

ADVISORY COMMITTEE ON ANIMAL FEEDINGSTUFFS

42nd Meeting of ACAF on 3 June 2008

Information Paper

EC DEVELOPMENTS

Secretariat May 2008

EC DEVELOPMENTS

1. This paper outlines the main developments in relation to EC legislation and related matters since the ACAF meeting held on 5 March 2008.

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

2. Since the last update there has been no progress in Brussels on the Commission's proposed implementing rules for import controls for 'high-risk' feed and food of non-animal origin. The Commission has indicated, that it will be consulting targeted stakeholders on the proposed rules shortly. 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. The Commission has initiated a review of the fees and charges that Member States are currently collecting for official controls under the financing framework laid down in Regulation 882/2004. The review is being undertaken on the Commission's behalf by a commercial organisation and a report of the review is expected by mid-July 2008.

Transposition of EC Animal Feed Measures

4. Commission Directive 2008/4/EC of 9 January 2008 amended Directive 94/39/EC on feedingstuffs intended for the reduction of the risk of milk fever. It makes two relatively minor amendments to Part B of the Annex to Directive 94/39/EC. A public consultation commenced on 13 March 2008 with a shortened period of consultation of six weeks. This was (a) to ensure that the deadline for Member States to bring the measure into force was satisfied; and (b) to allow the feed industry and feed purchasers to take advantage of the amendment to the existing entry for milk fever as soon as possible. The consultation ended on 24 April 2008 and no substantive comments were received. It is intended that the Regulations will be made in June 2008 and will come into force within the EC deadline of 30 July 2008.

GM Authorisations

5. The EC Developments Paper from ACAF's previous meeting (ACAF/08/04) referred to the consideration of the authorisation of three GM varieties of maize by SCoFCAH and the Council. Following inconclusive votes at a Council meeting in February, the Commission has announced that it will adopt authorisation decisions if and when the European Food Safety Authority has confirmed the safety of these products. An authorisation for GA21 maize was adopted by the

Commission on 29 March 2008. Authorisation decisions for GM cotton (LLcotton25) and GM soya (A2704-12) were referred to the Council at the end of April 2008 and votes are expected to be taken in June 2008.

Feed Incident – Contaminated Wheat Feed Pellets at Tilbury Docks

6. In early April 2008 the Food Standards Agency was informed by Defra about a potential feed contamination incident involving the presence of material of animal origin in wheat feed intended for ruminant rations. The potential contamination was detected following routine sampling undertaken as part of Defra's National Feed Audit, which gave positive results for the presence of muscle fibre, terrestrial animal bone and fish bone in stocks of wheat feed from Sweden in stores at Tilbury Docks.
7. The contamination incident concerns possible breaches of TSE and animal by-products legislation for which Defra is responsible. Investigations are being undertaken and led by Defra's Animal Health (formerly the State Veterinary Service).
8. The Food Standards Agency is being kept informed of developments and the Committee will be updated as necessary at its June 2008 meeting. The Commission has also been notified of this incident through its Rapid Food and Feed Alert System.

Imports of Guar Gum from India

9. Commission Decision 2008/352/EC of 29 April 2008 was published in the Official Journal of the European Union on 1 May 2008 and came into force on 5 May, imposing special conditions on guar gum originating in or consigned from India due to the risk of contamination by pentachlorophenol (PCP) and dioxins. The Decision that consignments of guar gum originating in or consigned from India, or compound feedingstuffs and foodstuffs which contain at least 10% guar gum originating in or consigned from India, be prohibited from being placed on the market unless they are accompanied by an original certificate of analysis stating that the consignment does not contain more than 0.01 mg/kg of PCP. The analytical report must be issued by a laboratory accredited according to EN ISO/IEC 17025 for the analysis of PCP in food and feed or by a laboratory pursuing the necessary accreditation procedures, endorsed by a representative of the competent authority from the country where the laboratory is based.
10. Commission Decision 2008/352/EC can be downloaded from the Commission's website at:

<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:117:0042:0044:EN:PDF>.

and has been implemented in England by Declarations made under Regulation 33 of the Official Feed and Food Controls (England) Regulations 2007 and Regulation 61 of the Products of Animal Origin (Third Country Imports) (England) Regulations 2006. Further information about the scope of the Decision and the requirements it imposes on feed business operators and enforcement authorities can be found in a letter to feed enforcement authorities published on the Agency's website at:

<http://www.food.gov.uk/multimedia/pdfs/enforcement/enfe08032.pdf>

Undesirable Substances

11. Further discussions have taken place at Commission Standing Committee meetings on the setting of tolerances for residues of coccidiostats in feed for 'non-target' animals. Member States and the Commission are being advised by EFSA's CONTAM Panel. Most Member States and the Commission prefer the setting of maximum limits that correspond to 1-3% carry over in to feed for non-target species. It is likely that these tolerances will be put in place via an amendment to the Undesirable Substances in Feed Directive (Directive 2002/32). It is not yet clear as to which legislation will be used to set maximum residue limits (MRLs) for foods derived from non-target animals. EFSA's CONTAM Panel has almost completed its work on carry-over, and it is likely that the Commission will submit a proposal for vote before August 2008.
12. A Commission proposal to amend Directive 2002/32 received a qualified majority vote in March. The amendment included the following changes:
 - a. an increase in the maximum limit for fluorine in fish feed from 150 to 300 mg/kg (i.e. the same as for complete feed for poultry);
 - b. deletion of the specific controls concerning *Lolium spp*, *Camelina sativa*, apricots and bitter almonds;
 - c. a change in the residue definition of DDT ('DDD' in place of 'TDE'); and
 - d. inclusion of 'photoheptachlor' in the residue definition of heptachlor.

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

13. Votes in favour were obtained concerning the authorisation of various feed additives at the March and April 2008 meetings of SCoFCAH. These are summarised below.

Enzyme preparations

Natuphos (a phytase) for use in feed for sows.

14. Quantum phytase for feed for broilers, laying hens, ducks for fattening, turkeys for fattening and weaned piglets.

Feed colour

15. Astaxanthin dimethylsuccinate for use in feed for salmon and trout.

European Food Safety Authority (EFSA)

16. 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

Quantum Phytase

17. The efficacy of this enzyme product has been demonstrated in broilers, laying hens, turkeys and for piglets. The Panel is of the view that efficacy in ducks for fattening can be extrapolated based on the data provided for chickens and turkeys for fattening and supported by a dose titration study. Based on the tolerance studies provided, the product has been shown to be safe in chickens for fattening, laying hens, turkeys for fattening, ducks for fattening and piglets at the respective maximum recommended doses. Given a lack of mutagenicity in three assays and the absence of any relevant effects in a 90-day study, it is concluded that the use of this enzyme as an additive in animal feed would pose no significant risks for the human consumer.

CONTAM - Panel on Contaminants in the Food Chain

Mercury in animal feed

18. A substantial number of feed materials have been analysed for total mercury in recent years within the EU Member States, and for the large majority, the concentrations were below the statutory maximum level. The most significant source of mercury in feed materials is fishmeal. However, no sample exceeded the maximum level of 0.5 mg/kg. In

contrast, approximately 8% of the complete feedingstuffs for fish analysed exceeded the maximum level of 0.1 mg/kg. There are relatively few data available on the speciation of mercury in fishmeals, but these suggest that it is mainly present as methylmercury. The most sensitive domestic animal species to methylmercury toxicity are cats and mink. However, on the basis of the available data, it is unlikely that these species will be exposed to toxic levels.

19. The maximum concentration reported in farmed salmonids is approximately five times lower than the maximum permitted level for mercury in fish for human consumption (500 µg/kg for salmonids). This maximum mercury concentration in salmonids would allow weekly consumption of two fish meals, as recommended by the Agency, without significant health risk from mercury exposure. EFSA is of the view that the statutory maximum level for fish feed is sufficient to ensure that mercury levels in farmed salmonids pose no appreciable risk to consumers.

Carry over of Nicarbazin (coccidiostat) to feed for non-target species

20. Based on limited tolerance data for non-target animal species the CONTAM Panel concluded that ingestion of feed containing nicarbazin at the maximum authorised level for chickens (50 mg/kg feed), is unlikely to cause adverse effects in non-target animal animals. Contamination of feed with nicarbazin at 10% (5 mg/kg feed) of the maximum authorised level for target animal species, would result in an intake for non-target animal species that would correspond to 0.25 mg/kg b.w. per day. This level is well below the no observed adverse effect level (NOEL) of 200 mg/kg b.w per day based on studies on studies performed in dogs and rats.
21. The Panel concluded that adverse health effects in non-target animal species are unlikely to occur as a result of cross-contamination of feed up to a hypothetical level of 10% of the maximum authorised level of nicarbazin in feed for target animal species.
22. CONTAM estimates consumer exposure from residue data from chicken eggs, liver and muscle and kinetic data from chickens for broilers at almost zero withdrawal time. The estimated exposure levels of nicarbazin resulting from eating chicken liver that received a diet containing 10% carry over of nicarbazin (5 mg/kg) was 1.4 µg/kg b.w. per day.
23. The consumer exposure via hens' eggs would be 1.8 µg DNC/kg b.w. per day. Data show that nicarbazin concentrations of up to 7200 µg/kg have been detected in chicken liver, 900 µg/kg in eggs and 110 µg/kg in chicken muscle. For a conservative daily intake estimate a person eating 100 g chicken eggs, 100 g chicken liver and 300 g chicken muscle would

be exposed to about 840 µg of nicarbazin (corresponding to 14 µg/kg b.w. per day for a 60 kg person).

24. The Panel concluded that there is no indication of an appreciable risk to consumer health from the ingestion of nicarbazin residues in products from animals exposed to cross-contaminated feed up to level of 10% of the maximum authorised level for feed for target species.

Carry over of Robenidine (coccidiostat) to feed for non-target species

25. Based on limited tolerance data provided for layers, pigs and ruminants, it is considered that accidental ingestion of feed intended for poultry and rabbits containing robenidine at the maximum authorised level of 36 and 66 mg/kg feed, respectively, does not present a health risk for non-target animal species. For a cross-contamination equivalent to 10% of the maximum authorised level, the intake of robenidine would be well below the overall no observed effect level (NOEL) of 7.5 mg/kg b.w. (based on liver enlargement derived from a 90 day study in the dog). Hence, the Panel concluded that adverse effects are unlikely to occur in non-target animals as a result of cross-contamination of feed at a level up to 10% of the maximum authorised level of the substance in feed for target animals.
26. No data were available to estimate the amount of robenidine residues in milk, meat or offal from non-target animal species. However, consumer exposure was estimated using data from chickens for fattening fed the maximum level authorised for rabbits (66 mg robenidine/kg feed). These were extrapolated to a concentration of 6.6 mg/kg feed to correspond to feed contaminated with a level of 10% of the maximum authorised level.
27. Consumption of such poultry products (100 g of liver, 300 g muscle, 90 g skin/fat and 10 g kidney and 100 g eggs) would give an intake of 1.6 µg/kg b.w. for a 60 kg consumer. This represents only 4.3% of the acceptable daily intake (ADI) of 37.5 µg/kg b.w. per day established by the Panel on Additives and Products or Substances used in Animal Feed (FEEDAP).
28. The Panel concluded that on the basis of the data available that there is no indication of an appreciable risk to consumer health from the ingestion of robenidine residues in food derived from animals exposed to feed cross-contaminated up to a hypothetical level of 10% of the maximum authorised level for robenidine.

Carry over of Decoquinate (coccidiostat) to feed for non-target species

29. Studies in laboratory animals have identified the dog as the most sensitive species to this substance with no observed adverse effect level (NOAEL) of 15 mg/kg b.w. per day. Based on limited tolerance data for pigs, ruminants, horses and rabbits, FEEDAP considered that ingestion of feed intended for chickens containing decoquinate at the maximum authorised level (40 mg/kg) does not present a significant risk for these non-target animal species. At a contamination level of 10% of the maximum authorised level, the intake of decoquinate would be well below the NOAEL.
30. Thus, CONTAM concluded that adverse effects are unlikely to occur in non-target animals as a result of cross-contamination of feed at a level up to 10% of the maximum authorised level of the substance in target animal feed. CONTAM has estimated that the maximum human exposure would correspond to 33.4 µg/person per day (0.56 µg/kg b.w. per day for a 60 kg person). This is only 0.75% of the ADI of 75 µg/kg b.w as established by FEEDAP.
31. Therefore, CONTAM has concluded that there is no indication of an appreciable risk to consumer health from ingestion of decoquinate residues in tissues of animals exposed to feed contaminated up to a level of 10% of the maximum level authorised for target animal species.

Commission Report on the Use Of Coccidiostats and Histomonostats as Feed Additives

32. The current UK view is that to phase out the control and use of coccidiostats and histomonostats as feed additives would mean they could only be available as veterinary medicinal products. This would create a new regulatory burden for the UK's poultry industry, without any significant advantages on the quality of assessment or control of the products, and with no discernible benefit to consumer protection.
33. Following agreement from the Defra Minister, the Veterinary Medicines Directorate wrote to the European Commission on 28 March 2008 to report that the UK is now minded to support the retention of the regulation and use of prophylactic coccidiostats and histomonostats under feed additive legislation, but that the UK will formally consider its position once it has seen and consulted stakeholders on the report and any accompanying legislative proposals the Commission eventually prepares.

ACAF/08/09

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