ADVISORY COMMITTEE ON ANIMAL FEEDINGSTUFFS

40th Meeting of ACAF on 4 December 2007

Information Paper

EC DEVELOPMENTS

Secretariat November 2007
EC DEVELOPMENTS

1. This paper outlines the main developments in relation to EC legislation and related matters since the ACAF meeting held on 11 September 2007.


2. Article 28 - expenses arising from ‘additional official controls’ - the legal measures needed to give this requirement effect (provision is to be included in the Official Feed and Food Controls (England) Regulations 2007 and parallel legislation being made in Scotland, Wales and Northern Ireland), and associated Guidance Notes which aim to ensure consistency in application by the regulatory authorities, have been finalised. It is expected that the Guidance Notes will be published in early December and that the legislation throughout the UK will come into force on 14 December 2007.

3. UK National Control Plan (January 2007 to March 2011) the Food Standards Agency (FSA) and the four Agriculture/Rural Affairs Departments in the UK undertook a review of the Plan in the Summer. 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 is available on the FSA website at:

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

4. Implementing rules for import controls for 'high-risk' feed and food of non-animal origin - Consideration of the Commission’s proposals is on-going at EU level. Progress is slow and a number of key issues remain unresolved. Despite this, the Commission remains optimistic that the rules will be agreed before the end of the year. 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

Feed Hygiene

5. The EC Feed Hygiene Regulation (183/2005) required virtually all feed businesses (including those outlined below) to be approved or registered with their local authority by 1 January 2006. Article 18(3) of the Regulation requires certain feed businesses to declare by 1 January 2008 'that the conditions laid down in this Regulation are being met'. This mainly includes those businesses, including farms which were not registered under previous legislation (Directive 95/69/EC). Such businesses include for example feed importers, merchants, hauliers, food
businesses selling co-products for feed use, livestock farms, fish farms (other than on-farm mixers) and arable farms selling crops for feed use.

6. The UK took advantage of the transitional requirements of Article 18(4) of Regulation 183/2005, which permitted enforcement authorities to use existing official registration schemes for registration under the Feed Hygiene Regulation. This included agriculture departments’ farm registration schemes (e.g. for grant purposes) and businesses registered with their local authority for the purposes of the Food Hygiene Regulation (852/2004). However, the requirement to submit a statement of compliance under Article 18(3) still applies to such businesses.

7. Feed businesses, except most farms, must apply the principles of a Hazard Analysis Critical Control Points (HACCP) system and comply with various requirements, including those set out in the Annexes to Regulation 183/2005. These requirements relate to standards concerning facilities and equipment, personnel, storage and transport and record-keeping (e.g. to help trace feeds in the event of a safety incident).

8. The Agency’s Animal Feed Unit has issued guidance to local authorities and the feed industry, including farmers to further publicise the requirement for feed businesses to submit a compliance statement to their local authorities that enforce the requirements of the Regulation.

9. A copy of this documentation has been lodged on the Agency's website and can be found at:

http://www.food.gov.uk/foodindustry/farmingfood/animalfeed/animalfeedlegislation

Feed Incidents -- Melamine in Pet Food from the USA

10. Due to continuing concerns about possible adulteration of imports of protein isolates from China, the European Commission had requested Member States to put in place increased surveillance for the possible presence of melamine and structurally related compounds (such as cyanuric acid, ammelide and ammeline) in consignments of these products. In the UK, only one positive sampling result was reported in response to this increased surveillance.

11. At its meeting held on 15 October 2007, the Standing Committee on the Food Chain and Animal Health (Animal Nutrition Section) considered that the control measures recently put in place in China were adequate to prevent the adulteration of protein isolates intended for export. The Commission and Member States therefore agreed that specific control
action for the presence of melamine and structurally related compounds in protein isolates could now be discontinued.

**Commission's Forthcoming Review of Feed Labelling**

12. The Committee was informed in the EC Developments paper considered at the previous meeting that it was expected that the finalised text of the proposed Regulation would be submitted to the College of Commissioners for adoption in the early autumn. The timescale has been extended, and recent information from the Commission indicates that the draft proposal may not be issued until the end of the year.

**GM Authorisations**

13. In the previous EC Developments paper, the Committee was informed that four GM varieties -- a herbicide tolerant sugar beet (H7-1) and three herbicide tolerant and insect resistant maizes (NK603xMON810, DAS-59122-7 and 1507xNK603) -- which had failed to gain a qualified majority vote in favour of authorisation in the Standing Committee on the Food Chain and Animal Health would be referred for consideration at Council meetings in September. In the event, authorisation of these GM varieties failed to obtain a qualified majority vote in favour, and under established comitology procedures were referred to the Commission for attention. The Commission subsequently issued formal authorisation (for import, processing and use in the EU but not for cultivation) for all four varieties in the form of separate Commission Decisions 2007/692/EC, 2007/701/EC, 2007/702/EC and 2007/703/EC.

**Emergency Controls on Bt10 GM Maize**

14. The Committee had previously been informed that the Regulations to implement Commission Decision 2007/157/EC repealing the emergency controls on imports of certain maize by-products from the USA were expected to be submitted for Ministerial signature in early October. In the event, this was deferred for several weeks to ensure that all parts of the UK made their submissions at the same time. In England, the Feed (Corn Gluten Feed and Brewers Grains) (Emergency Control) (England) (Revocation) Regulations 2007 was signed on 22 October and laid before Parliament on 26 October. The Regulations will come into force on 30 November 2007.

**Maximum permitted Levels for Organochlorine Compounds**

15. Regulations to implement Commission Directive 2006/77/EC amending the maximum permitted levels for organochlorine compounds in animal feed were expected to be submitted for Ministerial signature in early October. As with the Regulations for the Bt10 controls, this was deferred for several weeks to ensure that all parts of the UK made their submissions simultaneously.
Coccidiostats

16. Clinacox group of products - a request to change the company details went through with a qualified majority vote in favour at the Standing Committee on the Food Chain and Animal Health (SCoFCAH) on 22 October 2007.

Draft Report on the use of Coccidiostats and Histomonostats as feed additives

17. At the October 2007 meeting of SCoFCAH, Member States (MS) were invited to comment on the contents of the Commission draft report on the use of coccidiostats and histomonostats as feed additives. The report does not yet contain any conclusions or recommendations. There was some support for retaining the feed additive status, some support for legislating as veterinary medicines products. However, not many MS offered an opinion.

18. As regards the current UK position, this remains that coccidiostats and hisomonostats should be regulated as veterinary medicines. However, in response to the industry concerns, the Veterinary Medicines Directorate (VMD) asked the Veterinary Products Committee (VPC) to consider the latest information available. The VPC concluded that the current regulation of these products appeared to be well researched and assessed and advised the VMD that the regulation on coccidiostats and hisomonostats should remain under the feed additive legislation.

19. The next step is for the VMD to put a submission up to its Minister, along with recommendations agreed by the Food Standards Agency, as the Minister will be required to agree the UK position.

Undesirable Substances

20. At a meeting of the Commission Working Group on Undesirable Substances held on 15 October 2007, the Commission proposed tolerance levels of 5% for carry-over of coccidiostats which could be present in feeds for non target species. This was on the understanding that there would be scope for raising or lowering the proposed level depending on appropriate risk analyses. The matter will be discussed further at a future meeting of the Commission Working Group.

European Parliament and Council Regulation 1831/2003 on additives for use in animal nutrition
21. Votes in favour were obtained concerning the authorisation of feed additives at the September and October 2007 meetings of the Animal Nutrition Section of the Standing Committee on the Food Chain and Animal Health (SCoFCAH). These are summarised below.

Enzyme preparations

- **Safizym X** – Preparation of endo-1,4-beta xylanase produced by *Trichoderma longibrachiatum* (CNCM MA 6-10W) for use in ducks.


- **Hostazym C** – Preparation of endo-1,4-beta-glucanase produced by *Trichoderma longibrachiatum* (IMI SD 142) for use in weaned piglets.

- **Natugrain Wheat** – Preparation of endo-1,4-beta-xylanase produced by *Aspergillus niger* (CBS 109.713) for use in turkeys for fattening.

Microorganism preparations

- **Bonvital** – a feed microorganism preparation containing *Enterococcus faecium* (DSM 7134) for use in sows.

- **Biosprint** – a feed microorganism preparation containing *Saccharomyces cerevisiae* (MUCL 39885) for use in dairy cows.

- **Oralin** – a feed microorganism preparation containing *Enterococcus faecium* (DSM 10663/NCIMB 10415) for turkeys for fattening.

- **Lactobacillus acidophilus D2/CSL CECT 4529** – a feed microorganism preparation for use in laying hens.

22. Votes in favour were also obtained for amending Part B of the Annex to Directive 94/39/EC with respect to feedingstuffs intended for the reduction of the risk of milk fever in dairy cows. The amendments focused on the inclusion of high levels of zeolite (sodium aluminium silicate) and/or high level of calcium and highly available calcium salts as essential nutritional characteristics for the reduction of milk fever.

European Food Safety Authority (EFSA)

23. The following Opinions have been published by EFSA Scientific Panels recently:
FEEDAP – additives and products or substances used in animal nutrition

- **Natuphos** is a preparation of 3-phytase (EC 3.1.3.8) produced by the genetically modified micro-organism *Aspergillus niger* (CBS 101.672). The FEEDAP panel stated that the efficacy of phytase from Natuphos® has been established for chickens for fattening and turkeys for fattening, at the respective doses of 375 and 250 FTU kg⁻¹ and concluded that as the mode of action in ducks is the same as the major species, an extrapolation can be made provided the dose range is similar. The Panel considered there was sufficient evidence to support efficacy in ducks at 300 FTU Natuphos® kg⁻¹ complete feed. FEEDAP also concluded that Natuphos® is safe for ducks, consumers and the environment.

- **Calsporin** is a preparation of *Bacillus subtilis* C3102 (DSM 15544). The additive is authorised for chickens for fattening at a dose of 1 x 10⁹ cfu kg⁻¹ complete feedingstuff (equivalent to 100 mg product kg⁻¹ complete feedingstuff). The applicant is now seeking authorisation to change the authorised dose by introducing a minimum dose of 5 x 10⁸ cfu kg⁻¹ complete feedingstuff (50 mg kg⁻¹) and retaining the presently authorised dose as the maximum. The Panel considered that the product is safe for target animals, consumers and the environment. Consequently, this opinion focuses only on the evidence of efficacy at the lowest dose. FEEDAP concluded that efficacy was shown at the lowest dose proposed.

- **Lantharenol** (Lanthanum carbonate octahydrate) is a synthetic substance intended to be used in the feed of adult cats to restrict the intestinal absorption of phosphorus which may act to prevent/reduce chronic renal malfunction in ageing animals. Lantharenol is proposed to be added to complete feedingstuffs of adult cats at the dose range of 1500 to 7500 mg kg⁻¹ complete feed throughout the adult life of a cat. The Panel concluded that efficacy was demonstrated at the lowest recommended dose (1500 mg kg⁻¹). FEEDAP stated the product is safe for cats but could not comment on whether the changes to phosphorus absorption following the addition of Lantharenol would have any long-term effects on renal function, and therefore suggested that a post-market monitoring plan be introduced. FEEDAP concluded the product is safe for users and the environment.

- **Toyocerin** is a preparation containing spores of *Bacillus cereus* var. Toyoi (NCIMB 40112/CNCM I-1012). The product has already been granted authorisation for use in several animal species and the applicant is now seeking authorisation for use in turkeys from one day of age to slaughter at an inclusion level of 0.2 – 1.0 x 10⁹ CFU kg⁻¹ complete feedingsuff. Safety for animals, consumers and the environment was established as part of the previous authorisations so only the issues of safety and efficacy introduced by the extension of use to turkeys for fattening were considered in this Opinion. The Panel concluded that efficacy was demonstrated in turkeys for fattening at the highest recommended dose (1
x 10^9 CFU kg⁻¹) and on balance, the minimum recommended dose (0.2 x 10^9). Although no specific data on the compatibility of Toyocerin with authorised coccidiostats in turkeys was presented, the Panel considered it reasonable to assume that compatibilities established in chickens for fattening would also apply to turkeys for fattening. FEEDAP concluded that Toyocerin is safe for turkeys when used at the maximum recommended dose.

- **Panaferd – AX** is a feed additive consisting of dried sterilised cells of a red carotenoid-rich bacterium *Paracoccus carotinifaciens* (NITE SD00017) intended to provide farmed Atlantic salmon and rainbow trout with a source of astaxanthin which provides red colour to the flesh. Panaferd-AX contains approximately 4 % total red carotenoids, predominantly astaxanthin (2.2 %), adonirubin (1.3 %) and canthaxanthin (0.4 %). FEEDAP stated that the product is safe for salmonids and the environment. The Panel had some concerns regarding toxicity of adonirubin. FEEDAP concluded that no additional risk due to adonirubin exposure resulting from the use of Panaferd-AX is likely to occur. FEEDAP stated that Panaferd-AX is considered an eye irritant and a respiratory sensitiser. The Panel recommends a number of modifications to the Register entry as proposed by the applicant. In particular, it recommended a maximum content of 100 mg kg⁻¹ complete feed be applied for the sum of astaxanthin, adonirubin and canthaxanthin.

- The FEEDAP and GMO panels performed an assessment on the safety and efficacy of **Danisco Xylanase G/L** (endo-1,4-beta-xylanase) as a feed additive for chickens for fattening, laying hens and ducks for fattening. The thermotolerant enzyme is produced by a genetically modified strain of *Trichoderma reesei*. The efficacy of Danisco Xylanase G/L has been demonstrated in chickens for fattening at 625 U kg⁻¹ and extrapolated to ducks for fattening at the same dose, and in laying hens at 2500 U kg⁻¹. However, the Panel states that data provided do not support the minimum recommended dose proposed by the applicant for chickens for fattening (250 U kg⁻¹) and for laying hens (625 U kg⁻¹). Danisco Xylanase was considered safe for all target sp., consumers and the environment and concerns for user safety were limited to possible eye irritation and respiratory sensitation.

- The FEEDAP panel performed an assessment of the compatibility of the microbial preparation of **Bacillus licheniformis** and **Bacillus subtilis** (Bioplus 2B) with the coccidiostat lasalocid a sodium in feed for turkeys. The panel was unable to conclude on the compatibility of Bioplus 2B with this coccidiostat.

CONTAM – Panel on undesirable substances in the food chain
Following a request from the European Commission, the CONTAM Panel was asked to deliver an opinion on cross-contamination of non-target feedingstuffs by lasalocid authorised for use as a feed additive (coccidiostat). Lasalocid sodium is authorised as a coccidiostat for use in chickens for fattening, chickens reared for laying (up to 16 weeks of age) and turkeys (up to 12 weeks of age) with a maximum content of the active ingredient in feed of 125 mg/kg and a withdrawal period of 5 days. The Panel outlines the principles of carry over of coccidiostats into feed for non-target species.

The Panel concluded that accidental ingestion of poultry feed containing the highest authorised level of lasalocid (125 mg/kg feed) may be toxic to non-target animal species (dogs, calves, rabbits and horses being the most sensitive). It was concluded by the Panel that adverse health effects in non-target animals in the event of cross-contamination are unlikely to occur. Given the fact that exposure to lasalocid residues resulting from cross-contamination of feed is likely to be rare, the CONTAM Panel further concluded that adverse health effects in consumers resulting from exposure to lasalocid residues in products from animals exposed to feed cross-contaminated even up to a level of 10 %, is unlikely.

Following a request from the European Commission, the CONTAM Panel was asked to deliver an opinion on cross-contamination of non-target feedingstuffs by narasin (a coccidiostat) authorised for use as a feed additive. The Panel outlines the principles of carry over of coccidiostats into feed for non-target species. The Panel concluded that in sensitive non-target animal species (dogs, horses, cattle, turkeys and rabbits) adverse effects may occur at feed concentrations below the maximum level authorised for use in chickens for fattening. In contrast, it is expected that no toxicological or pharmacological effects will occur in non-target animals given feed containing narasin at the dietary levels resulting from cross-contamination up to 10 % of the maximum amount permitted in the feed of target animals. The Panel concluded that there is negligible risk to consumers from ingestion of narasin residues in tissues of animals exposed to feed cross-contaminated up to a level of 10 %.

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