SUMMARY MINUTES OF THE MEETING OF THE STANDING COMMITTEE ON THE FOOD CHAIN AND ANIMAL HEALTH

Animal Nutrition Section

Brussels, 26-27 January 2005

Standing committee

1. Discussion and possible request of opinion on a draft Commission Regulation concerning the authorisations without a time limit of certain additives and the authorisation of new uses of additives already authorised in feedingstuffs.

This draft concerned the conversion of 4 year provisional authorisations into authorisations without time limit and provisional authorisations of the following products:

a) authorisations without time limit
- four preparations belonging to the group of “Enzymes”:
  - Alpha-amylase and endo-1,3(4)-beta-glucanase produced by *Bacillus amyloliquefaciens* (DSM 9553), (E 1619), trade name Biofeed Alpha for chickens for fattening
  - endo-1,3(4)-beta-glucanase produced by *Aspergillus aculeatus* (CBS 589.94), endo-1,4-beta-glucanase produced by *Trichoderma longibrachiatum* (CBS 592.94), alpha-amylase produced by *Bacillus amyloliquefaciens* (DSM 9553), bacillolysin produced by *Bacillus amyloliquefaciens* (DSM 9554) and endo-1,4-beta-xylanase produced by *Trichoderma viride* (NIBH FERM BP 4842), (E 1620), trade name Kemzyme W dry, for chickens for fattening
  - endo-1,3(4)-beta-glucanase produced by *Aspergillus aculeatus* (CBS 589.94), endo-1,4-beta-glucanase produced by *Trichoderma longibrachiatum* (CBS 592.94), alpha-amylase produced by *Bacillus amyloliquefaciens* (DSM 9553) and endo-1,4-beta-xylanase produced by *Trichoderma viride* (NIBH FERM BP 4842), (E 1621), trade name Kemzyme W liquid, for chickens for fattening
  - endo-1,3(4)-beta-glucanase and endo-1,4-beta-xylanase produced by *Trichoderma longibrachiatum* (CBS 357.94), (E 1622), trade name Natugrain (Barlican)
- four colorants
  - Tartrazine (E 102) for grain-eating ornamental birds and small rodents
  - Sunset yellow FCF (E 110) for grain-eating ornamental birds and small rodents
  - Patent blue V (E 131) for grain-eating ornamental birds and small rodents
  - Chlorophyll copper complex (E 141) for grain-eating ornamental birds and small rodents
b) provisional authorisations
- two preparations belonging to the group of “Enzymes”:
  - Endo-1,4-beta-xylanase EC 3.2.1.8 (51), trade name Belfeed, for laying hens
  - 3-Phytase EC 3.1.3.8 (28), trade name Finase, for turkeys for fattening and sows
- one preparations belonging to the group of “Microorganisms”
• *Enterococcus faecium* NCIMB 10415 (10), trade name Cylactin, for cats and dogs.

The vote on the draft was taken and it was adopted with qualified majority.

2. Discussion and possible request of opinion on a draft Commission Recommendation on the co-ordinated inspection programme in animal nutrition for the year 2005 according to Council Directive 95/53/EC.

The Commission presented the Draft Commission Recommendation on the coordinated inspection programme in the field of animal nutrition for the year 2005 in accordance with the Council Directive 95/53/EC. The vote was taken and the proposal was adopted with 24 Member States in favour and one abstention.

The Spanish delegation made the following declaration:

“The Spanish delegates agree with the Draft Commission Recommendation. However some interpretation difficulties arises with the paragraph 2 in the Annex II (*The presence of unauthorised medicinal substances in feedingstuffs constitutes an infringement*). There are some legal interpretations that should be clarified to avoid interferences with national legal provisions “non-harmonized” in the different member states.”

3. Feed additives


3.1.1. Growth promoters

3.1.1.1. “FORMIT™LHS” potassium diformate. Animal category: pigs for fattening, piglets

Rapporteur: DK Application for permanent authorisation. The expiry date of temporary authorisation: 30.06.2005

3.1.2. Enzymes


Rapp FR

3.1.2.2. **Natuphos FTU 11**, preparation of 3-phytase produced by *Aspergillus niger* (CBS 491.94). Animal categories: Ducks, geese, salmonidae, channel catfish. Rapp NL. The clock has been reopened on 26 January 2005.

3.1.2.4. Avizyme 1210 Preparation of endo-1,4-beta-xylanase, EC 3.2.1.8, produced by *Trichoderma longibrachiatum* (ATCC 2105), endo-1,3(4)-beta-glucanase, EC 3.2.1.6. produced by *Trichoderma longibrachiatum* (ATCC 2106) (Enzyme 60). Dry form Extension of use Animal category: turkeys for fattening. Rap UK The clock has been reopened on 26 January 2005


3.1.2.6. Finase, 3-Phytase, EC 3.1.3.8 produced by *Trichoderma reesei* (CBS 528.94), (Enzyme N. 28). Extension of use for animal categories: laying hens. *Rapporteur: FI*

The clock has been stopped on 26 January 2005

3.1.3 Micro-organisms

3.1.3.1 “Fecinor” (*Enterococcus faecium* CECT 4515). Application for **extension of use** for the animal category: Chickens for fattening. Rapporteur: **ES**

The evaluation period (clock 3 as laid down in art. 4(6) of Directive 70/524/EEC) re-started as from 25 January 2005.


The clock of the evaluation period was stopped on 26 January 2005.

3.1.3.3 “Lactiferm” (*Enterococcus faecium* M74).

Application for **extension of use** for animal category: Chickens for fattening. Rapporteur: **SE**

The clock of the evaluation period was stopped on 26 January 2005.

3.2. Applications under Regulation (EC) No 1831/2003


4.1 Reduction of milk fever- Zeolite. Rapporteur: **DK**

The opinion from the European Food Safety Authority (EFSA) indicates that further data should be submitted by the applicant, therefore, a decision cannot be taken until these new data will be available and the request comply with the requirements of Directive 94/39/EC

4.2 Reduction of milk fever. Rapporteur: **SE**

All delegations agreed that the dossier falls within the scope of Directive 94/39/EC.

4.3 Support of respiratory function.
This is a request from a company to the Commission for a feedingstuff intended to support respiratory tract function. The dossier should be examined by the delegations to verify if these type of product falls within the scope of Directive 94/39/EC


5.1 L-Histidine monohydrochloride monohydrate

A representative of the Commission informed that an opinion to EFSA was requested already and invited the delegations to submit their comments as soon as possible.

5.2 Vitalys® liquid and Vitalys® dry, l-lysine-sulphate (produced by fermentation with corynebacterium glutamicum).

A representative of the Commission informed that a request for opinion will be addressed to EFSA in due time and invited the delegations to submit comments as soon as possible.

5.3 L-Arginine

Some delegations submit comments. A representative of the Commission invited the rest of delegations to submit comments as soon as possible.

5.4 BioProtein®. Rapporteur: DK

A representative of the Commission informed that the Commission has already asked EFSA to deliver an opinion on the complementary information submitted by the company.

The rapporteur informed that all the information has been submitted to the former Member States. A complete dossier was forwarded to the new Member States.

6. Update of lists of contact points of Delegations.

7. Undesirable substances in animal feed


The Scientific Panel on Contaminants in the Food Chain of the EFSA adopted on request of the Commission a scientific opinion as regards lead in animal feed on 2 June 2004, as regards cadmium also on 2 June 2004 and as regards fluorine on 22 September 2004.

* LEAD

The existing provisions as regards lead in products intended for animal feed are appropriate to ensure that these products do not represent any danger to human health, animal health or adversely affect the livestock production. However given that cattle and sheep are the most sensitive species and green fodder is a major component in of their daily ration, it is appropriate to review in view of a reduction of the level the existing provisions. In addition, given that the scope of the Directive provides for the possibility of maximum levels of undesirable substances in animal feed, a maximum level of lead is proposed for all additives belonging to the group of trace elements, binders and anti-caking agents and for premixtures. The provisions proposed are:
- green fodder: 30 ppm (*)
- trace elements: 100 ppm with the exception of zinc oxide (maximum level of 400 ppm (*)
  and manganous oxide, iron carbonate and copper carbonate (each a maximum level of 200 ppm
  (*)
- binders and anti-caking agents: 30 ppm (*) with the exception of clinoptilolite of volcanic
  origin (maximum level of 60 ppm (*)).
- premixtures: 200 ppm (*)

(*) maximum level to be reviewed by 31 December 2007 in view of a reduction. Control
programs should be performed in the next view years to gather sufficient reliable data to
underpin this review.

Furthermore, it was mentioned that the instructions of use on the premixtures should be in
accordance with the provisions on lead in the finished feed; Given that the extraction
procedure influences the analytical result, it was agreed to establish a specific extraction
procedure (nitric cid)

* FLUORINE

The existing provisions as regards fluorine in products intended for animal feed are
appropriate to ensure that these products do not represent any danger to human health, animal
health or adversely affect the livestock production In addition, given that the scope of the
Directive provides for the possibility of maximum levels of undesirable substances in animal,
the maximum level of fluorine (3000 ppm) in vermiculite is proposed to be transferred to the
annex to Directive 2002/32/EC. It is furthermore proposed to review by 31 December 2007 in
view of a reduction this level. Control programs should be performed in the next view years
to gather sufficient reliable data to underpin this review.

As the extraction procedure influences the analytical result, it was agreed to establish a
specific extraction procedure

* CADMIUM

The existing provisions as regards cadmium in products intended for animal feed are
appropriate to ensure that these products do not represent any danger to human health, animal
health or adversely affect the livestock production. In addition, given that the scope of the
Directive provides for the possibility of maximum levels of undesirable substances in animal
feed, a maximum level of lead is proposed for all additives belonging to the group of trace
elements, binders and anti-caking agents and for premixtures. Also a maximum level is
proposed for feed materials of mineral origin other than phosphates, for pet food and for
complementary feedingstuffs for which no maximum level was yet fixed.

- feed materials of mineral origin with the exception of phosphates: 2 ppm
- trace elements: 10 ppm with the exception of zinc oxide, manganous oxide, copper oxide
  and manganous sulphate monohydrate (30 ppm (*)
- binders and anti-caking agents: 2 ppm
- premixtures: 15 ppm (*)
- pet food: 1 ppm.

(*) maximum level to be reviewed by 31 December 2007 in view of a reduction. Control
programs should be performed in the next view years to gather sufficient reliable data to
underpin this review.
Furthermore, it was mentioned that the instructions of use on the premixtures should be in accordance with the provisions on lead in the finished feed;

Given that the extraction procedure influences the analytical result, it was agreed to establish a specific extraction procedure (nitric cid)

**b) Discussions on measures as regards deoxynivalenol, zearalenone and ochratoxin A**

The Scientific Panel on Contaminants in the Food Chain of the EFSA adopted on request of the Commission a scientific opinion as regards deoxynivalenol in animal feed on 2 June 2004, as regards zearalenone on 28 July 2004 and as regards ochratoxin A on 22 September 2004.

It was the majority view of the Committee that measures are appropriate as regards deoxynivalenol, zearalenone and ochratoxin A in animal feed in order to ensure that animal feed does not represent any danger to animal health or adversely affect the livestock production. As regards ochratoxin A, measures are appropriate in order to ensure that animal feed does also not represent any danger to human health.

Maximum levels for complete and complementary feedingstuffs were discussed for these mycotoxins, pigs being the most sensitive species as regards all three mycotoxins. An extensive discussion has taken place on the necessity of setting maximum levels for these mycotoxins in cereals and cereal products or if an alternative approach would be more appropriate. No final conclusion was reached. There was general agreement that if feed materials are directly fed to the animals, their use in a daily ration should not lead to the animal being exposed to a higher level of the mycotoxin than the corresponding maximum levels of exposure where only complete feedingstuffs are used in a daily ration.
c) Discussion on measures as regards the inclusion of dioxin-like PCBs in the maximum levels.

According to Directive 2002/32/EC, the Commission shall review the provisions as regards dioxins for the first time by 31 December 2004 at the latest in the light of new data on the presence of dioxins and dioxin-like PCBs, in particular with a view to the inclusion of dioxin-like PCBs in the levels to be set.

In order to ensure that all operators in the food and feed chain continue to make all possible efforts and to do all that is necessary to limit the presence of dioxins in feed and food, it was provided by Council Directive 2002/32/EC that the maximum levels applicable should be further reviewed by 31 December 2006 at the latest with the aim of significantly reducing the maximum levels. Taking into account the time required to determine these significant lower levels, it is proposed to slightly postpone this date.

It is proposed to set maximum levels for the sum of dioxins and dioxin-like PCBs expressed in World Health Organisation (WHO) toxic equivalents, using the WHO-TEFs as this is the most appropriate approach from a toxicological point. In order to ensure a smooth transition, it is appropriate to keep for a transitional period the existing levels for dioxins applicable in addition to the newly set levels for sum of dioxins and dioxin-like PCBs.

The scope of Directive 2002/32/EC provides for the possibility of the establishment of maximum levels of undesirable substances in feed additives. Given that at several cases high levels of dioxins have been found in trace elements, it is proposed to establish a maximum level for dioxins and the sum of dioxins and dioxin-like PCBs all additives belonging to the functional group of trace elements and to extend the maximum levels to all additives belonging to the functional group of binders and anti-caking agents and for premixtures.

In order to stimulate a pro-active approach to reduce the presence of dioxins and dioxin-like PCBs in food and feed, action levels have been set by Commission Recommendation 2002/201/EC of 4 March 2002 on the reduction of the presence of dioxins, furans and PCBs in feedingstuffs and foodstuffs. These action levels are a tool for competent authorities and operators to highlight those cases where it is appropriate to identify a source of contamination and to take measures for its reduction or elimination. Given that different sources of contamination exist for the presence in food of dioxins on the one hand and of dioxin-like PCBs on the other hand, it is important that separate action levels are determined for dioxins on the one hand and for dioxin-like PCBs on the other hand. Directive 2002/32/EC provides for the possibility to set action levels. It is therefore proposed to transfer the action levels from the Commission Recommendation to Annex II to Directive 2002/32/EC.

The proposed maximum levels take into account the current background level of dioxins and dioxin-like PCBs in all regions of the European Union. However, efforts have to be done by the operators to increase the capacity to remove effectively dioxins, furans and dioxin-like PCBs from fish oil, fish meal, fish protein hydrolysates and consequently in fish feed. A review of the maximum levels with the aim of significantly reducing of the maximum levels is foreseen by 31 December 2007 at the latest. As regards fish oil, fish meal, fish protein hydrolysates, it is proposed that this significant lower level shall be determined based on the technical possibilities of the most effective decontamination procedure.

Most Member States indicated that they would be in a position to accept this approach although some Member States clearly expressed their objection.

8. Report on the discussions at the Expert Committee “Methods of analysis and sampling in animal feed”
The Committee was informed on the outcome of the discussion at the Expert Committee meeting “Methods of analysis – Animal Feed” held on 10 January 2005


The Commission has the intention to consolidate all still valid official methods of analysis, adopted pursuant Council Directive 70/373/EEC of 20 July 1970 on the introduction of Community methods of sampling and analysis for the official control of feedingstuffs. All existing methods have been screened and it is proposed to keep 32 methods whilst deleting 18 methods of analysis. One delegation was of the opinion that methods of analysis can only be deleted if they are replaced. This position was neither shared by the Commission nor by the other delegations in the Committee.

b) Mandate to CEN

The Committee was informed on the addendum to the mandate for standardisation M/15/2001 addressed to CEN in the field of methods of analysis for animal feedingstuffs. 17 new work items are proposed. The Committee did not raise any objections.

c) Revision of sampling provisions

The Commission informed the Committee to consider to revise the sampling procedure laid down in Commission Directive 76/371/EEC of 1 March 1976 establishing Community methods of sampling for the official control of feedingstuffs and this on request of the Committee. The revision would consist of following major points:
- inclusion of useful elements currently provided for CEN sampling procedure (prEN ISO6497:2004. A comparative analysis between both sampling procedures has been presented
- adaptation of the sampling procedure for sampling situations where the current sampling procedure is not feasible such as silo’s, big heaps of feed materials in a warehouse, etc. It is the intention to provide feasible procedures for sampling in these situations even if this would result in decrease of representativity of a sample for a batch.

A specific working group will be established to work out a proposal.

A short exchange of views on this important issue has taken place in the Committee.

9. Other business

Referring to the situation on histomoniasis, Spain raised some problems on the situation on certain diseases that affected the “minor species” that the products to prevent or the treat are missing. So it has been asked to present a report on that in order to clarify the situation.

Dr Willem Penning