Summary Minutes of the Meeting of the Standing Committee on the Food Chain and Animal Health

Animal Nutrition Section

Brussels, 23-24 Mai 2005

Standing committee

1. Discussion and possible request of opinion on a draft Commission Regulation concerning the permanent authorisations of certain additives (SANCO/917/05)

This draft Regulation concerned the granting of authorisations without a time limit within the meaning of Directive 70/524 for uses of 1 microorganism preparation and 5 enzyme preparations previously authorised provisionally for 4 years. These preparations and their authorised uses are the following:

a. Microorganism preparation:
   - Preparation of *Enterococcus faecium* NCIMB 10415, trade name Cylactin, for chickens for fattening and pigs for fattening.

b. Enzyme preparations:
   - Preparation of endo-1,3(4)-beta-glucanase and endo-1,4-beta-xylanase produced by *Penicillium funiculosum* (IMI SD 101) trade name Rovabio Excel, for laying hens and turkeys for fattening.
   - Preparation of endo-1,4-beta-xylanase produced by *Trichoderma longibrachiatum* (CNCM MA 6-10 W), trade name Safizym X, for turkeys for fattening.
   - Preparation of endo-1,4-beta-xylanase produced by *Trichoderma longibrachiatum* (ATCC 2105) and subtilisin produced by *Bacillus subtilis* (ATCC 2107), trade name Avizyme 1300, for chickens for fattening.
   - Preparation of endo-1,3(4)-beta-glucanase produced by *Trichoderma longibrachiatum* (ATCC 2106) and endo-1,4-beta-xylanase produced by *Trichoderma longibrachiatum* (IMI SD 135), trade name Avizyme SX, for chickens for fattening.
   - Preparation of 3-phytase produced by *Trichoderma reesei* (CBS 528.94), trade name Finase, for piglets, and pigs for fattening.

The vote was taken. A favourable opinion was adopted with qualified majority. Two Member States were absent.
2. Exchange of views and possible opinion on a draft proposal authorising L-Histidine monohydrochloride monohydrate. (SANCO/1375/2005).

The proposal was not presented for vote because the Company should provide complementary information in order to comply with the requirements of Regulation (EC) No 1831/2003.

3. Exchange of views on a draft Regulation amending the conditions for authorisation of iodine salts for feed intended for certain categories of animals (SANCO/1437/2005).

There was a short exchange of views. In general the majority of delegations agreed with the draft proposal although two delegations expressed their opposition to the reduction of iodine levels in dairy cows.

4. Request for confidentiality on the application L-Histidine monohydrochloride monohydrate.

This request is under examination by the Commission services to verify if it is in compliance with Article 18 of Regulation (EC) No 1831/2003.


6. Feed additives

6.1 Applications under Regulation (EC) No 1831/2003

The forward application of new additives “PHYZYME XP 5000L and PHYZYME XP5000G” has been presented to the Member States.


6.2.1. Enzymes


The clock is stopped on 23 May 2005.


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7. Amino acids

7.1 Vitalys® liquid and Vitalys® dry, l-lysine-sulphate (produced by fermentation with Corynebacterium glutamicum). Rapporteur DK.
A representative of the Commission informed that the company must submit complementary information to comply with the requirements of Regulation (EC) 1831/2003

7.2 L-Arginine

A representative of the Commission informed that the company must submit complementary information to comply with the requirements of Regulation (EC) 1831/2003

8. Undesirable substances

* Update on issues under discussion

The Commission representative updated the Committee as regards the status of the measures under discussion - on lead, cadmium and fluorine - on dioxins and dioxin-like PCBs - on deoxynivalenol, zearalenone and ochratoxin A.

* Update on EFSA opinions on undesirable substances

The Commission representative informed the Committee that an EFSA opinion on the presence of rye ergot, endosulfan and alpha-, beta- and gamma-isomers of hexachlorocyclohexane (HCH) as undesirable substance in animal feed is expected to become available in the course of June 2005. The EFSA opinion on fumonisins as undesirable substance in animal feed is expected to become available in the course of July 2005.

On the request of a Member State, the Commission representative informed the Committee that a request for an opinion on carry-over of coccidiostats into non-target feeds will shortly be submitted to EFSA.

* Follow-up on recent EFSA opinions (Camphechlor and arsenic)

- Camphechlor: the Directive 2002/32/EC of the European Parliament and of the Council of 7 May 2002 on undesirable substances in animal feed establishes a maximum level of 0.1 mg/kg camphechlor (toxaphene) for all feedingstuffs.

Taking into account the conclusions of the opinion of the Scientific Panel on Contaminants in the Food Chain related to Camphechlor as undesirable substance in animal feed it is proposed:
- to define the maximum level as the sum of the camphechlor congeners CHB (or Parlar) 26,50 and 62 as they can serve as indicators of Camphechlor contamination.
- to replace the current maximum level for all feedingstuffs by a specific maximum level for fish oil, fish meal and fish feed, as fish oil and fish meal have been identified as the main sources of camphechlor exposure of farmed animals, particularly fish. This seems to be justified as fish is the most sensitive species to camphechlor toxicity and fish is the main source of human exposure.
- to consider following suggested maximum levels for camphechlor (sum of congeners HCB 26, 50 and 62) of 0.2 mg/kg for fish oil, 0.02 mg/kg for fish meal and 0.05 mg/kg for fish feed.
- **Arsenic:** Current maximum levels in Directive 2002/32/EC refer to total arsenic not differentiating between inorganic and organic forms of arsenic. Inorganic and organic forms of arsenic differ significantly in toxicity, the organic arsenic compounds exhibiting a very low toxic potential. Products like Fishmeal and fish oil have been identified as major sources of feed contamination with arsenic, however predominantly the non-toxic arsenobetaine and arslenocholine. Recently a method to analyse the inorganic arsenic and which can be applied routinely has been developed for products of marine origin. Urgently, further validation and development is necessary to ensure that this method is applicable to all feed materials and feedingstuffs. Then occurrence data of inorganic arsenic in feed materials and compound feedingstuffs have to be generated to serve as basis for the revision of the current provisions on total arsenic in view of setting maximum levels for inorganic arsenic, being the toxic form.

No comments were made by the Member States at this stage as regards these proposals for follow up to the EFSA opinions.

* **High levels of cadmium in zinc sulphate originating from China. Information from Norway.**

Norway provided an update on the contamination incident. No substantial new developments have been reported since the meeting in April. Liver and kidneys from cows and pigs originating from affected farms have still to be withdrawn.

9. **Request from UK regarding the issue of “non-feed uses of additives”**

An exchange of views took place on this issue. The following elements were raised: coverage by the feed legislation (mixtures or premixtures of additives, complementary feedingstuffs) or by the veterinary medicinal products legislation, possibility to use additives in water, need to control the administration of the products concerned.

The chairman proposed the following approach: the status of the products concerned will be examined on a case-by-case basis, taking into account in particular the definitions of “feed additives” and “premixtures” laid down in Regulation (EC) No 1831/2003 on additives for use in animal nutrition, as well of “feed” laid down in Regulation (EC) No 178/2002. As a rule, the type of products described by the UK delegation should comply with the provisions laid down in Regulation (EC) No 1831/2003. Consequently, the method of administration of the additives concerned must be considered as conditions for use which are fully taken into account in the authorisation procedure and are included in the authorisation regulation. Concerning the current situation, the use of additives is only allowed on the feedingstuffs as laid down in the existing authorisations.

10. **Any other business**

10.1 **Amaferm:** At the request of one Member State about the status of the product “Amaferm”, the President explained that this product has been requested, by the Commission, for an opinion to EFSA as a new additive for animal nutrition under Article 4 of Regulation (EC) No 1831/2003. Its assessment has just begun. Therefore this product can not be marketed until the adoption of a Regulation authorising this additive.
10.2 A Member State requested about the possibility to use up the stocks of feed containing the antibiotics as additive other than coccidiostats after 1 January 2006. The possibility to use up the existing stocks of feed containing the antibiotics other than coccidiostats as additive is not foreseen by Regulation (EC) No 1831/2003. Therefore after 31 December 2005 it is not possible to use any feed containing these antibiotics formerly authorised as growth promoters under Directive 70/524/EEC.

Dr Willem Penning