk assessors and risk managers. The European Commission has stated that it intends to hold discussions with Member States, EFSA and other stakeholders on the priority for re-assessment that should be given to each class of feed additive. Given the experiences of the 1990s and early 2000s in authorising the large number of feed enzyme and micro-organism products, it is envisaged that the assessment and authorisation processes for Directive 70/524 additives will take several years. The Food Standards Agency understands that such products can remain on the market post-2010 prior to being authorised, provided that an appropriate application for re-authorisation has been made. It is likely that some additives will not have an application for re-authorisation provided by November 2010. Such 'orphan' additives should be removed from the market.

Conclusion

10. There will need to be a lot of work undertaken by the feed industry, EFSA, Member States and Commission officials in order to meet the requirements in Article 10 of Regulation 1831/2003, concerning the re-assessment and re-authorisation of existing feed additive products. Whilst it is necessary to re-assess such products to help ensure the safety of consumers, workers, animals and the environment, there is the possibility that this process might lead to the withdrawal from the market of some useful feed additives.

ACAF Secretariat