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

Animal Nutrition Section

Brussels, 3.12.2004

STANDING COMMITTEE

1. Discussion and possible request of opinion on a draft Commission Regulation concerning the permanent authorisations of certain additives

This draft concerned the conversion of 4 year provisional authorisation into an authorisation without time limit of the following products:

- Two preparations belonging to the group of “Micro-organisms”:
  - *Bacillus cereus* var. *toyoi* NCIMB 40112 / CNCM I-1012 of trade name Toyocerin, for cattle for fattening
  - *Enterococcus faecium* DSM 10663 / NCIMB 10415 of trade name: Oralin, for calves

- Three preparations belonging to the group of “Enzymes”:
  - Endo-1,3(4)-beta-glucanase EC 3.2.1.6 and Endo-1,4-beta-xylanase EC 3.2.1.8 of trade name: Endofeed, for laying hens
  - 6-phytase EC 3.1.3.26 of trade name: Bio feed phytase, for chickens for fattening, laying hens, turkeys for fattening, piglets, pigs for fattening, sows
  - Endo-1,4-beta-xylanase EC 3.2.1.8 of trade name: Natugrain Wheat, for chickens for fattening and turkeys for fattening

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

Concerning the meaning of authorisations without a time limit granted after the full entry into application of the Regulation (EC) No 1831/2003 and for requests maintained under the transitional period of Article 25 of this Regulation, the interpretation appearing in Annex I of these summary minutes was agreed by Member States.

The Chairman explained that formaldehyde had not been included in draft, as it wished an assessment of worker safety to be performed relating to a particular use of this substance in feed. He said that it would write to the rapporteur setting out its reasons for non-inclusion and that the applicant would have the opportunity to provide the scientific committee with data and other information related to worker safety.

The German delegation made the following declaration:

Inverkehrbringen von Erzeugnissen fallen, die aus GVO bestehen, diese enthalten oder daraus hergestellt wurden, dass der Antragsteller nähere Angaben zu einer gemäß den geltenden Rechtsvorschriften erteilten Zulassung macht. Diese Angaben wurden nicht gemacht.

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.”

2. Discussion and possible request of opinion on a draft Commission Regulation on detailed rules for the implementation of Regulation (EC) No 1831/2003 of the European Parliament and of the Council on additives in animal nutrition, as regards the duties and tasks of the Community Reference Laboratory.

The draft Regulation was introduced and then discussed. During the discussion some adjustments were introduced in the text.

The vote on the draft with the modifications was taken and it was adopted with majority. Only one Delegation abstained as it was absent.

3. Discussion on a draft recommendation on the co-ordinated inspection programme in animal nutrition for the year 2005 according to Council Directive 95/53/EC

The exchange of views on the coordinated control programme for 2005 was preceded by a debate on the controls of the presence of bone fragments in feed materials and the feed ban.

The German delegation reported on the follow-up actions taken as regards the contamination of sugar beet pulp with bone fragments. Soil around the sugar beets is pointed to as the single carrier of bones. Dead small wild mammals, or bone meal legally used as a fertilizer in sugar beet fields, are outlined as the two possible sources of bones. Sugar beet factories in Germany have been placed under surveillance of competent authorities for official controls. Discussions between authorities and managers of those companies led to setting up a system
by which daily production of sugar beet pulp is tested. Batches have been found positive for bone fragments only in a limited number of cases.

Other delegations informed to have implemented precautionary measures at sugar beet factories, which cannot release goods until the competent authority has provided the results of analysis showing that these goods are free from bone fragments.

Although the German delegation did not ask for a revision of the zero-tolerance rule applicable to feed ban controls, other delegations raised concern about the pertinence of zero-tolerance if the widespread presence of bone fragments from non-reared animals is confirmed. One delegation commented that a deeper look into this matter could be appropriate, in order to verify whether control measures go beyond the scope of the TSE regulations. Moreover bone fragments have also been found in corn gluten consignments, which were impounded and a full recall of compound feed manufactured therefrom has been put in place.

The representative of the Commission commented on the main reasons for refraining from a lift of the zero-tolerance: the BSE-inducing potential of very low doses of meat-and-bone meal; and the difficulty of differentiation between animal species. However this should be a matter for further reflection. Further explanation was given on the use of RASFF, namely the decision on how to classify similar notifications as information or as alerts.

The draft recommendation for the coordinated control programme in the field of animal nutrition for 2005 should be adapted, so that Member States put more effort in the control of feed materials. Particular attention should be paid to the sugar beet campaign of autumn 2005.

4. Setting timetable for additives evaluation under Directive 70/524

4.1. Enzymes


In application of Art 25 (transitional measures) of Regulation 1831/2003, this application shall continue to be treated in accordance with Article 4 of Directive 70/524.

On expiry of the sixty-day period referred to in Article 4 (4) of Directive No 70/524/EEC, no objections regarding the acceptability of the dossier were registered. The process for an in-depth evaluation referred to in Article 4 (6) of Dir. 70/524/EEC was therefore considered to have started on 3 December 2004.

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4.2 Microorganisms


On the 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) of the Directive was therefore deemed to have started on 3 December 2004.


4.2.4 “Bonvital” (previous name: “Provita E”) (*Enterococcus faecium* DSM 7134). Application for extension of use for the animal category: Chickens for fattening. The second part of the evaluation period (clock 3, art. 4 par. 6 of Dir. 70/524/EEC) was stopped as from 3 December 2004. Rapporteur: AT

4.3 Binders, anti-caking agents and coagulants

4.3.1 “Clinoptilolite of sedimentary origin”,

4.3.2 “Sodium ferrocyanide”,
Animal category: all species or categories of animals
Rapporteur: DE Application for permanent authorisation. The expiry date of temporary authorisation: 01.03.2006

4.3.3 “Potassium ferrocyanide”
Animal category: all species or categories of animals
Rapporteur: DE Application for permanent autorisation. The expiry date of temporary authorisation: 01.03.2006

5. Contamination by dioxins of potato by-products intended for animal feed

Update and discussion on the recent dioxin contamination case – contamination with contaminated kaolinitic clay of potato by-products intended for animal feed

The Committee was informed that nearly all restrictive measures as the consequence the contamination incident by dioxins of potato by-products intended for animal feed have been lifted by the competent authorities in the concerned Member States. Restrictive measures are still in place on only two dairy farms in the Netherlands
In order to avoid any possible future contamination incident, it is evident that this highly contaminated kaolinitic clay should not be used anymore in any feed or food manufacturing process.

6. Undesirable substances in feed.
   Update on and continuation of the discussions on possible measures as regards deoxynivalenol, zearalenone, lead, cadmium, ochratoxin A, fluorine and dioxin-like PCBs in feed

The Committee was shortly updated on the discussions at the meeting of the Expert Committee “Undesirable substances” on 19 November 2004. As regards the measures concerning deoxynivalenol, zearalenone, and ochratoxin A a questionnaire has been made available to the delegations. As regards the additional measures on lead and cadmium a revised working document was made available. The Committee was informed that on these issues and on dioxin-like PCBs and fluorine an extensive discussion will be held at the next meeting of the Expert Committee “Undesirable substances” on 13 December 2004.


Reduction of milk fever- Zeolite. Rapporteur DK
This item was not treated during the meeting.

8. Update of lists of contact points of Delegations

The Commission services mentioned that the lists of the Heads of Delegations and Contact points for the different areas of animal nutrition were going to be circulated in order to be verified and completed.

9. Any other business

   • Status of the notifications of feed additives under Article 10 of Regulation (EC) No 1831/2003.
     The Commission services informed that at the end of the notification period on 7 November 2004, more than 9100 were received by the Commission. A preliminary estimate of the types of products as notified are: 8056 feed additives authorised pursuant to Directive 70/524/EEC, 217 products listed in the annexes to Directive 82/471/EEC and 532 products notified as silage additives. EFSA will verify the information included in the notifications in accordance Article 10 (1) b.

   • Labelling of feed additives according to Regulation (EC) No 1831/2003: further to a question from the Belgian delegation, the Commission services clarified that the new labelling requirements apply since 18 October 2004 to additives placed on the market, without prejudice to the provisions laid down as transitional measures (Article 25(2) of the Regulation) and for existing products as regards possible specific labelling requirements attached to those products. The labelling of the functional group has to include the name of the group as provided by the authorisation of the additive concerned.

   • Directive 93/74/EEC: Particular nutritional purposes. Support of respiratory tract function. (horses). The dossier presented by the applicant for the first time was distributed to the delegations.

   • Directive 82/471/EEC. BioProtein DK. Rapporteur DK
A letter of 22-10-2004 accompanying a complementary dossier was distributed to the Delegations. The letter indicated that the complementary dossier was submitted to all Member States and EFSA members

ANNEX I

Meaning of authorisations without a time limit granted after the entry into application of Regulation (EC) No 1831/2003.

Article 10 paragraph 2 of Regulation (EC) No 1831/2003 is applicable for the authorisations without a time limit granted by the Regulation voted at this meeting (Doc 3122/2004). This Article 10 paragraph 2 indicates that: "2. An application shall be submitted in accordance with Article 7, [...] within a maximum of seven years after the entry into force of this Regulation [i.e. 7.11.2010] for additives authorised without a time limit [pursuant to Directive 70/524] [...]."

This provision is obviously applicable for any such authorisation without a time limit granted under Directive 70/524/EEC. It is also therefore applicable for example for the authorisations without a time limit included in the 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 (SANCO/2403/2004)". This Regulation was already voted at the meeting of the Standing Committee of 4 October 2004 and is about to be published in the OJ.

Dr Wim Penning