ADVISORY COMMITTEE ON ANIMAL FEEDINGSTUFFS

41st Meeting of ACAF on 5 March 2008

Information Paper

EC DEVELOPMENTS

Secretariat February 2008

EC DEVELOPMENTS

1. This paper outlines the main developments in relation to EC legislation and related matters since the ACAF meeting held on 4 December 2007.

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

2. **Article 28 - expenses arising from 'additional official controls'** – the legal measures needed to give this requirement effect (a provision is included in the Official Feed and Food Controls (England) Regulations 2007 (SI 2007/3185) and parallel legislation in Scotland, Wales and Northern Ireland) have come into force (copies of the legislation may be downloaded from the Office of Public Sector Information website at: http://www.opsi.gov.uk

3. Guidance Notes which aim to ensure consistency in application by the regulatory authorities have been published and are available on the FSA website at:

http://www.food.gov.uk/foodindustry/guidancenotes/foodguid/offcexpenses

4. **UK National Control Plan (January 2007 to March 2011) –** the Food Standards Agency (FSA) and the four Agriculture/Rural Affairs Departments in the UK have undertaken a second review of the Plan. No substantive amendments have been made as a result of the review but the Plan has been updated to reflect organisational and legislative changes. The revised Plan was published in mid February 2008, and appears on the FSA website at:

http://www.food.gov.uk/foodindustry/regulation/europeleg/feedandfood/ncpuk

5. **Annual report on implementation of the National Control Plan** - Member States are required to report annually on the implementation of their national control plans and the first report is due by end of June 2008 this year. The Agency and the four Agriculture/Rural Affairs departments are currently preparing the first UK report.

6. **Implementing rules for import controls for 'high-risk' feed and food of non-animal origin** - consideration of the Commission's proposals is still on-going at EU level. The Commission remains optimistic that the rules will be agreed in the first half of 2008. Stakeholders are being kept up-to-date with developments via the Rapidly Developing Policy page on the Agency's website. The latest update is at:

http://www.food.gov.uk/foodindustry/regulation/europeleg/euupdates/euupdateoffcont0710

EU Transmissible Spongiform Encephalopathy (TSE) ROADMAP

7. In January 2008 the Commission convened an expert group to assess the dietary requirements of young ruminants. This was needed to progress the current proposal under the EC TSE Regulation on the feeding of fishmeal to young ruminants. Although it is difficult to establish that fishmeal is an essential component of young ruminant diets, the expert group's draft report highlighted a number of benefits of fishmeal over plant-based protein sources. These include its digestibility and its richness in essential amino acids, fatty acids, calcium and phosphorus.

8. The Commission discussed the expert group's report, along with the current proposal, with Member States in a TSE Working Group meeting on 12 February 2008. The proposal as drafted is intended to apply to feeding fishmeal in reconstituted milk replacer for unweaned ruminants. The discussion also covered necessary on-farm controls. The proposal will be developed further prior the next TSE Working Group meeting in March 2008 and a subsequent meeting of the Standing Committee on the food chain and Animal Health (SCoFCAH).

Transposition of EC Animal Feed Measures

9. The EC Developments Paper tabled at ACAF's previous meeting (ACAF/07/26) referred to the implementation of Commission Directive 2006/77/EC of 29 September 2006, which amended the maximum permitted levels for organochlorine compounds. This was transposed into law in England by the Feed (Specified Undesirable Substances) (England) Regulations 2007, which came into force on 30 November 2007. Separate but parallel legislation came into force on the same date in Scotland, Wales and Northern Ireland.

10. A public consultation will commence shortly on initial legislation implementing Commission Directive 2008/4/EC of 9 January 2008. This amends the existing entry for feedingstuffs intended for the reduction of the risk of milk fever made under Directive 94/39/EC on feedingstuffs for particular nutritional purposes. Member States are required to bring the measure into force by 30 July 2008.

GM Authorisations

11. The Committee was advised previous EC Developments Paper (ACAF 07/26) that the Commission had granted formal authorisation for the import, processing and use in the EU of three GM maize varieties and one GM sugar beet variety following inconclusive votes in SCoFCAH and the Council. A further three GM varieties of maize (MON863xNK603, MON863xMON810 and MON863xMON810xNK603) and one GM

variety of potato (EH92-527-1) - have since failed to gain qualified majority votes in favour of authorisation in SCoFCAH, and were referred for consideration at the Agriculture and Fisheries Council on 18-19 February 2008. Should these varieties fail to gain a qualified majority for authorisation at that meeting, they will be referred back to the Commission for action.

Undesirable Substances

12. Discussions have continued 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. This Panel has so far provided Opinions on residues of narasin, lasalocid, monensin, salinomycin, maduramicin and semduramicin. The Commission has drafted two possible alternative approaches for setting limits:

a) setting of maximum limits that correspond to 1 – 3% carry over; and

b) setting of maximum limits that correspond to 2 – 5%, plus action levels that correspond to 1 – 3% carry over.

13. Further Opinions are expected from CONTAM in the next few months. It is expected that the Commission will not attempt to set any residue limits until EFSA's advice on carry-over for all authorised coccidiostats is available.

14. The Commission and Member States have been discussing a proposal to amend the Undesirable Substances Directive. The aim of this proposal is broadly deregulatory. Action under considerations is as follows:

(i) a new limit for arsenic in trace element additives of 30 mg/kg;

(ii) an increase in the limit for fluorine in fish feed from 150 to 300 mg/kg;

(iii) deletion of the specific controls concerning *Lolium spp*, *Camelina sativa*, apricots and bitter almonds;

(iv) a change in the residue definition of DDT ('DDD' in place of 'TDE'); and

(v) inclusion of 'photoheptachlor' in the residue definition of heptachlor.

15. Points (i) and (v) require further discussion and the other items are to be included in the proposal for a vote at the March 2008 meeting of SCoFCAH.

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

16. Votes in favour were obtained concerning the authorisation of feed additives at the November 2007 and January 2008 meetings of SCoFCAH. These are summarised below.

Microorganism preparations

- **Biosaf** – a feed microorganism preparation containing *Saccharomyces cerevisiae* (SC47) for use in feed pigs for fattening.

- **Calsporin –** a feed microorganism preparation containing *Bacillus subtilis* (C-3102) for chickens for fattening.

Other zootechnical product

- **Lantharenol** – a preparation of lanthanum carbonate to reduce the uptake of dietary phosphorus for use in certain cats to help prevent renal malfunction.

- **Coxidin – Monensin sodium** – amending Regulation (EC) 109/2007 as regards the terms of the authorisation of Coxidin for use in turkeys, by reducing the minimum content of the additive from 90mg/kg to 60mg/kg.

- **Kokcisan – Salinomycin** sodium – authorisation of Kokcisan for use in chickens for fattening.

New guidelines for feed additive applications

17. A vote in favour was also obtained for a Commission Regulation providing new, extensive guidelines for feed additive applications. The Committee has been provided with further information on this issue which can be found in Information Paper ACAF/08/05.

European Food Safety Authority (EFSA)

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

FEEDAP – additives and products or substances used in animal nutrition

Feed enzyme Natuphos for sows

19. Natuphos® is a preparation of a 3-phytase (EC 3.1.3.8) produced by a genetically modified strain of *Aspergillus niger*, to be available in solid

and liquid form. It is already authorised in feed for weaned piglets, pigs, chickens, laying hens and turkeys. In a previous Opinion FEEDAP could not conclude on the safety of this enzyme preparation for sows due to the inadequate duration of the tolerance study. Based on data from a new tolerance study performed on sows during one reproduction cycle with a 200-fold overdose of Natuphos, the Panel concluded that the product is safe for sows at the recommended dose.

Feed micro-organism product Biosaf Sc 47 for pigs for fattening

20. Biosaf Sc 47 is a preparation of the yeast *Saccharomyces cerevisiae*. This is already authorised for use in feed for cattle for fattening, dairy cows, rabbits, sows, piglets, lambs, horses, dairy goats and dairy sheep. The Panel considered that the safety of this application for the consumer, the user and the environment had already been established and would not be changed by the proposed additional use. The efficacy of the product in pigs was demonstrated at the lowest recommended dose in three efficacy studies, in which significant improvements were seen in appropriate parameters. In all three studies daily weight gain was significantly improved, and in two of the studies there was a significant improvement of feed to gain ratio. Given that the product has already been shown to be safe for weaned piglets, the FEEDAP Panel was of the view that safety for pigs for fattening can be assumed.

Feed enzyme Danisco Xylanase G/L for turkeys

21. Danisco Xylanase G/L (dry and liquid forms, respectively) is a formulation of endo 1,4 beta-xylanase produced fermentation of a genetically modified form of the micro-organism *Trichoderma reesei*. The FEEDAP Panel considered that the safety aspects other than those related to the new target species are covered in a previous Opinion and would not be affected by this proposed new use. Data from four experiments were provided to support the efficacy of the product. In two studies, significant improvements in weight gain and feed conversion were observed at the minimum recommended dose (1,250 U/kg). The meta-analysis of the data from all four trials supports the efficacy of the product at the minimum recommended dose. Therefore, the FEEDAP Panel was of the view that there is evidence to support efficacy of this product at the minimum recommended dose. On the basis of the data from the tolerance study provided and the tolerance shown by other poultry species (chickens for fattening, laying hens and ducks), the FEEDAP Panel

concluded that this product is safe for turkeys for fattening at the recommended use level.

Feed colour Carophyll for salmon and trout

22. CAROPHYLL® Stay-Pink is a preparation of astaxanthin dimethyldisuccinate to be used as a colour in feed for salmon and trout intended to enhance the colour of the fish flesh. The Panel was of the view that the product was efficacious in colouring the flesh of salmonids. A dietary level of 908 mg astaxanthin equivalents kg^{-1} complete diet provided as astaxanthin-dimethyldisuccinate was well tolerated in rainbow trout over a period eight weeks. Taking into account also former assessments of astaxanthin, the FEEDAP Panel considered astaxanthin-dimethyldisuccinate safe for the target species. The Panel was of the view that the product was not genotoxic, carcinogenic or teratogenic. Consequently, supplementation of fish feed with astaxanthin at the highest approved level is unlikely to represent a significant additional risk to consumers.

CONTAM – Panel on undesirable substances in the food chain

Carry-over of residues of the coccidiostat monensin into non-target feed

23. The CONTAM Panel was of the view that human exposure resulting from consumption of food products from 'non-target' animals exposed to feed cross-contaminated up to a level of 10% of the maximum authorised level, would result in exposure well below the acceptable daily intake (ADI) of 3 µg/kg b.w./day. Therefore, the CONTAM Panel concluded that there is negligible risk to consumer health from ingestion of monensin residues in tissues of animals exposed to feed cross-contaminated up to a hypothetical level of 10% of the maximum level authorised target animal species. However, a carry over of 10% might be too high to tolerate for sensitive species such as horses.

Carry-over of residues of the coccidiostat semduramicin into non-target feed

24. The Panel was of the view that poultrymeat from non-target animals that had consumed feed with a 10% carry over of feed would result in a consumer exposure well below the semduramicin ADI of 1.25 µg/kg b.w./day. Therefore, the CONTAM concluded that the limited data provided no indication of a significant risk to consumer safety from this exposure to semduramicin residues in

products from animals exposed to feed cross-contaminated up to a hypothetical level of 10% of the maximum authorised level.

Carry-over of residues of the coccidiostat madduramicin into non-target feed

25. The Panel concluded that adverse health 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 maduramicin in feed for target animals. CONTAM Panel was also of the view that on the basis of the limited data available that there was no indication of a significant risk to consumers from the ingestion of maduramicin residues in products from animals exposed to feed cross-contaminated up to a hypothetical level of 10% of the maximum authorised level.

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