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

Brussels, 04.10.2004

STANDING COMMITTEE

1. Discussion and possible request of opinion on a draft Commission Regulation concerning the permanent and provisional authorisations of certain additives and the authorisation of new uses of an additive already authorised in feedingstuffs.

This draft Regulation concerned the following authorisations:

a) Conversion of a 4 year provisional authorisation into an authorisation without time limit of the following products:

- the additive belonging to the category “binders, anticaking agents and coagulants” clinoptilolite of volcanic origin, for pigs rabbits and poultry.
- three preparations belonging to the category “micro organisms”:
  - Preparation of *Bacillus licheniformis* DSM 5749 and *Bacillus subtilis* DSM 5750 of trade name Bioplus 2B, for pigs for fattening and piglets.
  - Preparation of *Saccharomyces cerevisiae* NCYC Sc47 of trade name: Biosaf Sc 47, for weaned piglets.
  - Preparation of *Enterococcus faecium* DSM 7134 and *Lactobacillus rhamnosus* DSM 7133, of trade name: Provita LE, for weaned piglets.
- three preparations belonging to the category “enzymes”:
  - Preparation of endo-1,3(4)-beta-glucanase produced by *Trichoderma longibrachiatum* (CNCM MA 6-10 W) of trade name: “Safizym G”; for chickens for fattening.
  - Preparation of endo-1,4-beta-glucanase produced by *Trichoderma longibrachiatum* (IMI SD 142) of trade name: “Hostazym X”; for chickens for fattening.
  - Preparation of endo-1,4-beta-xylanase produced by *Trichoderma longibrachiatum* (IMI SD 135) of trade name: “Hostazym C”.for chickens for fattening.

b) New 4-year provisional authorizations for the following products:

- the micro-organism preparation based on *Kluyveromyces marxianus* of trade name Kluyten, for dairy cows.
- the enzyme preparation of endo-1,3(4)-beta-glucanase and endo-1,4-beta-xylanase produced by *Penicillium funiculosum* (IMI SD 101) of trade name: Rovabio Excel, for two additional animal categories: piglets and ducks for fattening.

The vote on the draft was taken and it was adopted with qualified majority in favour with 3 abstentions.
The Czech delegation raised language reservation because of absence of documents presented for voting in Czech language.

The German delegation made the following declaration:

„Die Zulassungsvoraussetzungen für eine vorläufige Zulassung des Zusatzstoffes *Kluyteromyces Marxianus var. Lactis* K1 (BCCM/MUCL 39434) in der Tierernährung für die Tierkategorie Milchkühe sind nach der Auffassung Deutschlands, insbesondere hinsichtlich des Wirksamkeitsnachweises, nicht erfüllt. Bezüglich des Effizienznachweises ist aufgrund der derzeit vorliegenden Daten kein ausreichender Hinweis auf einen positiven Effekt dieses Zusatzstoffes bei Milchkühen gegeben, so dass eine vorläufige Zulassung dieses Zusatzstoffes von Deutschland nicht befürwortet werden kann.“


The Commission Directive concerns the authorisation of a by-product from citric acid fermentation consisting of cells of *Candida guilliermondii* cultivated on substrates of vegetable origin.

The vote was taken and the Committee adopted, by qualified majority, an opinion in favour. Two Member States abstained.

The Czech delegation raised language reservation because of absence of documents presented for voting in Czech language.

2.1 Possible discussion and possible request for opinion on a draft Commission Regulation concerning the authorisation for ten years of the additive “Cycostat 66G” in feedingstuffs, belonging to the group of coccidiostats and other medicinal substances.

The vote was taken and the Committee adopted, by a qualified majority, an opinion in favour of a Regulation concerning the authorisation – for ten years – as a coccidiostat of the additive “Cycostat 66G”.

The Czech delegation raised language reservation because of absence of documents presented for voting in Czech language.

The French delegation made the following declaration:

« Au cours de la réévaluation, selon l’article 9g de la directive 70/524, de l’additif Cycostat (robenidine) destiné aux poulets à l’engrais, aux lapins à l’engrais et aux dindons, le pétitionnaire n’a pas répondu de façon satisfaisante aux questions des experts français sur l’efficacité ni
mêmes sur la sécurité de l’additif. La France vote donc contre le texte proposé par la Commission. »

3. Setting timetable for additives


On the expiry of the sixty-day period provided for in Article 4(4) of Directive 70/524/EEC, an objection was raised on the accordance of the dossier with the Directive 87/153/EEC.


No objection on this dossier has been raised. This dossier has been considered acceptable according to Dir. 87/153. According to Art. 4 of Directive No 70/524 the clock three, expert evaluation, starts.


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3.9 Trace elements:

3.9.1: Chelated forms of the trace elements iron, copper, manganese and zinc with chemically synthesised aminoacids: request for authorisation under Article 4 of Directive 70/524/EEC. Rapporteur: UK.

On expiry of the sixty-day period laid down in Article 4(4) of Directive 70/524/EEC, no objections regarding the acceptability of the dossier were noted. The in-depth evaluation process laid down in Article 4(6) that Directive was therefore deemed to have started on 4 October 2004.

The comments regarding the method of analysis submitted by one delegation shall be treated during the evaluation period.

3.9.2: Selenized yeast SEL-PLEX: (Saccharomyces cerevisiae CNCM I-3060) composed by selenomethionine with other organic selenium components. Rapporteur: BE

The company has withdraw the request for authorisation, so that, the procedure was closed.

3.10. Enzymes

3.10.1 “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 longi-brachiatum (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 2.06.2004.

On expiry of the sixty-day period laid down in Article 4(4) of Directive 70/524/EEC, no objections regarding the acceptability of the dossier were noted. The in-depth evaluation process laid down in Article 4(6) that Directive was therefore deemed to have started on 4 October 2004.


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3.10.11. **Avizyme 1500.** Preparation of endo-1,4-beta-xylanase produced by *Trichoderma longibrachiatum* (ATCC 2105), endo-1,3(4)-beta-glucanase and


3.10.15 Avizyme 1100. 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) (Enzyme 40). Animal category: chickens for fattening. Request for permanent authorisation. Rapp UK.


At a request by a Delegation and as a follow-up of the discussions at the earlier meeting of the Standing Committee in July, the Commission services indicated that in the case of feed additives having been the object of a 4-year provisional authorization under Article 9a of Directive 70/524, applications under Article 9d of this Directive 70/524 could be considered as being supplementary information relating to the initial application submitted under Article 4 of Directive 70/524, and, therefore, this supplementary information could be construed as an application meeting the requirements mentioned in Article 25 (transitional measures) of Regulation 1831/2003, in the sense of having been submitted under Article 4 of Directive 70/524 before the date of application of this Regulation 1831/2003, including in the event that this new information is submitted after the date of application of the Regulation 1831/2003, the 18 October 2004.

additives in animal nutrition as regards the duties and tasks of the Community Reference Laboratory.

The Commission services introduced the revised draft following the earlier meetings of the working group additives and the workshops organised by the Joint Research Centre with candidate laboratories to become part of the consortium. Delegations formulated a number of comments. The draft will be amended with the objective to submit it to vote at the meeting of the Standing Committee in November.

Delegations were also informed about the details of the official inauguration of the Community Reference Laboratory to take place on 9 of November at the premises of the Joint Research centre’s Institute of Reference Materials and Measurements in Geel, Belgium. Further details will be communicated to Delegations soon after this meeting of the Standing Committee.

6. Exchange of views and possible opinion on:


The draft proposes to amend Directive 2002/32/EC of the European Parliament and of the Council of 7 May 2002 on undesirable substances in animal feed as regards:
- clarification of the term “green forage”
- the establishment of a specific level for mercury in calcium carbonate;
- the establishment of the maximum level for fluorine for complementary feedingstuffs per kg feed instead of per % of phosphorus.

The Czech delegation raised language reservation because of absence of documents presented for voting in Czech language.

The German delegation made the following declaration:

„Mit der Richtlinie der Kommission soll der Höchstgehalt für Quecksilber in Kalziumcarbonat von bisher 0,1 mg/kg auf 0,3 mg/kg angehoben werden. Die deutsche Delegation ist der Auffassung, dass diese Regelung der ursprünglich durch die Einführung des Verschneidungs- und Vermischungsverbots für höher belastete Futtermittel in der Richtlinie 2002/32/EG verfolgten Minimierungsstrategie entgegensteht und kann daher einer Anhebung des Höchstgehaltes nicht zustimmen.“

The vote on the draft was taken and it was adopted with qualified majority in favour with two Member States abstaining.

- Draft Commission Directive amending Directive 2002/70/EC establishing requirements for the determination of levels of dioxins and dioxin-like PCBs in feedingstuffs

It is important that analytical results are reported and interpreted in a uniform way in order to ensure a harmonised enforcement approach across the European Union of the

The draft proposes to amend Directive 2002/70/EC establishing requirements for the determination of levels of dioxins and dioxin-like PCBs in feedingstuffs to provide that a consignment is considered as non-compliant with the maximum level on dioxins as laid down in Directive 2002/32/EC, if the analytical result exceeds the maximum level beyond reasonable doubt taking into account the expanded measurement uncertainty.

Furthermore it is foreseen that for the official control of dioxin levels in feedingstuffs, the sampling procedure as laid down in Commission Directive 76/371/EEC of 1 March 1976 establishing Community methods for the official control of feedingstuffs for the control of substances or products uniformly distributed throughout the consignment of feedingstuffs has to be applied. Finally for the purposes of this Directive only the accepted specific limit of quantification has been defined.

The vote on the draft was taken and it was adopted with qualified majority in favour with one Member States abstaining.

The Czech delegation raised language reservation because of absence of documents presented for voting in Czech language.


It is important that analytical results are reported and interpreted in a uniform way in order to ensure a harmonised enforcement approach across the European Union of the provisions provided for in Directive 2002/32/EC of the European Parliament and of the Council of 7 May 2002 on undesirable substances in animal feed.

The draft proposes to amend Directive 71/250/EC establishing Community methods of analysis for the official control of feedingstuffs to provide that a consignment is considered as non-compliant with the maximum level on undesirable substance as laid down in Directive 2002/32/EC, if the analytical result, corrected for recovery exceeds the maximum level beyond reasonable doubt taking into account the expanded measurement uncertainty. This procedure os only applicable in cases where the method of analysis enables the estimation of measurement uncertainty and correction for recovery.

The vote on the draft was taken and it was adopted with qualified majority in favour with one Member States abstaining.

The Czech delegation raised language reservation because of absence of documents presented for voting in Czech language.
7. State of play regarding the application of Directive 2002/2/EC in the Member States
No new development was referred to by the Member States.

Delegations were briefed about the draft proposed recommendation. The programme suggested for 2005 comprises the items covered in 2004: mycotoxins, antimicrobials, feed ban. It also includes checks on the contents of copper and zinc in feedingstuffs. Debate extended to the possible inclusion of coordinated checks on heavy metals and *Salmonella*.

9.- OTHER BUSINESS

**Codex**

The representative from the Netherlands informed about a half-day meeting in the Council for 8 of December 2004.

The draft prepared for the Commission on possible future works will be distributed to the delegations for comments. Taking into account the relevant comments from the MS, the Commission will prepare a new document that will be the basis for the discussions at the Council.

Dr. Willem Penning