European Food Safety Authority

MINUTES OF THE 18TH PLENARY MEETING OF THE SCIENTIFIC PANEL ON ADDITIVES AND PRODUCTS OR SUBSTANCES USED IN ANIMAL FEED (BRUSSELS, 1-2 MARCH 2005)

(ADOPTED ON 12TH APRIL 2005)

PARTICIPANTS

Panel Members:
Arturo Anadón, Margarita Arboix Arzo, Georges Bories, Paul Brantom, Joaquim Brufau de Barberà, Andrew Chesson, Joop de Knecht, Gerhard Flachowsky, Anders Franklin, Jürgen Gropp, Anne-Katrine Haldorsen, Ingrid Halle, Alberto Mantovani, Kimmo Peltonen, Guido Rychen, Amadeu Soares, Pieter Wester and Wilhelm Windisch

Apologies
Pier Sandro Cocconcelli, Noël Dierick, Pascal Sanders

EFSA
Liisa Vahteristo, Claudia Roncancio, Jaume Galobart, Gloria López (scientific staff), Dominique Byron, Ana-Bera Barran (administrative staff)

European Commission
Taina Säteri (DG Health and Consumer Protection)

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1. WELCOME AND APOLOGIES FOR ABSENCE

The Chair opened the meeting and welcomed all the participants to the 18th Plenary meeting of the FEEDAP Panel.

Members not able to attend the meeting had sent their apologies (see under participants).

2. DECLARATIONS OF INTEREST

There were no specific interests declared.

3. ADOPTION OF THE AGENDA

The agenda was adopted.

4. ADOPTION OF THE DRAFT MINUTES OF THE 17TH PLENARY MEETING ON 25-26 January 2005

The minutes of the 17th Plenary meeting of the Scientific Panel held on 25-26 January 2005 were reviewed and adopted. The previously adopted minutes of the 16th plenary meeting were distributed to all the members.

5. GENERAL INFORMATION FROM EFSA

The scientific co-ordinator informed the Panel Members about the arrangements for the next Plenary to be held in Parma.

6. WORK PROGRAM

6.1. Discussion of the following scientific opinions

Kemzyme W Liquid for Laying Hens (EFSA-Q-2005-029)

The Rapporteur from the Working Group on Enzymes introduced the question and the draft opinion. EFSA is requested to assess the safety of this 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), to be used as a feed additive for laying hens. This product is intended for use in cereal-based diets for laying hens.

The discussion focussed on the tolerance study that the applicant presented in support of the application. The length of the study was shorter than that proposed in the SCAN opinion "Guidelines for the assessment of feed additives. Part II: Enzymes and Micro-organisms", which suggests a three-month experiment to demonstrate the tolerance for adult animals. However, the Panel agreed that, in this particular case, the available evidence, including the toxicological profile and target animal safety data for other animal categories, showed that the product would be tolerated. The opinion was adopted after minor editorial changes.

The Panel asks the Working Group on Enzymes to review the scientific evidence for the tolerance studies that would be necessary/recommended for the different animal species/categories and to report back to the Panel.

Porzyme 9100 'twice the concentration' for Piglets (EFSA-Q-2005-027)

The rapporteur from the Working Group on Enzymes introduced the draft opinion. EFSA is requested to assess the safety of this product for the piglets. The product was considered safe for piglets based on the results of the tolerance study with this target species.

After a short discussion the opinion was adopted, with minor editorial modifications.

Natugrain Wheat + for chickens for fattening (EFSA-Q-2004-068)

The Rapporteur from the Working Group on Enzymes introduced the question and the draft opinion. EFSA is requested to assess the safety of Natugrain Wheat+, a preparation of endo-1,4-β-xylanase, EC 3.2.1.8 for the consumer, the user, the environment and for the target species. This enzyme preparation is produced by a genetically modified strain of *Aspergillus niger*. The assessment of the genetic modification showed that the production strain of *Aspergillus niger* is expected to be as safe as the established industrial strain. The tolerance study reported showed that the product is well tolerated by chickens for fattening. The Panel

did not expect any negative effect on the user, consumer and the environment. The Rapporteur was asked to introduce some further details before submitting the final document to all the Panel members for adoption through written procedure.

L-Histidine for salmonids (EFSA-Q-2004-030)

The Rapporteur of the Working Group introduced the new draft opinion, modified to take account of the discussion from the last Plenary.

The discussion focused mainly on the appropriateness of using conventional toxicology studies for testing pure substances which are dietary nutrients and which have a physiological concentration that is optimum for health and performance. For this reason the Panel decided that for those substances where the purity is well established, with the source and method of production sufficiently well characterised (i.e. there is evidence that no toxic contaminants will be present in the product) there is no requirement for further toxicity data.

For those substances, where there are major impurities, or the source is poorly characterised some evidence of safety from toxicological studies will be required and the testing programme would need to be designed to cover all likely areas of potential consumer risk. In this case, the Panel was satisfied that the safety and the bioavailability of L-Histidine monohydrochloride monohydrate was adequately demonstrated and the opinion was adopted.

Maximum Residue Limits for Canthaxanthin (EFSA-Q-2003-113)

The Rapporteur of the Working Group on MRL for Canthaxanthin introduced the new modified draft opinion. EFSA is requested to make a proposal for the establishment of Maximum Residue Limits (MRLs) for canthaxanthin in eggs, poultry meat, trout and salmon resulting from the addition of canthaxanthin to feed intended respectively for laying hens, other poultry, salmon and trout on the basis of the relevant levels for inclusion in feed fixed in the legislation.

The new draft was discussed and further changes were proposed on the presentation of the data. It was observed that the shortness of data could pose problems for the assessment and a possibility of refinement for the exposure assessment taking into account human consumption data was discussed. The rapporteur will search and incorporate this new information to be discussed during the next plenary.

Safety of use of colouring agents in animal nutrition – red pigmenting carotenoids (Astaxanthin) (EFSA-Q-2003-060)

The Rapporteur of the Working Group on Carotenoids introduced the draft opinion. EFSA is asked to assess the safety of use of capsanthin (E160c), beta-apo-8'-carotenal (E160e), ethyl ester of beta-apo-8'carotenic acid (E160f), lutein (E161b), cryptoxanthin (E161c), zeaxanthin (E161h), citranaxanthin (E161i), astaxanthin (E161j) in feedingstuffs for laying hens, other poultry, salmon, trout, on the basis of currently available scientific literature. In making its assessment, EFSA is requested to prioritise the substances which may be used as alternatives to canthaxanthin.

The working group focus presented a draft document on the safety of astaxanthin. The main aim of this document was to introduce and confirm the approach taken for the assessment of the red colouring carotenoids, using asthaxanthin as a model. The Panel agreed on the approach and some changes were proposed. The rapporteur will inform the working group about the feedback in order to finalise the draft opinion on the red carotenoids.

Kemzyme W Dry for Laying Hens and Turkeys (EFSA-Q-2005-029)

Not discussed

6.2. Discussion on the approach for future guidelines – silage additives

Not discussed.

6.3. Progress on ongoing work

Not discussed.

7. NEW REQUESTS TO EFSA RECEIVED FROM THE EUROPEAN COMMISSION

7.1. Applications under Directive 70/524/EEC

Question on the safety of "Avizyme 1500" for turkeys for fattening (EFSA-Q-2005-026).

The Commission requests the European Food Safety Authority to deliver an opinion on the safety of the enzyme preparation "Avizyme 1500", which is a preparation of endo-1,4-beta-xylanase produced by *Trichoderma longibrachiatum* (ATCC 2105), endo-1,3(4)-beta-glucanase and alpha-amylase produced by *Bacillus amyloliquefaciens* (DSM 9553), subtilisin produced by *Bacillus subtilis* (ATCC 2107) and polygalacturonase produced by *Aspergillus aculeatus* (CBS 589.94) to be used as a feed additive for turkeys for fattening. The request will be dealt by the Working Group on Enzymes. The deadline proposed by the Commission for the assessment is June 2005.

Question on the safety of Porzyme 9100 'twice the concentration' for piglets (EFSA-Q-2005-027).

The Commission asks the European Food Safety Authority to issue an opinion on the safety of the enzyme preparation "Porzyme 9100", which is a 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), to be used as feed additive for piglets. This product has been assessed and the opinion adopted during the present Plenary meeting (see under 6.1).

Question on the safety of Kemzyme W Dry for laying hens and turkeys for fattening (EFSA-Q-2005-028).

EFSA is requested to deliver an opinion on the safety of the enzyme preparation "Kemzyme W dry", which is a 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), for the laying hens and turkeys for fattening. The request will be dealt by the Working Group on Enzymes. The deadline proposed by the Commission for the assessment is September 2005.

Question on the safety of the enzymatic product Kemzyme W Liquid for use as feed additive for laying hens (EFSA-Q-2005-029).

The Commission asks the European Food Safety Authority to deliver an opinion on the safety of the product "Kemzyme W Liquid", which is a 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), for the laying hens. This product has been assessed and the opinion adopted during the present Plenary meeting (see under 6.1).

Question on the safety and efficacy of the enzymatic product Phytase SP 1002 for use as feed additive for piglets, pigs for fattening, sows, chickens for fattening, turkeys and laying hens (EFSA-Q-2005-030).

The Commission asks the European Food Safety Authority to deliver an opinion on the safety of the enzyme preparation "Phytase SP 1002", which is a preparation of 3-phytase, EC 3.1.3.8, produced by *Hansenula polymorpha* (DSM 15087), for the target animals, the user, the consumer and the environment and on its efficacy. The request will be dealt by the Working Group on Enzymes with assistance from the GMO Panel or its members. The deadline proposed by the Commission for the assessment is September 2005.

7.2. Valid applications under Regulation (EC) 1831/2003

EFSA has finalised the completeness check for the application regarding the product Avatec 15% (lasalocid sodium). Modification of terms of authorization (EFSA-Q-2004-172). This application has been considered complete and valid by EFSA as of 14 February 2005. The assessment has been started following the nomination of the rapporteur.

7.3. New applications under Regulation (EC) 1831/2003

The Commission has forwarded to EFSA five applications of feed additives that seek authorization under Regulation (EC) No 1831/2003. Those applications are currently under validity/completeness check by EFSA.

- Vevovitall (Benzoic Acid) - Zootechnical additive for Weaned Piglets up to 35 kg (EFSA-Q-2005-007)
- Biomin IMB52 (*Enterococcus faecium* DSM 3530) - Zootechnical Additive for Chickens for Fattening (EFSA-Q-2005-020)
- *Bacillus cereus* var. *toyoi* NCIMB 40115/CNCM I-1012 - Modification of the Terms of Authorisation of a feed additive for chickens for fattening authorised under Directive 70/524/EEC (EFSA-Q-2005-021)
- Coxidin (Monensin Sodium) - Coccidiostat for Chickens for Fattening and Turkeys for Fattening (EFSA-Q-2005-024)
- Biosaf (*Saccharomyces cerevisiae* NCYC Sc 47) - Zootechnical additive for Horses (EFSA-Q-2005-025)

The new applications were presented to the panel for information. Preliminary discussion about the Working Groups and experts to be involved for the assessment of those product took place in the anticipation that these dossiers will likely be considered valid for the start of the scientific evaluation later on this spring.

8. MISCELLANEOUS

Results of the public consultation on the working document on the antibiotic resistance criteria used in the assessment of bacteria were provided to the panel members. Experts of the working group will consider the comments recieved and revise, where necessary, the draft opinion.