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

ANIMAL NUTRITION SECTION

Brussels, 22 October 2007

1. Feed Additives

1.1. Application under Regulation (EC) n°1831/2003

1.1.1. New applications

1.1.2. Monensin sodium (Elancoban/Sylvata). As coccidiostat for calves for rearing

A discussion took place. Following the discussion, the applicant will be consulted.

1.1.3. L-Lysine sulphate (VitaLys® Liquid and VitaLys Dry®)

The l-Lysine sulphate produced by fermentation with *Corynebacterium glutamicum* is currently authorised in accordance with the rules under the Feed additive Regulation (EC) 1831/2003 in the category of "nutritional additives" under the functional group "amino acids, their salts and analogues".

The company of Agro& Ferm notifies minor change in production of l-Lysine sulphate, the adjustment of the current production process by leaving out the final drying phase which will produce a liquid product containing 25% l-Lysine (appr. 47.5 % l-Lysine on a dry matter base). This minor change affects neither the quality of the product, nor the manufacturing process.

The discussion will continue on the next Committee.

2. Exchange of views and possible opinion on the draft Regulation (EC) concerning amending Regulations (EC) Nos 2430/1999, 418/2001 and 162/2003 as regards the terms of the authorisation of certain additives in feedingstuffs belonging to the group of coccidiostats and other medicinal substances (Document SANCO/2893/2007)

A discussion took place.

The vote was taken.

The draft Regulation received a favourable opinion by qualified majority.

3. Exchange of views and possible opinion on the draft Regulation (EC) concerning the authorisation of a preparation of Bonvital (*Enterococcus faecium*) as feed additive (Document SANCO/2277/2007)

A discussion took place.

The vote was taken.

The draft Regulation received a favourable opinion by qualified majority.
4. Exchange of views and possible opinion on the draft Regulation (EC) concerning the authorisation of a preparation of Safizym X (endo-1,4-beta-xylanase) as feed additive (Document SANCO/2282/2007)

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

5. Exchange of views and possible opinion on a draft Regulation (EC) concerning the authorisation of a preparation of Ronozyme (6-phytase) as feed additive (Document SANCO/2281/2007)

A discussion took place.
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) concerning the permanent authorisation of certain additives in feedingstuffs (Biosprint (dairy cows), Orlalin (turkeys for fattening, dogs), Lactobacillus Acidophilus D2/CSL (laying hens) Hostazym C (piglets) (Document SANCO/3010/2007)

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

The German delegation made the following declaration:

„Deutschland stimmt dem Verordnungsentwurf insgesamt zu, wenngleich der Wirksamkeitsnachweis von E 1710 Saccharomyces cerevisiae MUCL 39885 für Milchkühe und von E 1715 Lactobacillus acidophilus D2/CSL CECT 4529 für Legehennen gegenwärtig als nicht ausreichend erbracht angesehen wird.„

The French delegation made the following declaration:


The Dutch delegation made the following declaration:

Nederland onthoudt zich van stem omdat naar onze mening de dossiers voor de producten Hostazym C (doeldiercategorie biggen) en Orlalin (doeldiercategorie kalkoenen) niet aan de vereisten voor definitieve toelating voldoen.

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

The German delegation made the following declaration:


Until the entering in force of Regulation (EC) 727/2007 on 17 July 2007, Annex VII to Regulation (EC) 999/2001 provided for a derogation regarding the destruction of animals following the confirmation on a holding of a TSE case in ovine or caprine animals. Member State may decide to delay the destruction of certain animals. The derogation was no longer necessary with the entering in force of the measures provided for in Regulation (EC) 727/2007. On 17 July 2007 an action was brought against the European Commission in order to contest certain provisions of Regulation (EC) 727/2007 regarding the measures to apply in TSE affected flocks and to request its annulment. In its Order of 28 September 2007 the Court of First Instance of the European Communities (the Court) suspended the operation of the referred provisions until a final judgement is delivered. Following the Order of the Court, the Member States had no longer the possibility to delay the destruction of certain animals up to five breeding years. Some Member States experienced difficulties to proceed with the
immediate destruction of animals. It seems therefore necessary to reintroduce that possibility until a final judgement is delivered in order to allow Member States the proper implementation of Regulation (EC) 999/2001. The Commission representative replied to questions and observations from DE, SI and AT. Following the discussion, the proposal was put to the vote.

Vote: in favour by qualified majority, 10 votes abstaining

8. Discussion on a draft Regulation (EC) amending Regulation (EC) No 1444/2006 as regards the terms of the authorisation of Bacillus subtilis C-3102 (Calsporin) as feed additive (Document SANCO/3078/2007) Annex entry

A discussion took place.

9. Discussion on a draft Regulation (EC) concerning the authorisation of a preparation of Natuphos (3-phytase) as feed additive (Document SANCO/3079/2007) Annex entry

A discussion took place.

10. Discussion on a draft Regulation (EC) concerning the authorisation of a preparation of Toyocerin (Bacillus cereus var. Toyoi) as feed additive (Document SANCO/3080/2007) Annex entry

A discussion took place.

11. Discussion on a draft Regulation (EC) concerning the authorisation of a preparation of Danisco Xylanase G/L (endo-1,4-beta-xylanase) as feed additive (Document SANCO/3082/2007) Annex entry

A discussion took place.

12. Discussion on a draft Discussion on a draft Regulation (EC) concerning the authorisation of a preparation of Lantarenol (Lanthanum carbonate octahydrate) as feed additive (Document SANCO/3090/2007) Annex entry

A discussion took place.


A discussion took place.

14. Discussion on a draft Regulation (EC) concerning the authorisation of a preparation of Kokcisan 120G as feed additive - Annex entry

A discussion took place.
15. Exchange of views on the use of coccidiostats and histomonostats as feed additives

Following the earlier discussions regarding this point at the previous meeting, the Commission services mentioned that it was finalising the report with a view to its approval, translation and adoption by the College in order to have the Report of the Commission ready by the end of the year. Member States’ delegations could send in further comments or suggestions for inclusion in the final report at the latest three weeks from the meeting.

16. Outcome of the discussions on the undesirable substances in feed in the meeting of the Expert Committee "undesirable substances" on 15 October 2007

* Melamine and related compounds

Member States were asked by the Commission on 2 May 2007 by note of Mrs Paola Testori Coggi to the heads of delegation of the Standing Committee on the Food Chain and Animal Health, section Animal Nutrition and section Toxicological Safety of the Food Chain to control consignments of wheat gluten, corn gluten, corn meal, soy protein, rice bran and rice protein concentrate originating from third countries, in particular from China, for the presence of melamine and related compounds and to report the results of the control.

A note containing an overview of the results of these controls was made available to the Committee.

The competent authorities from China (AQSIQ) informed the Commission that they have included rice protein products into the legal inspection commodity list as of 15 May 2007 (was previously not the case) and therefore all rice protein products shall go through compulsory official melamine examination and will only be permitted for export after having passed examination. Furthermore the control by local authorities on the production of rice protein concentrate will be strengthened. The Chinese authorities have confirmed that all consignments of rice protein concentrate which have left China after 15 May 2007 should be free of melamine.

All RASFF notifications on findings of melamine and related compounds in feed ingredients originating from China relate to shipments which left China before 15 May 2007.

The Committee agreed that, taking into account the results of the controls, the conclusions of the scientific statement issued by EFSA and the measures taken and commitment by the Chinese authorities, there is no longer a need to maintain an increased frequency of import controls at import for the presence of melamine and related compounds in protein-rich feed ingredients and an ‘at random’ official import control regime is sufficient and appropriate.

* Report of the discussions at the Expert Committee "Undesirable substances in animal feed" on 15 October 2007

- Cross contamination of non target feedingstuffs by coccidiostats authorised for use as feed additive.

Following the availability of the first EFSA scientific opinions (on narasin and lasalocid-sodium) on the assessment of the risks for animal and public health resulting from the
presence of authorised feed additives in non target feeds as the consequence of unavoidable carry-over, a first discussion on the legal follow-up took place in the Expert Committee. The possibility to set tolerances for unavoidable residues of feed additives in non-target feeds is considered to fall within the scope of Directive No 2002/32/EC of the European Parliament and of the Council of 7 May 2002 on undesirable substances in feed. Such tolerances should be set following the ALARA principle (As Low As Reasonably Achievable) taking into account good manufacturing and hygienic practices. These tolerances should not have a pharmacological activity and not threaten animal and public health. As regards non-target feeds it was considered that two different kinds must be considered: feeds for non-target animal species (with different sensitivity) and feeds for target animals but for periods in which the feed additive is not authorised (e.g. in the withdrawal period before slaughter). Besides tolerances in feed also residue levels in food of animal origin will have to be considered. In the Expert Committee a carry-over rate of 5% (with a possible lower rate of 2% for some animal species/feeds) was considered. It was agreed that the Expert Committee shall continue the technical discussions in detail at a further meeting. The Standing Committee asked the Commission to urge EFSA to complete the scientific opinions on the 9 remaining coccidiostats as soon as possible, and by early 2008 at the latest in order to enable the Commission to finalise the discussions on this important issue for public health, animal health and to ensure a uniform approach of enforcement across the EU.

- **Follow-up of the EFSA opinions on heptachlor, cyanogenic compounds and pyrrolizidine alkaloids**

Following the scientific opinion on cyanogenic compounds, the listing of "Apricots-Prunus Armenica" and eventually "Bitter almond – Prunus dulcis" in the Annex to Directive 2002/32/EC whereby it may only be present in feedingstuffs in trace amounts not quantitatively determinable should be reconsidered, as these provisions seem to be no longer necessary and appropriate. The other provisions as regards hydrocyanic acid require a more in depth examination.

Following the scientific opinion on pyrrolizidine alkaloids, the specific listing of Lolium temulentum and Lolium remotum in the Annex to Directive 2002/32/EC should be reconsidered, as their inclusion seems to be no longer necessary and appropriate. Other initiatives as regards the presence of pyrrolizidine alkaloids in feed will be discussed in detail at a future meeting.

Following the scientific opinion on heptachlor, it seems appropriate to include photoheptachlor in the residue definition as photoheptachlor is in particular of relevance in feed samples of marine origin.

- **Other issues discussed at the Expert Committee**

The Committee was furthermore informed that following issues were discussed at the Expert Committee:
- dioxin in glycine feed and guar gum. As regards the guar gum, the importance of having clear separate production lines and distribution channels in case as guar gum for industrial use and for feed and food are produced within the same company.
• The listing of *Camelina sativa* and *Jatropha curcas* in the list of undesirable substances. The Committee asked the Commission to urge EFSA to finalise very urgently the long awaited scientific opinion on glucosinolates to enable the initiation of the discussion on the appropriateness of the listing of Camelina sativa in the Annex to Directive 2002/32/EC as soon as possible. Also, as regards the listing of Jatropha curcas, the outcome of the opinion from EFSA on the presence of ricin in feed will be awaited.

• Fluorine in fish feed (request FEFAC) and fluorine in mussel shells

• Arsenic in copper sulphate (request EMFEMA)

• Heavy metals in mineral feed additives, premixtures and mineral feed. The Committee was informed that the discussion on the review of the levels as foreseen in the legislation will be initiated.

• Levels of dioxins and dioxin-like PCBs in fresh fish fed to farmed fish; tuna in particular.

• Mycotoxins in cereals and cereal products. The Committee was informed that a forum to discuss the monitoring results will be organised in January 2008, this would also involve also the professional organisations. The Committee was informed of the finding of very high levels of zearalenone in soya hulls originating from Argentina and were asked to pay particular attention to this issue and to inform the feed business operators of this finding.

• Furthermore the concern of the presence of methanol in glycerine (a by-product from vegetable oils used in the manufacture of biodiesel) intended for animal feed was raised. Reference was made to a scientific opinion from AFSSA issued in May this year in which it was concluded that a level of 0.5 % methanol in glycerine would not lead to animal or public health problems, on the condition that the glycerine is not incorporated at more than 10% in the feed. This issue will be discussed in more detail at a next meeting and could be the subject of a request for scientific opinion to EFSA.

• The Committee was informed of a request from EFSA for data on the presence of saponins, gossypol, ricin and theobromine in feed, preferably by 1 December 2007.

17. A.O.B.

- Export to third countries of feed additives which are not authorised in the EU: a representative of the Commission informed the Committee that the opinion received from the Legal Affairs unit of DG Health and Consumer Protection on this matter confirmed the interpretation that had already been indicated to the Committee:

According to Article 3(1) of Regulation (EC) No 1831/2003, any additive, within the meaning of that Regulation, which is placed on the market, processed or used in animal feeding in the Community must comply with the authorisation and labelling requirements provided by the Regulation, even if it is exported to a third country in a second phase.

As regards the mere production of a feed additive in the Community, it does not appear to require an authorisation under Regulation (EC) No 1831/2003, as this action is not covered by the definition of "placing on the market", "processing" or "use". The export of such product outside the Community must however comply with the conditions laid down in Article 12 of Regulation (EC) No 178/2002. In addition, it will still have to be checked whether the production of particular feed additives is subject to other requirements – or even prohibited - on the basis of other pieces of Community legislation.

Bernard VAN GOETHEM,  
Director (signed)