ADVISORY COMMITTEE ON ANIMAL FEEDINGSTUFFS

43rd Meeting of ACAF on 24 September 2008

Information Paper

EC DEVELOPMENTS

Secretariat
September 2008

EC DEVELOPMENTS

1. This paper outlines the main developments in relation to EC legislation and related matters since the ACAF meeting held on 3 June 2008.

Official feed and food controls - Regulation (EC) No 882/2004

2. Implementing rules for import controls for 'high-risk' feed and food of non-animal origin - there has been little progress at EU level on the Commission's proposals but discussions are expected to resume in October 2008 with the aim of seeking adoption of the measures by the end of the year. Stakeholders will be kept up-to-date on developments via the Rapidly Developing Policy page on the FSA's website at:

http://www.food.gov.uk/foodindustry/regulation/europeleg/euupdates/

3. Review of fees and charges for official controls - the Commission is expected to provide an interim report on its study of current arrangements in Member States for collecting fees and charges for official controls this autumn.

4. Better Training for Safer Food (BTSF) - this is the Commission's strategy for training the officials of the competent authorities in Member States that carry out official controls in the feed, food, animal health and welfare and plant health sectors. The programme of fully funded courses for 2009/10 will include 10 five-day workshops on the application of European feed law. Further details of the 'Better Training for Safer Food' strategy can be found at:

http://ec.europa.eu/food/training/index_en.htm

Transposition of EC Animal Feed Measures

5. Since the last update, no substantive comments were received in the six-week public consultation on Commission Directive 2008/4/EC of 9 January 2008, which amended Directive 94/39/EC on feedingstuffs intended for the reduction of the risk of milk fever. The Feeding Stuffs (England) (Amendment) Regulations 2008 to transpose this EC measure received Ministerial approval on 11 June 2008 and came into force on 30 July, the EC deadline for Member States to complete implementation of the Directive. The Regulations can be viewed using the link below:

   http://www.opsi.gov.uk/si/si2008/uksi_20081523_en_1

Feed Incident – Contaminated Wheat Feed Pellets at Tilbury Docks

6. Following the last EC developments update, the Food Standards Agency had been working with Defra on a potential feed contamination incident involving the presence of material of animal origin in wheat feed intended for ruminant rations, from a contaminated consignment imported into the UK at Tilbury Docks.

7. Animal Health, an agency of Defra with responsibility for the enforcement of Transmissable Spongiform Encephalopathy (TSE) law, completed its investigations into this potential incident at the end of May 2008. An extensive tracing exercise had been carried out to establish the distribution of the feed material. Temporary movement restrictions were imposed on cattle and sheep on farms that had received this material or feed products containing it.

8. A total of 815 feed samples were collected and tested, of which 13 proved positive for low level contamination. It was established that this material was present at very low levels. At the Agency's request, other tests were carried out which eliminated any possibility of other types of contamination (e.g. chemical). Animal Health's veterinary risk assessment supported a decision to be made that it was safe to lift the precautionary animal movement restrictions. In light of the test results, Agency advice and the veterinary risk assessment, the temporary movement restrictions imposed on cattle and sheep were lifted on 29 May 2008.

Update on Microbiological Criteria

9. The Committee was informed in ACAF paper 07/10 about Article 5(3) (a) of the EC Feed Hygiene Regulation (183/2005) which enables specific microbiological criteria to be adopted (e.g. measures to control salmonella). The European Commission had requested an opinion from the European Food Safety Authority (EFSA) on the microbiological risks from feedingstuffs for food-producing animals for both public and animal health. Committee members are requested to note that EFSA has issued its opinion, a copy of which can be found at:

http://www.efsa.europa.eu/cs/BlobServer/Scientific_Opinion/biohaz_op_ej720_mra_feedingstuffs_en.pdf?ssbinary=true

10. It is expected that the Commission will discuss the EFSA opinion with Member States in forthcoming working group meetings on Feed Hygiene.

Transposition into national legislation of two EC measures

11. Commission Directive 2008/82/EC of 30 July 2008 amended: (a) an existing Annex entry for Directive 2008/38/EC regarding dietetic feedingstuffs for the support of renal function in case of chronic renal insufficiency for cats and dogs; and (b) Commission Directive 2008/76/EC of 25 July 2008 amended Annex I to Directive 2002/32 on undesirable substances in animal feed. Details of the amendments are described below:

Directive 2008/82

12. Directive 2008/82/EC introduces a minor amendment regarding the particular nutritional purpose "Support of renal function in case of chronic renal insufficiency" in Part B of the Annex to Directive 2008/38/EC. The amendment involves the addition of a new essential nutritional characteristic of 'reduced phosphorous absorption by means of incorporation of Lanthanum carbonate octahydrate'. This measure will require an amendment to Schedule 7 (on 'Permitted Feeding Stuffs Intended for Particular Nutritional Purposes and Provisions relating to their use') of the Feeding Stuffs (England) Regulations 2005.

Directive 2008/76

13. Directive 2008/76 makes a number of minor amendments. It: (a) increases the permitted level of fluorine in feed for fish; (b) clarifies the existing entry for DDT; and (c) deletes a number of entries for named species of weeds on the grounds that they are rarely found in Europe, or are already controlled by other more general entries, or have an alternative use in oilseed production. Schedule 5 of the Feeding Stuffs (England) Regulations 2005 will need to be amended accordingly.

14. Member States are required to bring the first of these measures into force no later than 20 February 2009, and the second by 1 April 2009. Given that the measures are not controversial and the EC deadlines for their transposition are close together, it is intended that there will be one consultation package on a single Statutory Instrument covering both measures with a shorter period for comments of six weeks in order to meet the EC transposition deadline for the measure on dietetic feedingstuffs.

Imports of Guar Gum from India

15. In July 2008 the Commission updated its list of approved testing laboratories to include ones in Germany and these can be found at:

http://ec.europa.eu/food/food/chemicalsafety/contaminants/new_measures_guar_gum_india.pdf

16. Decision 2008/352/EC requests quarterly reports of analytical results, and the Agency has written to enforcement agencies in the UK requesting the required data. A copy of the letter sent to local authorities can be found at:

http://www.food.gov.uk/multimedia/pdfs/enforcement/enfe08049.pdf

17. It is anticipated that very few consignments of guar gum from India, intended for use in animal feed are entering the United Kingdom.

Betaine produced from GM sugar beet

18. The European Commission has informed Member States of the potential import of betaine (a nutritional vitamin-like feed additive) produced from an EU-authorised GM sugar beet, H7-1. Companies within the EU are importing betaine from third countries where the EU-authorised GM sugar beet is grown. Regulation 1829/2003 permits placing on the market of any additive made from this GM sugar beet, as long as it complies with labelling rules and there are no live cells in the product.

Undesirable Substances

19. The Commission and Member States have recently been discussing the limits of arsenic (As) in fishmeal. There has been a request to increase the maximum residue level (MRL) for total As in fishmeal, whilst retaining the current MRL for inorganic As. Organic As is virtually non-toxic, whereas inorganic As is highly toxic. The basis for this request is that some fishmeal based wholly on off-cuts from fish for human consumption often has high levels of organic As, which result in the sample exceeding the MRL for total As.

20. Discussions have also taken place regarding *Ambrosia*. The pollen of this plant is highly allergenic, and highly persistent in the environment. It is thought the pollen is being spread in Northern Europe by its occurrence in wild bird feed. There is currently no Community legislation setting maximum levels in feedingstuffs for *Ambrosia*. The majority view of Member States is that an opinion should be sought from EFSA with a view to setting maximum limits in feed.

21. The EFSA opinion on mercury (Hg) in feed has been discussed. The EFSA opinion on Hg suggested that the maximum limit for cat food was too high to provide adequate protection. The UK is querying the EFSA opinion on the grounds that it is based on data with a moisture content well above normal moisture levels of 12%. The UK believes the data shows the current MRLs are safe and that the status quo should remain.

Carry over of Coccidiostats

22. The Commission has set out draft documents concerning the presence of authorised coccidiostats in feed for non-target animals. Maximum content levels in terms of mg/kg have been proposed for lasalocid sodium, narasin, salinomycin sodium, monensin sodium, semduramycin, maduramycin, robenidine, docoquinate, halofuginone, nicarbazin and diclazuril. These are based on tolerance levels of 3% for non-sensitive species, and 1% for sensitive species (such as horses and small ruminants). There will be a vote at the September or October meeting of SCoFCAH.

New applications for authorisation

23. The UK will act as rapporteur for the application for authorisation for Rovabio Excel (a zootechnical additive) for two species. The UK will present the dossier for one of the species at the September or October SCoFCAH meeting.

European Parliament and Council Regulation 1831/2003 on additives for use in animal nutrition

24. Votes in favour were obtained concerning the authorisation of various feed additives at the June and July 2008 meetings of SCoFCAH. These are summarised below.

Feed colours

25. *Paracoccus carotinifaciens* is a bacterium used to produce carotenoids for salmon and trout flesh. Conditions of authorisation included MRLs set for canthaxanthin, astaxanthin and adonirubin in salmon and trout flesh. The MRLs are applicable irrespective of source of the carotenoid (natural or synthetic).

26. Votes in favour were obtained for amending the terms of conditions for authorisation of canthaxanthin (a sensory additive used to colour salmon and trout flesh, poultry flesh and egg yolk). The amendment decreased the MRLs in salmon flesh, trout flesh, poultry liver, skin and fat and egg yolk, and again is applicable irrespective of source of the carotenoid (natural or synthetic).

Coccidiostats

27. Clinacox 0.5% – Diclazuril – amending Regulations (EC) No 2430/1999, (EC) No 418/2001 and (EC) No 162/2003 as regards the terms of the

authorisation of Clinacox for use in chickens for fattening and laying and turkeys for fattening, by introducing a maximum residue limit

28. Clinacox 0.5% – Diclazuril – authorisation for a new use of Clinacox for use in rabbits.

Feedingstuffs intended for the support of the renal function in case of chronic renal insufficiency

29. Lantharenol (lathanum carbonate octahydrate) is a zootechnical feed additive for adult cats. It restricts the intestinal absorption of phosphorus which may act to prevent/reduce chronic renal malfunction in ageing animals.

Re-assessment of additives authorised without a time limit

30. There have been discussions regarding Article 10 of Regulation (EC) 1831/2003. This Article provides a requirement for re-evaluation of additives ("feed additive Regulation") that have been authorised under Directive 70/524/EEC without a time limit. All such additives need an application for authorisation and a dossier to be submitted for re-assessment by 8 November 2010. The application should be written according to new and revised guidelines for the preparation and presentation of applications set down in Regulation (EC) 429/2008. Applications are also required for silage additives, which are now included in the scope of Regulation (EC) 1831/2003. Provided a valid application has been submitted in line with the requirements of Regulation (EC) 1831/2003, the additive will be maintained in the Community Register of feed additives until the Commission makes a decision about the authorisation. If an application is not submitted by 8 November 2010, the authorisation for use in Europe will lapse.

31. Any company can provide the application to maintain the authorisation of a feed additive in the EU, and no one applicant has responsibility for any generic additive. As a result, there is the possibility that some additives will not be covered by an application for authorisation. The European Feed Additives and Premixtures Association (FEFANA) has set up several consortia aimed at co-ordinating, preparing, submitting and following up applications for re-authorisation of feed additives.

32. With up to 2000 dossiers expected, EFSA has considered how to manage the workload. It has set out its priority list for dossier consideration, with safety as the main criterion. It has proposed that the additives should be

divided into different groups in order to improve efficiency and facilitate administrative handling. High priority groups are additives not already reviewed by EFSA or its processor SCAN (e.g. flavourings or silage agents), substances not authorised in food, and substances with *a priori* higher concern (such as substances with a tendency to bioaccumulate). Lower priority groups are additives recently evaluated by EFSA/SCAN and additives currently authorised in food.

European Food Safety Authority (EFSA)

33. The following Opinions have been published by the EFSA Scientific Panels FEEDAP and CONTAM since the Committee was updated in 2007:

FEEDAP – additives and products or substances used in animal nutrition

Additive	**Additive group**	**EFSA Opinion**	**Reason for negative opinion**
Ecobiol & Ecobiol plus	Zootechnical additive – gut flora stabiliser	Positive	n/a
Sorbiflore	Zootechnical additive – gut flora stabiliser	Positive	n/a
Levucell SC10ME / SC20	Zootechnical additive – gut flora stabiliser	Positive	n/a
Econase XT	Zootechnical additive – digestibility enhancer	Positive	n/a
Copper chelate of hydroxy analogue of methionine (Mintrex Cu)	Nutritional additive – compounds of trace elements	Positive for chickens for fattening only	Lack of efficacy data for other species
Zinc chelate of hydroxy analogue of methionine (Mintrex Zn)	Nutritional additive – compounds of trace elements	More information required	Unable to conclude on target animal safety
Manganese chelate of hydroxy analogue of methionine (Mintrex Mn)	Nutritional additive – compounds of trace elements	More information required	Unable to conclude on consumer and target animal safety
L-Valine produced by GM E.Coli K-12 strain	Nutritional additive – amino acid	More information required	Unable to conclude on safety at purity 95%, but positive opinion on purity >98%

CONTAM - Panel on Contaminants in the Food Chain

Tropane alkaloids

34. Tropane alkaloids are a group of more than 200 compounds occurring in the family *Solanaceae* (over 3000 plant species). High concentrations of alkaloids are found in *Datura* species, and poisoning can occur if these are present in hay, or its seeds contaminate grain or oilseed products (soybean or linseed). Previous reports of adverse health effects in animals mostly refer to accidental intoxication from consumption of *Datura* plants rather than by contamination. No conclusive exposure assessment could be presented for farm animals as very little information on contamination of feed materials was available. Tropane alkaloids are readily absorbed following oral ingestion, but are rapidly biotransformed or excreted. As a result, the Panel concluded that it is unlikely that residues of tropane alkaloids in edible tissues, milk and eggs constitute a significant risk for consumers.

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