ACAF/08/08

# **ADVISORY COMMITTEE ON ANIMAL FEEDINGSTUFFS**

42<sup>nd</sup> Meeting of ACAF on 3 June 2008

**Discussion Paper** 

# THE PROPOSED NEW EC REGULATION ON THE MARKETING AND USE OF FEED

Action: The Committee is invited to note the requirements of the proposed EC Regulation on the placing on the market and use of feed and make any comments on the issues raised in the attached paper and on any other points.

Secretariat May 2008

# PROPOSED REGULATION OF THE EUROPEAN PARLIAMENT AND THE COUNCIL ON THE PLACING ON THE MARKET AND USE OF FEED

## Purpose

1. The European Commission has made a proposal for an EC Regulation on the marketing and use of animal feeds. This paper describes the main provisions of the proposal and identifies a number of areas where the advice of the Committee is requested.

# Background

2. Existing requirements on the marketing and use of animal feeds are mainly contained in four separate EC measures as follows:

- Council Directive 79/373/EEC of 2 April 1979 on the circulation of compound feedingstuffs;
- Council Directive 82/471/EEC of 30 June 1982 concerning certain products ('bioproteins') used in animal nutrition;
- Council Directive 93/74/EEC of 13 September 1993 on feedingstuffs intended for particular nutritional purposes; and
- Council Directive 96/25/EC of 29 April 1996 on the circulation and use of feed materials.

3. The proposed Regulation will bring together most of the requirements of the above legislation into one measure and is part of the Commission's modernisation and simplification programme. A copy of the proposed Regulation is attached at Annex A and a copy of a summary of the Commission's Impact Assessment is attached at Annex B.

# **Previous ACAF review**

4. The Committee reviewed legislation on feed labelling in 2001. The summary of recommendations from its report Review of Animal Feed Labelling is set out at Annex C. The Committee received a paper in 2006 (ACAF/06/11) on the Commission's plans to review feed labelling legislation, which was discussed at its meeting on 24 April 2006.

# Scope

5. The proposed Regulation is largely a technical measure, covering controls on business-to-business activities, although it also applies to pet foods.

6. In broad terms the Regulation will apply to the marketing and use, including labelling, of a number of types of feeds. These include compound feeds (manufactured feeds, often marketed in pelleted form), feed materials (ingredients of compound feeds or feeds that can be fed directly to animals) and feedingstuffs for particular nutritional purposes or dietetic feeds. Dietetic feeds are those that can be marketed for the dietary management of certain often short-term nutritional conditions such as the reduction of urate stone formation or regulation of glucose supply.

7. The requirements for the labelling of feed additives (e.g. vitamins and trace elements) and premixtures (mixtures of feed additives, or a mixture of one or more feed additives with a feed material as a carrier) are set out in the EC Feed Additives Regulation (1831/2003). However, the proposed Regulation on Marketing and Use amends certain labelling requirements for these products. The Regulation does not contain provisions on feed containing or produced from genetically modified organisms, which are subject to a separate EC measure (EC Regulation 1829/2003). Specific requirements relating to the labelling of medicated feedingstuffs are also outside the scope of the legislation, and it is understood there will be considered as part of a revision of EC Directive 90/167/EEC on medicated feedingstuffs.

# Main requirements

8. Many of the provisions of the proposed Regulation reflect existing requirements. However, the following paragraphs set out details of the main new or modified requirements.

#### General safety controls on non-food producing animals (Articles 4 and 5)

9. Although existing feed marketing legislation applies to pet foods, they are exempt from the feed provisions of EC Regulation 178/2002 on the principles of food law. These provisions require that feed must not be placed on the market if it is unsafe and set out the responsibilities of feed business operators, including assisting in feed recalls and provisions on traceability. The proposed Regulation would apply these provisions to feed for non-producing animals.

# Feed additives in complementary feeds (Article 8)

10. Additives in complementary feeds and premixtures are not currently subject to maximum permitted levels although, when these products are used in combination with other feeds, the maximum permitted levels for complete feeds must be observed. The proposed Regulation specifies that complementary feeds should not contain levels of additives more than 100 times the maximum permitted levels in complete feeds. For coccidiostats and histomonostats the factor proposed is five times the maximum permitted level of these additives in complete feeds.

## Dietetic Feeds (Article 9 and 10)

11. The Regulation will introduce a formal procedure for the addition of new nutritional purposes to the list of conditions for which dietetic feeds may be marketed. This is similar to the procedure that already exists for the authorisation of feed additives and included in EC Regulation 1831/2003 on feed additives.

## *Tolerances* (*Article 11* (5))

12. Existing legislation lays down upper and lower limits of variation within which analytical ingredients (protein, fibre, moisture, etc) must fall to be congruent with the values declared on the label. This is to allow for unavoidable minor variations in manufacturing processes and the natural decay of some ingredients such as vitamins during product shelf life. The proposed Regulation would simplify these limits by reducing the number of declarations subject to them.

#### Claims (Article 13)

13. In existing legislation there are a number of general principles for feed labelling, including a requirement that labelling should not claim that the feed will treat, prevent or cure disease, and that additional claims that concern objective or quantifiable factors which can be substantiated. The Marketing and Use Regulation would extend these general principles by requiring that any claim for a specific composition or function be understandable by purchasers and verifiable by enforcement authorities. Also any claim must be supported by either documented company research or published scientific evidence.

## ACAF/08/08

Percentage declaration of the ingredients of compound feeds (Article 17 (1) (e) and 2)

14. The Regulation will repeal the existing requirement to declare the ingredients of compound feed by their percentage weight of inclusion, which was introduced in 2002 following a number of feed safety incidents. The previous requirement to declare ingredients (names only) in descending order by weight will be restored, but manufacturers will be required to provide quantitative compositional data to customers on request, subject to confidentiality considerations.

# Labelling of additives contained in feeds (Article 15 (f))

15. Existing labelling rules require the declaration only of certain additives (e.g. copper, vitamins A, D and E, enzymes, micro-organisms). The Regulation proposes that where additives subject to a maximum inclusion rate have been incorporated in livestock feeds, the labels must include information on such additives, including their identification number, the added amount, and the functional group (e.g. preservatives) to which they belong. This requirement would also apply to additives in pet foods.

# Labelling of contaminated material (Article 20)

16. The Annex to Council Directive 2002/32/EC on undesirable substances in animal feed specifies the maximum permitted levels for a range of contaminants. Feed which contains contaminants above these levels may, in some cases, be sent for cleaning or detoxification to reduce the level of contamination. There is the potential for such feed to be diverted back into the feed chain and the proposed Regulation will therefore introduce a provision requiring such feed to be labelled to indicate that it is intended to be cleaned or detoxified prior to use.

#### Derogations (Article 21)

17. Most of the derogations set out in Article 21 of the proposal are reflected in existing legislation. However, the EC Feed Materials Directive (95/25/EC) has a derogation for the provision of certain labelling information for by-products of agro-industrial processes where the moisture content of such feeds exceed 50%. This derogation is not reflected in the proposed Regulation on the Marketing and Use of feeds.

# Community catalogue of feed materials (Article 25)

18. The names and descriptions of the most commonly used feed materials are currently listed in an Annex to Directive 96/25/EC. The proposed Regulation would replace this Annex with a Community catalogue, which would be subject to amendment and extension by the feed industry in consultation with Member States, the European Food Safety Authority (EFSA) and feed users. Adoption of the Catalogue would be subject to the agreement of the Commission and Member States. Use of the catalogue would be voluntary, but if the names and descriptions in the catalogue were not used this would be required to be indicated on the feed label.

## *Codes of practice (Article 26)*

19. To supplement the mandatory labelling requirements, it is proposed that there will be codes of practice for feed labelling - one for feed for food producing animals and one for pet food. As with the Community Catalogue of feed materials, it is envisaged that these codes will be drawn up by the feed industry in consultation with Member States, EFSA and feed users.

# Amendment of the labelling requirements for feed additive and premixture products. (Article 30)

20. The proposed Regulation will also amend Article 16 of the EC Feed Additives Regulation (1831/2003/EC) which relates to the labelling of premixtures. The existing provision requires the labelling of a range of information for each additive contained in a premixture, some of which (e.g. the date of manufacture and the batch number of each additive) is of minimal use to purchasers. The amendment would therefore delete the requirement to include this information on the labels of premixtures.

#### Bioproteins (Article 31)

21. Under existing legislation, new bioproteins (or 'certain products') must undergo a safety assessment based on a dossier submitted by the applicant before such products can be marketed for use in feed. The Regulation proposes to repeal this requirement and regard bioproteins as feed materials, to be controlled by post-marketing surveillance. Any products previously found to fail the requirements of the Certain Products Directive (82/471/EEC) would be added to the list of prohibited ingredients in EC Decision 2004/217/EC.

#### **Implications of main requirements**

22. In general, it is expected that the proposed Regulation will reduce administrative burdens on the feed industry without compromising feed safety. However, the Committee may wish to consider the following points and issues that the Food Standards Agency has identified in relation to the implications of a number of the new or modified requirements.

#### Feed additives in complementary feeds (Article 8)

23. This provision will provide a demarcation between premixtures and complementary feeds. The Committee considered this subject at its meeting on 7 February 2006 (paper ACAF/06/01). The issue that the Commission seeks to address in the proposed legislation is that, because complementary feeds are not subject to maximum permitted levels of additives, there is no legal distinction between complementary feeds and premixtures. Farmers using premixtures are subject to more stringent controls e.g. the application of HACCP under the EC Feed Hygiene Regulation (183/2005/EC) and requirements relating to facilities and equipment.

24. Previously, the Commission proposed that the levels of additives in complementary feeds be controlled by a range of maximum concentration factors (MCFs). The MCF was related to the amount an additive in a complementary feed, could exceed the equivalent maximum level for that additive in a complete feed. Thus an additive with an MCF of 50 could be included in a complementary feed up to 50 times the maximum permitted level for that additive in complete feeds. Under this system, the Commission proposed some 17 MCFs for different types of additives (certain vitamins/trace elements, coccidiostats and histomonostats). The Committee thought that this was a complicated and disproportionate approach.

25. The Commission's approach in the Marketing and Use Regulation is more simple and involves using only two factors (100 and 5) and it is understood that most complementary feeds currently marketed will comply with the 100 factor. However, there may be implications for the marketing of products in the form of pastes, drenches and boluses (slow–release capsules) which have higher levels of additives.

26. Regarding the regulation of coccidiostats and histomonostats, the UK considers that it would be preferable that these substances should be used in premixtures rather than complementary feeds. In contrast to premixtures, complementary feeds can be fed directly to animals and without dilution with other materials. In addition, the use of complementary feeds at farm level is

subject to less stringent requirements. As mentioned previously, farmers using premixtures must apply the principles of HACCP.

#### *Tolerances* (*Article 11* (5))

27. The feed manufacturing industry has indicated that the simplification of the tolerances (limits of variation) would result in a tightening of some of the limits (e.g. for the declaration of the ash content of feeds) which could mean that some feeds will not comply with the new limits. The UK intends to seek clarification from the Commission of the criteria to be applied to the new limits, such as whether the limits will take into account uncertainties naturally part of the sampling and analytical process.

#### Claims (Article 13)

28. This provision has been included to ensure that claims made for feeds can be substantiated and is mainly intended to protect purchasers of feeds and pet foods.

# Percentage declaration of the ingredients of compound feeds (Article 17 (1) (e) and 2)

29. The feed manufacturing industry considers that the existing requirement to declare the ingredients of compound feeds by their percentage weight of inclusion reveals the commercial confidentiality of feed formulations and compromises feed businesses' intellectual property. The UK did not support this requirement when it was originally introduced in EC legislation. The Food Standards Agency considers that feed and food safety is not enhanced by percentage ingredient declarations, since enforcement authorities have powers under other provisions to obtain feed formulation information (see Article 5.2 of the proposed Regulations).

#### Labelling of additives contained in feeds (Article 15 (f))

30. The feed and pet food manufacturing industries have indicated that the labelling of all additives in feeds subject to a maximum inclusion level including their identification number, the added amount, and the functional group may also compromise commercial confidentiality. It may also detract from more important labelling information such as directions for use. One alternative approach would be to require the declaration of the names only of the additives subject to a maximum inclusion level. The proposal also includes a requirement for the inclusion of a freephone number on pet food labels, in order that purchasers can obtain more detailed information on additives and ingredients of pet foods. This may have implications for small and medium sized enterprises and there may be

other ways in which such information could be made available e.g. the internet, email.

Amendment of the labelling requirements for feed additive and premixture products (Article 30)

31. It is hoped that this amendment will simplify labelling and correct some anomalies. (e.g. if the existing legislation is interpreted strictly the directions for use should be indicated for each additive in a premixture).

## Bioproteins (Article 31)

32. The proposal to remove the pre-marketing assessment for new bioproteins will remove an administrative burden on businesses as they would not be required to provide a dossier of information to the Commission and Member States to demonstrate safety, quality and efficacy. Bioprotein products are sources of protein often produced from novel processes. Many may be innocuous substances (e.g. certain proteins derived from yeast fermentation). However, a pre-marketing assessment may be appropriate for some types of products such as by-products from the production of pharmaceutical production.

#### Views of Stakeholders

33. The Food Standards Agency is undertaking a public consultation on the proposed Regulation:

#### http://www.food.gov.uk/consultations/consulteng/2008/feedmarketeng08

which ended on 21 May 2008. Responses are being considered and an oral update will be provided to the Committee at its meeting on 3 June 2008. However preliminary informal contacts with the feed and pet food industry has indicated that these sectors generally welcome the proposal.

#### Stage of the Negotiations

34. There was a Council working group meeting under the Slovenian Presidency on 21 April 2008 and another is scheduled for 9/10 June. It is expected that most of the detailed negotiations will take place during the French Presidency in the second half of 2008 and it is thought that the Commission hopes to obtain the agreement of the European Parliament (EP) to the proposed Regulation at the First Reading stage, so that the negotiations on the measure can be concluded prior to EP elections in June 2009.

## **Implications for UK legislation**

35. When adopted, the Regulation would apply directly in all Member States and those parts of the Feeding Stuffs Regulations 2005, which implement the four directives the EC Regulation would replace, would therefore need to be revoked and replaced by new legislation to enforce the EC Regulation.

#### Action

36. The Committee is requested to:

a) note the requirements of the proposed EC Regulation on the Placing on the Market and Use of Feed (Annex A), the main new provisions of which are summarised at paragraphs 8 to 21 above; and

b) make any comments on the issues raised in paragraphs 22 to 32 above and on any other issues related to the proposed Regulation.

ACAF Secretariat May 2008