1. Discussion and possible request of opinion on a draft Commission Regulation concerning the permanent authorisation of an additive and the provisional authorisation of new uses of certain 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) authorisation without time limit
- one preparation belonging to the group of “Enzymes”:
  - 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), (E 1623), trade name Avizyme 1200 for chickens for fattening. The company should provide additional data to support the efficacy of the preparation at the contents of glucanase of 25 Units of activity/kg of complete feedingstuff in a reasonable time period.

b) provisional authorisations
- one preparation belonging to the group of “Enzymes”:
  - 6-phytase produced by *Aspergillus oryzae* (DSM 14223), trade name Bio Feed Phytase, for salmonids.

- one preparation belonging to the group of “Micro-organisms”:
  - *Enterococcus faecium* DSM 7134, trade name Bonvital, for chickens for fattening.

The German delegation made the following declaration:


Deutschland ist der Auffassung, dass die Zubereitung der 6-Phytase aus Aspergillus oryzae (DSM 14223) zunächst einer Zulassung gemäss der Verordnung (EG) 1829/2003 über genetisch veränderte Lebensmittel und Futtermittel bedurft hätte.


Aus den genannten Gründen kann D dem vorliegenden Verordnungsvorschlag nicht zustimmen und enthält sich der Stimme.

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

2. Feed additives

Concerning the additives listed below, the clock has been stopped (Article 4 Directive 70/524/ECC):

**Clinacox 0.5%** Active substance: Diclazuril (R064433) CAS 101831-37-2. Coccidiostat for rabbits for fattening and breeding. Request for permanent authorisation. Rapporteur: **BE**

**Farmatan** Active substance: Tannin. Request for permanent authorisation as grown promoter for rabbits and piglets. Rapporteur: **AT**

**Astaxantin-rich (Aquasta)** Active substance: Phaffia rhodozyma. Colourant for trout and salmon Request for permanent authorisation. Rapporteur: **BE**

**Kemzyme W DRY.** Preparation of 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) (Enzyme No. 53). Extension of use for animal category: laying hens, turkeys for fattening. Rapp BE. **Day O: 4.10.2004.**

**Kemzyme W liquid,** preparation of 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) (Enzyme No. 54). Request of provisional authorization (4 years) for animal category: laying hens (extension of use). Rapp BE. **Day O: 04.10.2004 **

**Bio feed Combi,** preparation of endo-1,3(4)-beta-glucanase, EC 3.2.1.6., produced by *Aspergillus aculeatus* (CBS 589.94) and xylanase, EC 3.2.1.8, produced by *Aspergillus oryzae* (DSM 10287), coated and liquid forms. Request for provisional authorisation for animal categories: chickens for fattening, piglets. Rapp. **DK Day O: 29.10.2004.**


3.1 Reduction of milk fever. Rapporteur: SE

Three delegations submitted comments and support the general approach proposed for changes to the Annex of Directive 94/39/EC. The rapporteur presented a new proposal to modify the Annex entry in accordance with the suggestions expressed in the previous meeting.

3.2 Support of respiratory function in horses.

The discussion focuses on the issue whether dossier falls within the scope of Directive 94/39/EC.

Two delegations submitted comments. The Commission agreed to prepare a document assessing the different aspects to take into consideration to decide if this dossier falls within the scope of the above-referred Directive. This document will be discussed in the next meeting.


4.1 L-Histidine monohydrochloride monohydrate

A representative of the Commission informed that the EFSA panel progress a lot with the opinion on this dossier.

One delegation submitted comments in favour of the request.

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

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

4.3 L-Arginine

One delegation submitted comments. A representative of the Commission invited other delegations to submit comments as soon as possible.
Following the consultation of the stakeholders on the provisions under discussion following points have been considered at the meeting

5. - Legal status for creatine in animal nutrition.

This product falls within the scope of Regulation (EC) 1831/2003, therefore, it needs an authorisation to be placed on the market.

6. Undesirable substances:

a) Measures under discussion as regards
- dioxins and dioxin-like PCBs
- lead, cadmium and fluorine

Discussion on the outcome of the consultation of the stakeholders

- As regards the provisions on dioxins and dioxin-like PCBs under discussion, it was considered to keep the current existing maximum levels of dioxins for kaolinitic clay, calcium sulphate dehydrate, vermiculite, natrolite-phonolite, synthetic calcium aluminates and clinoptilolite of sedimentary origin and not to extend it to the whole functional groups of binders and anti-caking agents whilst foreseeing the maximum level for the sum of dioxins and dioxin-like PCBs for the whole functional group of binders and anti-caking agents. In addition, an expert working group will be convened within short notice to determine the extraction procedure to which the maximum levels refer to for products intended animal feeding in particular those of mineral origin.

- As regards the provisions on lead, fluorine and cadmium under discussion it was considered to establish a maximum level for cadmium of 2 ppm in complementary and complete feeds for pet animals and of 1 ppm in fish feed.

As regards the request to increase the level of fluorine in marine krill and consequently also in fish feed, delegations indicated the need for further examination of this request before being able to express an opinion.

The Commission indicated to finalise the internal consultation procedure on these proposals and to notify thereafter the measures to WTO following the obligations under the SPS agreement before submitting the proposals for an opinion of the Committee at a next meeting.

b) Continuation of the discussions on the measures as regards deoxynivalenol, zearalenone and ochratoxin A

Following the scientific opinions of EFSA, measures are considered in order to protect animal health (deoxynivalenol, zearalenone and ochratoxin A) and public health (ochratoxin A). Maximum levels for cereal and cereal products and for complementary and complete feeds for several animal species are under discussion.

In addition to maximum levels, action levels for deoxynivalenol, zearalenone and ochratoxin A are proposed for cereals and cereal products taking into account the most sensitive animal species. When these action levels are exceeded it is proposed that special attention should be paid that these cereals and cereal products are not used for the production of feedingstuffs for the most sensitive animal species and that the use of such feed materials is diverted to the production of animal feed for less sensitive or non-sensitive animal species.
Since the new version of the working document has only been very late available, several delegations indicated that it was premature to express a view on these proposed provisions and that further examination is necessary.

The Commission representative acknowledged this and indicated that these provisions will be discussed in more detail at a next meeting of the Expert Committee “Undesirable substances” and of the Standing Committee.

7.1 Other business

SE request for legal status of a blood product used as iron supplement.

The Swedish delegation asked for the legal status of a blood product used as source of iron in pigs. The discussion was postponed for the next meeting.

Dr. Willem Penning