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

Animal Nutrition Section

Brussels, 28-29 June 2005

Standing committee

1. Draft Commission Regulation concerning the permanent and provisional authorisation of certain additives

This draft Regulation concerned the granting of authorisations without a time limit within the meaning of Directive 70/524 for uses of 6 micro-organism preparations previously authorised provisionally. These preparations and their authorised uses are the following:

- *Bacillus cereus* var. *toyoi* (NCIMB 40112/CNCM I-1012) of trade name Toyocerin for chickens for fattening and for rabbits for fattening.

- *Enterococcus faecium* (NCIMB 10415) of trade name Cylactin for sows.

- *Enterococcus faecium* (DSM 10663/NCIMB 10415) of trade name Oralin for piglets.

- *Saccharomyces cerevisiae* (MULC 39 885) of trade name Biosprint for piglets.

- *Saccharomyces cerevisiae* (CNCM I-1077) of trade name Levucell SC for dairy cows and cattle for fattening.

- *Pediococcus acidilactici* (CNCM MA 18/5M) of trade name Bactocell for chickens for fattening.

Moreover, the draft Regulation concerned the granting of authorisation linked to the company BASF for the potassium diformate of trade name Formi LHS for sows as growth promoter provisionally for a period of 4 years.

The vote was taken. The draft regulation was adopted by qualified majority. All present Member State voted in favour and one other Member State was not represented.

2. Draft Commission Regulation concerning the permanent authorisation of certain additives

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

- preparation of endo-1,4-beta-glucanase, endo-1,3(4)-beta-glucanase and endo-1,4-beta-xylanase produced by *Trichoderma longibrachiatum* (ATCC 74 252) of trade name Roxazyme G2, for turkeys for fattening.

- preparation of endo-1,3(4)-beta-glucanase and endo-1,4-beta-xylanase produced from *Penicillium funiculosum* (IMI SD101) of trade name Rovabio Excel, for pigs for fattening.
preparation of endo-1,4-beta-xylanase produced by *Bacillus subtilis* (LMG S-15136), of trade name Belfeed, for piglets.

- preparation of endo-1,3(4)-beta-glucanase produced by *Trichoderma longibrachiatum* (ATCC 2106), endo-1,4-beta-xylanase produced by *Trichoderma longibrachiatum* (ATCC 2105) and subtilisin produced by *Bacillus subtilis* (ATCC 2107), of trade name Avizyme 1100, for chickens for fattening.

The vote was taken. The draft regulation was adopted by qualified majority. One Member State abstained and one other Member State was not represented.

The French delegation made the following declaration:

"Considérant que l'efficacité de la préparation de 1,3(4)-beta-glucanase, endo-1,4-beta-xylanase et subtilisin, commercialisée sur le nom Avizyme 1100, n'avait été démontrée à la dose minimum que sur un seul essai et durant une période bien inférieure à celle préconisée dans les lignes directrices, la délégation française s'est abstenu lors du vote de l'autorisation définitive de cet additif.

### 3. Feed additives

#### 3.1 Setting timetable for additives (Art 25 Regulation (EC) No 1831/2003):

##### 3.1.1 Micro-organisms

3.1.1.1 “Biomin IMB 52” (*Enterococcus faecium* DSM 3530). A representative of the Commission introduced the Member States to the application for permanent authorisation of the product Biomin IMB 52 for the animal category calves, in such way the evaluation period begins today.

##### 3.1.2 Enzymes

3.1.2.1. “Porzyme 8100”. A representative of the Commission asked to the Member States introduced the Member States to the application for permanent authorisation of the product Porzyme 8100 for the animal category piglets, in such way the evaluation period begins today.

3.1.2.2. “Avizyme 1500”. A representative of the Commission informed the Member States that the second part of the evaluation period in clock 3 for the product Avizyme 1500 for laying hens has been restarted as from today.

##### 3.1.3 Aminoacids and their salts

3.1.3.1 L-Histidine monohydrochloride monohydrate A representative of the Commission asked to the Member States to keep confidentiality on the information requested by the company until the procedure laid down in Regulation (EC) 1831/2003 will be finalised. It also informed that a letter was submitted to the company to submit complementary information.

3.1.3.2 Vitalys® liquid and Vitalys® dry, l-lysine-sulphate (produced by fermentation with *corynebacterium glutamicum*). The company has provided the complementary information requested by the Commission. All the comments in regard to this application must be submitted to EFSA which is responsible for the risk assessment.
3.1.3.3 L-Arginine

A letter was submitted to the company to request for complementary information. All comments in regard to this application must be submitted to EFSA which is responsible for the risk assessment.

3.1.4 Coccidiostats

3.1.4.1 Aviax (seduramicin ammonium) as coccidiostats for chickens for fattening for authorisation for ten years. This additive is already provisional authorised until on 01 June 2006.

3.1.4.2 Clinacox 0.5% Active substance: Diclazuril (R064433) CAS 101831-37-2. Coccidiostat for rabbits for fattening and breeding. Request for permanent authorisation. Rapporteur: BE. The second part of clock 3 started.


BioProtein®. Rapporteur: DK

The company provided response to the comments of various Member States. The EFSA panel will publish soon its opinion and a discussion will take place in the Standing Committee.

5. Particular nutritional purposes

Reduction of risk of milk fever DK

The rapporteur informed that the company is preparing the information that was indicated in the EFSA opinion on this product.

6. Status of water in animal nutrition legislation

All legislation in feed was adopted taking into account that water is not a feed material. For this reason, the change of the status of water cannot be decided without considering the legal consequences of such approach and the necessary changes in Community legislation. The status quo should be maintained until it will be decided in the proposal recasting feed legislation.

Annex I and II and III of Regulation (EC) No 183/2005 laying down the requirements for feed hygiene set up general requirements for water to be used in feedingstuffs, as well as water for drinking and aquaculture. In the recommendations for guides to good practice the Regulation also provides for the inclusion of measures for the use of water. If specific requirements are necessary for water they can be established by comitology procedure.

7. Opinion on mycotoxin-detoxifying products

The Representative of a Member State, supported by two Delegations, asked the Committee
– to proceed in the authorisation procedure for the micro-organism preparation Biomin BBSH 797 for use in piglets, pigs for fattening and chicken for fattening and
– to create under Regulation 1831/2003 a new sub-category for “mycotoxin-detoxifying products” under category zootechnical additives.

According to the Delegate “Biomin BBSH 797” supposed to be an innovative product, which is successfully used in many countries outside the EU. There would be some advantage to use this product within the EU without undermining the high EU-level in the field of feed safety.
The President reminded the Committee about the EFSA-opinion adopted on 25.01.2005 on the product, which could not conclude on various safety issues and demands further data. This supplementary information has not yet fully been delivered by the company. The creation of a new sub-category could be envisaged, once such a product is ready for authorisation. The Delegate confirmed, that there is still some data missing, which the company is trying to compile soon.

8. Undesirable substances

* Discussion on possible measures as regards deoxynivalenol, zearalenone and ochratoxin A in animal feed.

The Scientific Panel on contaminants in the Food Chain of the European Food Safety Authority (EFSA) adopted scientific opinions on the risks for public and animal health related to the presence of these mycotoxins in animal feed. These opinions conclude that all three mycotoxins exhibit toxic effects in several animal species. Deoxynivalenol and zearalenone are only to a very limited extent transferred from feed into meat, milk and eggs and therefore food of animal origin do only contribute marginally to the total human exposure to these toxins. Ochratoxin A can be transferred from the feed into food of animal origin but exposure assessments indicate contributes only to a minor extent to human dietary exposure to ochratoxin A.

Directive 2002/32/EC of the European Parliament and of the Council of 7 May 2002 on undesirable substances in animal feed provides that products intended for animal feed can only be used for animal feeding if these do not represent any danger to human health, animal health or to the environment or could adversely affect livestock production.

Taking into account the conclusions of the scientific opinions, but also the concerns expressed as regards the large year to year variation in occurrence of these mycotoxins, it is appropriate to collect in the next few years, in addition to the data available from the co-ordinated control programs 2002, 2004 and 2005, more data on the presence of these mycotoxins in the different feed materials and feedingstuffs and this in a joint effort between competent authorities and feed business operators. These monitoring will provide a better picture on the possible year to year variance of the occurrence of these mycotoxins in cereals and cereal products.

To provide orientation to the competent authorities on the acceptability of cereals and cereal products and compound feed for animal feeding, guidance or orientation values are proposed at EU level. Such an approach should avoid disparities in the acceptable level applied by the different Member States and the consequent risk of distortion of competition. These guidance values should also be used as guidance for the determination of critical limits at critical control points in HACCP systems.

These provisions are proposed in a draft Commission Recommendation. An evaluation of the monitoring results and the application of the recommendations is foreseen within three years in order to evaluate the need for further possible legal measures.

Given that the Scientific Panel on contaminants in the Food Chain of the European Food Safety Authority (EFSA) adopted very recently a scientific opinion on the risks for public and animal health related to the presence of fumonisins in animal feed, it will be considered once the opinion is available to possibly include also fumonisins in this approach.
The Committee generally welcomed this new approach but indicated that more in depth examination as well further consultations are necessary before having a more definitive opinion on the proposed provisions.

* Follow-up on EFSA opinion as regards camphechlor in animal feed

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, a proposal was discussed whereby the current existing provisions on camphechlor would be replaced by:
- defining 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 of 0.2 mg/kg, fish meal of 0.02 mg/kg and fish feed of 0.05 mg/kg. The reason is that fish oil and fish meal have been identified as the main sources of camphechlor exposure of farmed animals, particularly fish and fish has been identified as the most sensitive species to camphechlor toxicity and fish is the main source of human exposure to camphechlor.

Comments were made as regards the proposed levels being too low taking into account levels found in fish oil and fish meal produced from blue whiting in certain periods of the year. However no information was available as regards the compliance of these samples with other provisions on undesirable substances such as dioxins. For future considerations analytical results from samples where simultaneously the level of camphechlor, dioxins and dioxin-like PCBs has been determined are necessary.

* Follow-up on EFSA opinion as regards undesirable substances endosulfan, HCH isomers and ergot alkaloids in animal feed

The scientific opinions on endosulfan and HCH isomers were not yet available and were consequently not discussed.

The Scientific Panel on contaminants in the Food Chain of the European Food Safety Authority (EFSA) adopted on 19 April 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 milligrammes (0.1 %) in all feedingstuffs containing unground 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.

The Commission representative indicated that a call for a research project will be launched shortly for the development of methods of analysis to determine ergot alkaloids in animal feed. The availability of a method of analysis as well occurrence data are necessary in order to be able in the future to replace the current legal provisions on ergot sclerotia by maximum levels on ergot alkaloids.

In the meantime, it has to be considered if the current level of 1000 milligrammes (0.1 %) sclerotia in feedingstuffs containing unground cereals should not be decreased given that adverse effects may occur at concentrations close to that level in farm animals particularly in pigs.

* Other business

The Norwegian delegate informed the Committee that the total cost related to the contamination of one batch of zinc sulphate with very high levels of cadmium was estimated to be 10-12 million €.

9. Update of lists of contact points of Delegations

10. Any other business
10.1 Letter from Greece on the status of a product consisting of dried extracted Aspergillus meal (inactivated Aspergillus and the residues of fermentation).

The group agreed that more information was necessary to determine the legal status of this product.

The representative of the Commission indicated that such product should be regarded as a feed material. Similar products are listed in the Annex to Directive 96/25/EC.

The representative of the Commission indicated that the competent authorities of the Member States should verify that the information (other than mandatory information) given on the label of feed materials comply with the requirements laid down in Directive 96/25/EC. The information must be related to objective or quantifiable parameters which can be substantiated and it can not mislead the purchaser.

10.2 Co-ordinated inspection programme in the field of animal nutrition for 2006

The Commission representative introduced a request for topics for the co-ordinated inspection programme in the field of animal nutrition for 2006. An exchange of views on this subject shall take place in the forthcoming meetings.

Trace elements

1.9.1 Chelated trace elements Rapp. UK

A representative of the Commission informed that the company was requested by EFSA to submit complementary information.
19.2 Chelated trace elements

The Commission informed that there was information from a company that a company put on the market chelated amino acids that are not authorised. These are chelated forms of Mn, Zn Copper and Iron with glycine and not with hydrolysed soy protein which is the cheated form authorised.

Dr Willem Penning