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

Animal Nutrition Section
Brussels, 26-27 September 2005

1. Discussion and possible request of opinion on:
   - draft Commission Regulation amending the conditions for authorisation of a feed additive belonging to the group of trace elements and of a feed additive belonging to the group of binders and anti-caking agents (Document SANCO/2361/2005)

When Directive 2002/32/EC of the European Parliament and of the Council of 7 May 2002 on undesirable substances in animal feed was adopted, the Commission stated that the provisions laid down in Annex I to that Directive would be reviewed on the basis of updated scientific risk assessments and taking into account the prohibition of any dilution of contaminated non-complying products intended for animal feed.

The Scientific Panel on contaminants in the Food Chain of the European Food Safety Authority (EFSA) adopted opinions on request from the Commission related to lead, fluorine and cadmium as undesirable substance in animal feed on respectively 2 June 2004, 22 September 2004 and 2 June 2004.

Taking into account the conclusions of the scientific opinions and recent occurrence data, the draft Commission Directive proposes to amend the current provisions as regards lead, fluorine and cadmium as follows:

- setting of maximum levels for lead and cadmium in additives belonging to the functional group of compounds of trace elements and additives belonging to the functional group of binders and anti-caking-agents and in premixtures.
- reducing the level for lead in green fodder as occurrence data indicate that contamination levels are currently significantly lower and ruminants are the most sensitive species to the toxic effects of lead.
- increasing the level for fluorine in marine crustaceans such as marine krill as new processing techniques to improve the nutritional quality and to reduce the biomass loss, results also in higher levels of fluorine in the final end product.
- increasing the level for cadmium in fish feed and setting a level for cadmium in feed materials of mineral origin and in feedingstuffs for pet animals.

The other provisions as regards lead, fluorine and cadmium are existing provisions and are mentioned in the current proposal for reasons of clarity.

The extraction procedure used for the analysis of lead, cadmium and fluorine in materials intended for animal nutrition has a large influence on the analytical content in particular in materials with a high mineral content. Therefore a specific extraction procedure has been provided for and equivalent procedures with demonstrated equal extraction efficiency can be used.

As for some binders and anti-caking agents and for one trace element already maximum levels were laid down as condition for authorisation, it is necessary to delete these maximum levels as
they will be replaced by the maximum levels established in the frame of the Directive on undesirable substances. For legal reasons this has to be done through a separate Commission Regulation.

One delegation could not agree on the increase of the level of cadmium in fish feed and of fluorine in marine krill. Another delegation could not agree on the reduction of the maximum level of lead in clinoptilolite of volcanic origin.

The vote was taken. The draft Directive and draft Regulation received a favourable opinion by qualified majority.

The delegation of Denmark made the following declaration:

“At the meeting in the Standing Committee on food chain and animal health - Animal Nutrition, on the 26th of September 2005, a vote was taken upon the proposal SANCO/0216/2005 – rev. 4 on a draft Commission Directive amending Annex I to Directive 2002/32/EC of the European Parliament and of the Council on undesirable substances in animal feed as regards lead, fluorine and cadmium. Denmark voted against the proposal, as Denmark can not support the proposed increase in the allowed maximum content for cadmium in fish feed from 0,5 ppm to 1,0 ppm and for fluorine in marine crustaceans from 2000 ppm to 3000 ppm”


The Scientific Panel on contaminants in the Food Chain of the European Food Safety Authority (EFSA) adopted an opinion on request from the Commission related to camphechlor as undesirable substance in animal feed on respectively 2 February 2005.

Taking into account the conclusion of the scientific opinion and recent occurrence data, the draft Commission Directive proposes to replace the current maximum level of 0.1 mg/kg camphechlor for all feedingstuffs by specific maximum levels of 0.02 mg/kg fish meal, 0.2 mg/kg for fish oil and 0.05 mg/kg for fish feed.

Comments on these proposals were received from FEFAC and discussed at the meeting.

One delegation raised concerns as regards the analytical methodology and the fact that using feed materials complying with the EU legislation do not always result in feed complying with EU legislation. This is particularly the case for fish feeds containing a high proportion of fish oil in their composition.

The Commission representative indicated that CEN is currently elaborating a standard for the analysis of camphechlor in animal feed and committed to raise the issue of the analytical variability. The point will also be raised at the forthcoming meeting of the Expert Committee “Methods of Analysis in feedingstuffs”. As regards the divergence of the maximum level established for feed materials and the maximum levels established for feedingstuffs, the Commission representative indicated that this unavoidable and this problem is not limited to camphechlor. It is the responsibility of the feed manufacturer to purchase feed materials not only complying with EU legislation but also taking into account the feed composition in order to ensure that the compound feed is complying with EU legislation.

The vote was taken. The draft Directive received a favourable opinion by qualified majority.

The delegation of United Kingdom made the following statement:

“The UK is concerned that existing methods for analysing camphechlor in feeds may provide variable results. This issue needs to be addressed, particularly in the light of the reduction in the maximum permitted levels of camphechlor in fishmeal and compound fish feeds.”

As the internal Commission procedure was not yet finalised, no vote was taken on the draft Commission Directive.

Comments were made as regards
- the extraction procedure to be used for the analysis of dioxins and dioxin-like PCBs for additives and compound feedingstuffs with high mineral content;
- the approach followed: new maximum levels for the sum of dioxins, furans and dioxin-like PCBs and separate action levels for dioxins and dioxin-like PCBs;
- the date of application;
- the consistency between the maximum levels of dioxins in feed and the maximum levels for dioxins in food of animal origin.

The Commission representative indicated
- to undertake initiatives in order to determine the extraction procedure to be used before the entry into application of the new maximum levels;
- that the different possibilities as regards the approach have been carefully considered and that the proposed approach was the result of this careful consideration and that the approach proposed for feed is in full accordance with the approach proposed for food.
- to consider the date of application
- that extensive monitoring results did not reveal an inconsistency between the existing maximum levels of dioxins in feed and the maximum levels for dioxins in food of animal origin. This was also confirmed by another delegation.

Once the internal Commission procedure has been finalised the draft Commission Directive will be submitted for opinion to the Committee together with the draft measures foreseen for food.

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4. Exchange of views on a draft Commission Recommendation on the reduction of the presence of dioxins, furans and PCBs in feedingstuffs and foodstuffs (SANCO/0314/2005)

No comments were made as regards the draft Commission Recommendation.


Comments received by stakeholder organisations on the draft Commission Recommendation were made available and discussed.

Some delegations indicated that the proposed guidance values for cereals and cereal products are too high, in particular the levels proposed for fumonisins. On the other hand data were submitted to the Committee indicated that for maize by-products, higher guidance values for deoxynivalenol and zearalenone might be appropriate.

The Commission representative indicated to consider the comments made and to submit a revised document for final consideration at the next meeting.


The draft Recommendation was circulated for comments to the competent authorities and the stakeholder organisations at the beginning of August 2005 with the request to submit the comments, if any, before 15 September 2005. Comments were received from the competent authorities of France, Denmark, Germany and United Kingdom and from the stakeholder organisations COPA-COGECA, FEFAC, BEUC, COCERAL, IDACE and ECPA.
The Commission representative indicated to revise the document taking into account the comments made. In case there are additional comments, these should be submitted as soon as possible as it is the intention to finalise the document by mid-October...

7. Discussion on current legal provisions as regards ergot in view of the EFSA opinion on ergot alkaloids in animal feed and letter from Germany.

The Scientific Panel on contaminants in the Food Chain of the European Food Safety Authority (EFSA) adopted on 19 April 2005 a scientific opinion on the risks for public and animal health related to the presence of ergot in animal feed. Directive 2002/32/EC establishes a maximum level for rye ergot of 1000 milligram (0.1 %) in all feedingstuffs containing ungrounded cereals.

The Scientific Panel concluded that no consistent relationship can be established between the amount of sclerotia and the total ergot alkaloid concentration. Due to variations in ergot alkaloid pattern, the available data do not allow identifying marker ergot alkaloids that could be monitored in all feed materials as indicators for ergot contamination. Data on the sensitivity of agricultural animal species towards ergot alkaloids are incomplete and do not allow the establishment of tolerance levels for individual ergot alkaloids and mixtures thereof. Available data indicate that adverse effects may occur in agricultural animals particularly in pigs after intake of feed with ergot at levels close to the current EU level. The limited data available do not provide any evidence that ergot alkaloids accumulate in edible tissues, including milk and eggs and thus food from animal origin is unlikely to be an important source of human exposure.

Germany proposed to focus on the ergot alkaloids ergometrine, ergotamine and ergocryptine and proposed for control purposes guidance values for these individual ergot alkaloids which correspond to the current maximum level for sclerotia. The Commission representative indicated that it is appropriate for future monitoring purposes to determine the ergot alkaloids of relevance eventually combined with guidance values and is favourable to consider the proposal from Germany. Nevertheless the German delegation was requested to clarify why ergocristine was not identified as indicator ergot alkaloid in the German proposal while in the EFSA opinion ergocristine was identified to be the major ergot alkaloid present in sclerotia from rye, wheat and triticale. The German delegation promised to provide this clarification before the next meeting of the Committee.

8. Follow-up on EFSA opinions as regards undesirable substances endosulfan and HCH isomers.

Endosulfan:
The Scientific Panel on contaminants in the Food Chain of the European Food Safety Authority (EFSA) adopted on 20 June 2005 a scientific opinion related to the presence of endosulfan as undesirable substance in animal feed.

From the conclusions of the opinion, it appears that the existing legal provisions as regards endosulfan in products intended for animal feed, including the strict level for fish feed, are appropriate to ensure that these products do not represent any danger to human health, animal health or adversely affect the livestock production. The Committee agreed therefore that it was appropriate to maintain endosulfan in the Annex to Directive 2002/32/EC on undesirable substances in animal feed.

Following extensive occurrence data and data from processing trials submitted by FEDIOL in advance of the meeting, the Commission representative indicated that it is appropriate to reconsider the existing maximum level for endosulfan in products (oil, oilseed meals, oilseed cake, etc) of the oilseed industry (oilseed crushers). Taking into account the provided information, following suggestion for future consideration was made as regards endosulfan in...
oilseeds and products derived from the processing thereof:
- oilseeds and products derived from the processing thereof with the exception of crude vegetable oil: 0.5 ppm
- crude vegetable oil: 2 ppm.
No comments were made at this stage

**HCH isomers**
The Scientific Panel on contaminants in the Food Chain of the European Food Safety Authority (EFSA) adopted on 4 July 2005 a scientific opinion related to the presence of gamma-HCH and other hexachlorocyclohexanes as undesirable substances in animal feed. From the conclusions of the opinion, it appears that the existing legal provisions as regards HCH-isomers 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.

Nevertheless, the Commission representative indicated that it is appropriate to consider in more detail the current legal provisions in order to provide more clarity as regards the specific (higher) level for fats versus the 10x lower maximum level for all other feed materials and feedingstuffs (including high fat containing feedingstuffs). Delegations were requested to verify how the existing provisions are enforced in practice in view of the discussion on this item at the next meeting.

The Commission representative presented a draft proposal for a regulation amending annex IV of the feed hygiene regulation aiming to extend the approval procedure to feed establishments manufacturing and/or placing on the market feed additives of the group of coccidiostats and histomonostats. There was also some debate over which sort of zootechnical additives should be included in Chapters 2 and 3 of Annex IV. The proposal received favourable comments from the delegations.

**10. Overall summary report on the results of official controls in the field of animal nutrition carried out by the Member States in 2004.**
The Commission services announced that it is their intention to prepare an overall summary report soon, although some Member States had not submitted their contributions through annual national reports. The report should include a section dedicated to the results of the coordinated inspection programme in the field of animal nutrition.

**11. Exchange of views on a draft proposal for a coordinated inspection programme in the field of animal nutrition for 2006 (SANCO/2676/2005).**
The Commission representative presented a draft proposal of recommendation for the coordinated inspection programme in the field of animal nutrition for 2006. The proposal received favourable comments from the delegations. Some delegations showed interest in a programme for monitoring the levels of vitamin A in complete feed. It was also remarked that the programme for mycotoxins should be extended to cover checking of T-2 and HT-2 toxins to be in line with a Commission recommendation on the presence of certain mycotoxins in products intended for animal feeding.

**12. Discussion and possible request of opinion on a draft Commission Regulation concerning an authorisation for ten years of an additive, a permanent authorisation and a provisional authorisation of certain additives in feedingstuffs. (Document SANCO/2074/2005)**
This draft Regulation concerned the authorisation of one growth promoter, three preparations belonging to the additive category binders, anti-caking and coagulants, one enzyme
preparation and two micro-organisms as feed additives. The authorisation of the additive belonging to growth promoters is for ten years and the three additives belonging to binders, anti-caking and coagulants are without time limit. An additional one is an authorisation without a time limit of an enzyme preparation which was object of an earlier provisional 4-year authorisation. Two additional ones concern the provisional authorisation of 2 microorganisms for four years.

The identification number, the trade names of the preparations, the animal categories subject of the authorisations, and the rapporteur MS of the applications are as follows:

• Authorisation for ten year for Potassium diformate (LHS), as growth promoter, for weaned piglets and pigs for fattening. This product had been provisionally authorised for four years.

• Authorisation without time limit for Clinoptilolite of sedimentary origin (E568), sodium ferrocyanide (E535) and potassium ferrocyanide (E 536), as binders, anti-caking and coagulants, for piglets for fattening, chickens for fattening, turkeys for fattening, bovines and salmon.

• Authorisation without time limit: E 1613, Safizym X, for laying hens. It was given enzyme preparation number 23 in the temporary authorisation.

• Provisional authorisations:
  - micro-organism No 15, Lactiferm, for chickens for fattening: (4 years-period from entry into force of the regulation)
  - micro-organism No 18, Fecinor for chickens for fattening: (4 years-period from entry into force of the regulation)

The vote was taken. The draft regulation was adopted by qualified majority.

13. Discussion and possible request of opinion on a draft Commission Regulation amending the conditions for the authorisation of a number of additives in feedingstuffs belonging to the groups of enzymes and micro-organisms (Document SANCO/2546Rev1/2005)

This draft Regulation concerned the change of the conditions of authorisation as feed additives of two enzyme preparations authorised without time limit and of one microorganism for three target species (two authorisations without time limit, one authorisation provisionally until 20.03.2008).

One concerned the doubling of the minimum enzyme activity in the preparation without changing the maximum, minimum or recommended contents in complete feedingstuffs (E 1623, Avizyme 1202, for chickens for fattening). In the other enzyme preparation the liquid form is added without changing the maximum, minimum or recommended contents in complete feedingstuffs (E 1627, Porzyme 9102, for pigs for fattening). For the microorganism the Colony Forming Units minimum content of the preparation is increased without changing the maximum, minimum or recommended contents in complete feedingstuffs (Yeasacc, E 1704 for calves and cattle for fattening, No 5 for horses).

The vote was taken. The draft regulation was adopted by qualified majority.

14. Discussion and possible request of opinion on a draft Commission Regulation concerning the provisional and permanent authorisations of certain additives in feedingstuffs and the provisional authorisation of a new use of an additive already authorised in feedingstuffs (Document SANCO/2556/2005).

This draft Regulation concerned the permanent authorisation of two micro-organism and two enzyme preparations. These products have been granted a provisional authorisation previously. Moreover, it concerned the provisional authorisation of two enzyme preparations for 4 years.
The identification number, the trade names of the preparations and the animal categories subject to the authorisations are as follows:

Authorisation without time limit:

a) enzymes:
- E 1603, Energex, for piglets. It was given enzyme preparation number 6 in the temporary authorisation.
- E 1635, Avizyme betaglucanase, for chickens for fattening. It was given enzyme preparation number 32 in the temporary authorisation.

b) micro-organisms:
- E 1702, Biosaf SC 47, for dairy cows. It was given micro-organism preparation number 3 in the temporary authorisation.
- E 1704, Yeasacc, for dairy cows. It was given micro-organism preparation number 5 in the temporary authorisation.

Provisional authorisations for four years:
- enzyme preparation No 11, Roxazyme G2, for ducks.
- enzyme preparation No 63 (new), Econase Wheat plus, for chickens and turkeys for fattening.

The vote was taken. The draft regulation was adopted by qualified majority.

15. Feed additives

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15.1.1 Enzymes

15.1.1.1 “Porzyme 9100”, preparation of endo-1,3(4)-beta-glucanase produced by Trichoderma longibrachiatum (ATCC 2106) and endo-1,4-beta-xylanase produced by Trichoderma longibrachiatum (ATCC 2105) (E 1627, ex 39). Extension of use for piglets. Rapp.: UK.

Second part of the evaluation period in clock 3 has been opened.

15.1.1.2 “Bio-feed Combi”, preparation of endo-1,3(4)-beta-glucanase produced by Aspergillus aculeatus (CBS 589.94) and xylanase produced by Aspergillus oryzae (DSM 10287), coated and liquid forms, request for provisional authorisation for animal categories: chickens for fattening, piglets. Rapp.: DK

Second part of the evaluation period in clock 3 has been opened.

15.1.1.3 “Bio-feed Wheat”, preparation of endo-1,4-beta-xylanase produced by Aspergillus oryzae (DSM 10287) (Enzyme 5), extension of use pigs for fattening, ducks for fattening. Rapporteur : DK

Second part of the evaluation period in clock 3 has been opened and an Annex Entry has been discussed. It will be included into the next draft Regulation.

15.1.1.4 “Avizyme 1300”.
Preparation of endo-1,4-beta-xylanase produced by Trichoderma longibrachiatum (ATCC 2105) and subtilisin produced by Bacillus subtilis (ATCC 2107 (Enzyme 37). Animal category: ducks. Request of extension of use. Rapp UK

Second part of the evaluation period in clock 3 has been opened and an Annex Entry has been discussed. It will be included into the next draft Regulation.

15.1.1.5 “Avizyme 1500”, 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, and alpha-amylase, EC 3.2.1.1, produced by Bacillus amyloliqufaciens (DSM 9553), subtilisin EC 3.4.21.62, produced by Bacillus subtilis (ATCC 2107), polygalacturonase EC 3.2.1.15, produced by Aspergillus aculeatus (CBS 589.94) (Enzyme 59). Animal category: ducks.

Request of extension of use. Rapp.: UK

Second part of the evaluation period in clock 3 has been opened and an Annex Entry has been
discussed. It will be included into the next draft Regulation.

15.2.2 Trace elements
Chelated trace elements. Rpp. UK
Second part of the evaluation in clock 3 has started again on 27/09/2005

15.3 Aminoacids and their salts
15.3.1 L-Histidine monohydrochloride monohydrate
The company provided response to the comments submitted by one Member State
15.3.2 Vitalys liquid and Vitalys dry, l-lysine-sulphate (produced by fermentation with
corynebacterium glutamicum).
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The company submitted complementary information to comply with the additional
requirements laid down in Regulation (EC) No 1831/2003

15.3.3 L-Arginine
A representative of the Commission informed that the European Food Safety Authority
requested additional information to the company.

15.4. Exchange of views on minor changes in the production process of authorised feed
additives
The Committee exchanged views on the question of how to consider information concerning
minor changes in the production process of already authorised feed additives, details which do
not explicitly appear in the text of the relevant authorisation Regulation. This issue had to be
looked at under the current framework of the new Regulation 1831/2003, which may treat
these cases differently than under the old system of the Directive 70/524. After the discussion,
the Commission representative concluded that the Commission will elaborate a document for
discussion at the next Committee meeting with the aim to conclude on this issue.

BioProtein. Rapporteur: DK
A representative of the Commission informed that a meeting took place with the company, the
Commission and the rapporteur.
The Company agreed basically to give response to the various questions addressed by the
Member States and the EFSA opinion and to present a roadmap on the future actions that the
company intends to carry out and the timing.

17. Vitamin A in animal feed.
The level of vitamin A in feedingstuffs raised some concerns about the possibility to induce
an upper level in food, derived from animals fed by these products, causing risks to human
health. The Commission asked to the Member State to provide data on effective use levels of
vitamin A in their countries. The Commission decided also to submit a question to EFSA to
obtain an opinion on correct use of vitamin A.

18. Plant sterols in animal nutrition
It concerns the legal status of plant sterols. The conclusion was postponed for the next
meeting.

19. Any other business.
• At the request of one delegation, the Commission representative informed the
  Committee about the precise consequences of the entry into the Register mentioned in
  Art. 10 of Reg. 1831/2003 of feed additives with respect to their conditions of use as
  laid down in Directive 70/524/EEC, which has been repealed. As laid down in Art 10
  (1) of Reg. 1831/2003, for products placed on the market pursuant Directive
  70/524/EEC and the ones listed in points 2.1, 3 and 4 of the Annex to Directive
  82/471/EEC, the conditions specified in Directives 70/524/EEC or 82/471/EEC and
  their implementing measures, including in particular specific labelling provisions
concerning compound feed remain in force. These provisions remain in force from the entry into force of Reg. 1831/2003 until the publication of the Register as well as after the entry of a feed additive into the Register, as long as the authorising Regulation is not modified. The Commission representative indicated that this fact will be confirmed in a disclaimer being part of the publication of the said Register.

- One delegation had requested to discuss the issue of the legal situation regarding the use of an enzyme to treat copra meal, following correspondence from an operator. There was a discussion about the status of the treated copra meal but the discussion focused around the issue of whether the enzyme, an hemicellulase, could be regarded as a processing aid or a feed additive and therefore would fall or not under the scope of Regulation 1831/2003 on feed additives and whether the procedure of article 2 para. 3 of the Regulation 1831/2003 would be applicable. This issue will be re-discussed at next meeting in order to reach a conclusion on this point.

- One delegation had asked the commission of the need too report via Rapid Alert for Food and Feed of findings of salmonella in feed material in examinations conducted on the basis of national legislation. The Commission representative underline the obligations in regulation (EC) no 187/2003 " Where a member of the network has any information relating to the existence of a serious direct or indirect risk to human health deriving from food or feed, this information shall be immediately notified to the Commission under the rapid alert system".

- At the request of a delegation the Commission representative indicate to resume the discussions on sampling of feedingstuffs and in particular the use of targeted sampling in official control versus representative sampling.

20. Particular nutritional purposes
Reduction of risk of milk fever SW

The dossier introduced by Sweden was modified in order to incorporate certain changes. Member States were invited to submit comments and to provide additional information to support the scientific background of the request.

21. Agreement with Switzerland on feed hygiene.

A representative of the Commission informed the delegations that, in the context of the Agreement between the European Community and the Swiss Confederation on trade in agricultural products (OJ 30.4.2002); the Swiss confederation has the intention to introduce changes in its legislation to be equivalent with the Community legislation on feed hygiene (Regulation (EC) No 183/2005). This will facilitate trade.

The Commission services examined the Swiss legislation and concluded that the rules achieve the same effects. The Commission shall prepare a decision to adopt a Common Position by comitology procedure. After the Common Position is adopted, the decision is submitted to the Joint Committee on Agriculture for adoption and publication in the Official Journal.