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

ANIMAL NUTRITION SECTION

Brussels, 18 & 19 September 2008

President: Mr Willem PENNING

All Member States were represented, except Malta

1. Feed Additives

1.1. Applications under Regulation (EC) No 1831/2003 Art. 4

1.1.1. New applications (5)

The new applications were presented.

1.2. Applications under Regulation (EC) No 1831/2003 Art. 25

1.2.1. Enterococcus faecium NCIMB 10415 (Micro-organism 10) for cats and dogs.
Application for permanent authorisation.
Expiry of temporary authorisation: 06.03.2009. Rapp: DE

A discussion took place.

1.2.2. Endo-1,4-beta-xylanase (EC 3.2.1.8) produced by Trichodermalongibrachiatum (IMI SD 135) (enzyme 17) for laying hens.
Application for permanent authorisation. Rapp: UK

A discussion took place.

1.2.3. Endo-1, 4-beta-xylanase (EC 3.2.1.8) produced by Trichodermalongibrachiatum (IMI SD 135) (enzyme 17) for piglets.
Application for permanent authorisation. Rapp: UK

A discussion took place.

1.2.4. Endo-1, 4-beta-xylanase (EC 3.2.1.8) produces by Bacillus subtilis (LMG S-15136) (enzyme 51) for laying hens.
Application for permanent authorisation.
Expiry of temporary authorisation: 06.03.2009. Rapp: BE

A discussion took place.

1.2.5. *Kluyveromyces marxianus var. lactis K1* BCCM/MUCL 39434 (Microorganism 24) for dairy cows.
Application for permanent authorisation.

A discussion took place.

1.3. **Categorisation of a clay commercialized as E 558 – montmorillonite**

As requested by one delegation, a discussion took place with the Member States on the status of this product-like bentonite-montmorillonite. Since this product (montmorillonite and 10 to 20% of algae) is derived from a manufacturing process, it was considered as a new product not covered by the old authorisation. If a company wants to market it as feed additive, it should submit an application under Article 4 of Regulation (EC) No 1831/2008 accompanied with related information under Article 7 of the same Regulation.

1.4. **Different uses of ammonium chloride (E 510) in animal nutrition**

On request of one delegation, a discussion took place on the status of ammonium chloride. One Member State indicated to accept the incorporation of this substance into feed for ruminants to reduce the risk of urinary calculus as laid down in Directive 2008/38/EC. Others raised the point that ammonium chloride is an authorised feed additive only for use in dog and cat feed. One Member State suggested that the initial applicant for the extension of use to other animal species should come back with supplementary information in order to pursue the approval procedure for ruminants. The Commission representative clarified that ammonium chloride has to be authorised as feed additive for ruminants in advance of its possible use for particular nutritional purposes for these species.

With respect to the alleged national authorisation of ammonium chloride as a feed material, the Commission representative reminded the Member States that positive lists of feed materials where national authorities authorise feed materials are not in line with the EU law.

1.5. **Discussion of new use of products as adsorbent or denaturant of mycotoxins and possible new functional group of additives**

The Commission representative referred to the dossier provided for by European Federation of Additives in Animal Nutrition (FEFANA) in order to establish a new functional group for adsorbents or denaturants of mycotoxins. Many Member States supported in general the creation of a special group for such products whereas some of them pleaded to wait for the first application of a concrete feed additive. Further comments were whether the new functional group is correctly characterised with the category "technological additive"
because the products in the pipeline act more within the gastro-intestinal tract and not in the feed. Additionally, several Member States recalled that there is already a functional group "1l: denaturants" with a totally different objective use and therefore suggested another name for the new functional group. The Commission representative concluded that any use of such products must not jeopardise the hygienic efforts in the feed businesses in order to minimise the mycotoxin load in feed, in concrete with respect to the guidance values laid down in Commission recommendation 2006/576/EC and the maximum content for Aflatoxin B1. The use of such feed additives shall only be allowed in feed as long as maximum contents of mycotoxins are not exceeded. Furthermore, it must be assured that the analytical detection of the mycotoxins is not impeded and that possible metabolites are safe. Considering the potential benefits of such products the Commission representative indicated the intention to launch the establishment of a new functional group. The proactive approach to create the group before the submission of a concrete application should encourage the industry to be innovative in this field and to impede misleading advertisement with products for which such a function is claimed without proper approval.

1.6. Exchange of views on additives to be re-evaluated under Article 10 of Regulation 1831/2003: advance information to interested parties

The Commission circulated the language versions in the official languages of the model letter that will be sent to interested parties about the re-evaluation process of feed additives foreseen in Regulation (EC) N° 1831/2003. Member States reported about their activities relating to the increase of awareness of operators regarding this process. The Commission also reported about the coming publication of electronic application forms on the website on Regulation (EC) N° 1831/2003. The Commission also circulated the reply from European Food Safety Authority (EFSA) about the list of priorities for additives for the re-evaluation, foreseen in Article 10 of the Regulation. There was consent to use this list for the prioritization, while recognising that an accurate estimate of the workload involved for EFSA, Community Reference Laboratory (CRL) and the Commission in the re-evaluation exercise will be reliable only after all the applications have been submitted.

2. Use of substances with antibacterial activity in fermentation/distillation processes and the presence of residues in by-products destined for feed use – updating and discussion

Early August 2008, several findings of high levels of monensin in yeast produced from molasses as by-product from bio-ethanol industry from Brazil were notified to the Rapid Alert System for Food and Feed (RASFF). The levels reported ranged from the low 0.2/0.5 mg/kg level, to the 20-30 mg/kg level with a maximum of 96 mg/kg.

Monensin is used as processing aid in fermentation processes to prevent bacterial growth in fermentation processes. It is, in particular, used in the bio-ethanol production process. The application of monensin in fermentation processes under the agreed conditions of use should however not lead to high levels of monensin in by-products for animal feeding.
The high residual level of monensin in yeast produced from molasses as by-product from bio-ethanol industry seems to be due to the use of low quality, low soluble monensin and continuous application of monensin (while according to good practice monensin should only apply when there is bacterial growth and with a minimum interval of 8-10 days). The high levels are therefore the consequence of bad practice.

After discussions at the meeting, it was considered that the level of 1.25 mg/kg is to be taken as the unavoidable residue level of the application of monensin as a processing aid in fermentation processes when good practices are applied.

According to a recent EFSA opinion\(^1\), this level of 1.25 mg/kg does not pose any danger for animal health and public health in case it is present in feed for animal species for which monensin is not authorised.

As regards the use of antibacterial substances in fermentation processes in the European Union, it appears from the survey that monensin is only very rarely used. In the EU, hop extracts seem to be regularly used as antibacterial substance. Other substances could potentially be used but further investigations are necessary to enable an accurate estimation of their real use.

3. **Exchange of views on activities relating to future work in Codex Alimentarius relating to animal feed**

The Commission reported about the progress relating to this work in Codex. The creation of an electronic Working Group had been agreed at the Codex Alimentarius Commission last July. This electronic Working Group, chaired by Denmark and Mexico, had just distributed the first draft of the proposal for the scope and terms of reference for future work at Codex on animal feeding. The Group should finalise a proposal by the end of this year. Once the proposal is made by the electronic Working Group it will be circulated to Codex Members for comments. In order to take a position at the Codex Commission in July 2009, the necessary discussions will take place at the beginning of 2009 to coordinate the position of the EU. An exchange of views took place about the possible proposals, taking into account the previous proposals already made in the reply of the European Community to the Codex Circular Letter of 2007.

4. **Microbiological criteria in feed**

Presentation and discussion of the Scientific Opinion of the Panel on Biological Hazards on the microbiological risk assessment in feedingstuffs for food-producing animals by a member of the EFSA – BIOHAZ Unit.

It was agreed to establish a working group and many of the representatives of the Member States showed interest to participate in this working group. As soon as the list of the participants willing to participate will be completed, a first meeting will be held in November (date to be confirmed).

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5. Exchange of views and possible opinion on a draft Regulation (EC) amending Regulation (EC) No 109/2007 as regards the terms of the authorisation of the feed additive monensin sodium (Coxidin)
(Document SANCO/2226/2008)

A discussion took place and the vote was taken.
The draft Regulation received a favourable opinion by qualified majority.

6. Exchange of views and possible opinion on a draft Regulation (EC) amending Regulation (EC) No 1356/2004 as regards the terms of the authorisation of the feed additive "Elancoban", belonging to the group of coccidiostats and other medicinal substances
(Document SANCO/2225/2008)

A discussion took place and the vote was taken.
The draft Regulation received a favourable opinion by qualified majority.
United Kingdom abstained. Here attached the declaration in the original language.

United Kingdom declaration:

UK Voting Position: Abstain

"The UK does not support the proposed changes. Although the UK generally agrees with the proposed MRLs, it cannot support the decrease in withdrawal period until the method used in the residue studies is shown to be sufficiently sensitive at the proposed MRL of 8 µg/kg, or until a sufficiently sensitive analytical method is developed and used in a new residue study.

The UK voting position is not to support the decreased withdrawal periods for this application. A fully validated analytical method capable of measuring marker residue levels with an acceptable level of accuracy and precision should be submitted before the applications are considered further."

7. Discussion on a draft Regulation (EC) concerning the authorisation of Lactobacillus rhamnosus and Lactobacillus farcininis (Sorbiﬂore) as a feed additive
(Document SANCO/2793/2008)

A discussion took place. A draft Regulation will be presented for the discussion.

8. Discussion on a draft Regulation (EC) concerning the authorisation of Bacillus amyloliquefaciens (Ecobiol) as a feed additive
(Document SANCO/2795/2008)

A discussion took place. A draft Regulation will be presented for the discussion.

9. Discussion on a draft Regulation (EC) concerning the authorisation of a new use of Saccharomyces cerevisiae (Levucell SC20/Levucell SC10ME) as a feed additive
(Document SANCO 2796/2008)
A discussion took place. A draft Regulation will be presented for the discussion.

10. Unavoidable carry-over of authorised coccidiostats into non target-feed: discussion on a working document

An outline of the draft proposal for regulating unavoidable carry-over of coccidiostats or histomonostats in non-target feed was presented to the Committee.

It foresees:
- the setting of maximum levels of coccidiostats and histomonostats in feeds (referred to as non-target feeds) for which the coccidiostats are not authorised but in which they are present following unavoidable carry-over as a consequence of production, storage and transport practices.
- the setting of maximum levels for these coccidiostats and histomonostats in food of animal origin present as a consequence of the unavoidable presence of these substances in non-target feed.

Production, storage and transport practices may result in the contamination of feed produced subsequently by the presence of technically unavoidable traces of coccidiostats or histomonostats in "non-target feed", i.e. in feed for which the use of these substances are not authorised, such as feed intended for animal species or categories not provided for in the additive authorisation.

Taking into account the application of good manufacturing practices, the maximum levels of unavoidable carry-over of coccidiostats or histomonostats in non-target feed should be established following the As Low As Reasonably Achievable (ALARA) principle.

EFSA concluded that the presence of the coccidiostats or histomonostats authorised as feed additives, in non-target feed at levels resulting from an unavoidable carry-over, and taking into account all prevention measures resulting from an unavoidable carry-over, is unlikely to result in adverse animal health effects and in any risk to consumers' health from the ingestion of residues in products from animals exposed to cross-contaminated feed.

A discussion took place and, although agreeing on the approach, several Member States made comments which will be taken into account into the text before putting for a vote at a next meeting.
11.A.O.B.

1.a) continuation of the discussion as regards arsenic in

- trace elements and microtracers

The discussion on these issues was continued and taking into account the data available on arsenic in trace elements and microtracers, the following will be proposed for a final discussion at the next meeting

* additives belonging to the functional group of compounds of trace elements : 30 mg/kg, with the exception of
  -- copper sulphate pentahydrate: 50 mg/kg
  -- zinc oxide, manganous oxide and copper oxide: 100 mg/kg

* iron particles as tracer: 50 mg/kg

- fish products for animal nutrition

The discussions on this issue continued. New data on the occurrence of arsenic in fish meal and fish oil produced from the by-products of the filleting of fish were provided. The data refer to findings in recent years. The arsenic present in these fish products for animal nutrition is for more than 95 % the less toxic organic form.

The Commission representative indicated its intention to propose for discussion at the next meeting the following maximum levels for arsenic in
- feedingstuffs obtained from the processing of fish or other marine animals: 25 mg/kg
- complete feedingstuffs for fish and complete feedingstuffs for fur animals: 10 mg/kg

The related footnote in the current legislation providing that upon request of the competent authorities, the responsible operator must perform an analysis to demonstrate that the content of inorganic arsenic is lower than 2 mg/kg remains applicable.

1.b) continuation of discussion as regards follow-up of EFSA opinion on mercury in feed

The Commission representative informed the Committee that the Panel on Contaminants in the Food Chain (CONTAM Panel) from EFSA has in detail examined at its last meeting in September 2008 the comment made by European Federation Pet Food Industry (FEDIAF) as regards the interpretation of publication of Charbonneau et al (1976) as regards the chronic toxicity of methylmercury in cats. The opinion will be slightly amended but the overall conclusion will remain unchanged.

The discussion on the follow-up to the scientific opinion on mercury as undesirable substance in animal feed will be continued at a next meeting of the Committee.
1.c) exchange of views on follow-up on three recent EFSA opinions (opinions enclosed)

- tropane alkaloids

The CONTAM Panel from EFSA adopted on 9 April 2008 a scientific opinion on tropane alkaloids as undesirable substance in animal feed\(^2\). One of the conclusions is that pigs have been shown to be among the most sensitive species to *Datura* poisoning. A worst case exposure estimate indicated that adverse pharmacological effects in pigs following exposure to *Datura ferox* seeds, mainly containing scopolamine, can not be entirely excluded at the current statutory limits of 3000 mg/kg feed. However, the limited data also suggested that it is not likely that the presence of *Datura stramonium* impurities in animal feed up to the current statutory level of 1000 mg/kg would present a risk to animal health. Following that conclusion, it appears that it is appropriate to extend the current limitation of 1000 mg/kg for seeds and unground and uncrushed fruits from *Datura stramonium* to all Datura spp. (including *Datura ferox*)

- theobromine

The CONTAM Panel from EFSA adopted on 10 June 2008 a scientific opinion on theobromine as undesirable substance in animal feed\(^3\). One of the conclusions is that the current EU regulations on maximum levels (ML) of theobromine in feed material (300 mg/kg for complete feedingstuffs with the exception of 700 mg/kg for complete feedingstuffs for adult cattle) may not be fully protective for some target animal species, e.g. as effects on milk production in dairy cows and adverse effects in pigs may occur. Owing to the recognized susceptibility to theobromine toxicity, feed manufacturers do not include by-products of cocoa manufacture or confectionary by-products in feeds for dogs and horses. The Commission representative indicated following this opinion, a possible review of the maximum levels of theobromine in feed will be extensively discussed at a next meeting of the Committee.


- ricin

The CONTAM Panel from EFSA adopted on 10 June 2008 a scientific opinion on ricin (from *Ricinus communis*) as undesirable substance in animal feed\(^4\). One of the recommendations is that more information is needed on the occurrence of seeds *Ricinus communis*, *Croton tiglium* and *Jatropha curcas* as botanical impurities in feed materials. The follow-up to the opinion will be discussed into more detail at a next meeting of the Committee.

2. Legal status of calcium butyrate

Resuming the discussion which took place in the Standing Committee in April 2008, the Commission representative concluded that calcium butyrate is to be considered a feed material as it belongs to the products listed under 12.05 (salts of a fatty acids) in part B of the Annex to Directive 96/25/EC.

Bernard VAN GOETHEM
Director (signed)