



MINUTES OF THE 17TH PLENARY MEETING OF THE SCIENTIFIC PANEL ON ADDITIVES AND PRODUCTS OR SUBSTANCES USED IN ANIMAL FEED (BRUSSELS, 25-26 JANUARY 2005)

ADOPTED ON 1ST MARCH 2005

PARTICIPANTS

Panel Members:

Arturo Anadón, Margarita Arboix Arzo, Georges Bories, Paul Brantom, Joaquim Brufau de Barberà, Andrew Chesson, Pier Sandro Cocconcelli, Joop de Knecht, Noël Dierick, Gerhard Flachowsky, Anders Franklin, Jürgen Gropp, Anne-Katrine Haldorsen (2nd day), Ingrid Halle, Kimmo Peltonen, Guido Rychen, Pascal Sanders, Pieter Wester and Wilhelm Windisch

Apologies

Anne-Katrine Haldorsen (1st day), Alberto Mantovani, Amadeu Soares

EFSA

Liisa Vahteristo, Claudia Roncancio, Jaume Galobart, Gloria López (scientific staff), Dominique Byron, Nathalie Conreur (administrative staff)

European Commission

Taina Säteri (1st day) (DG Health and Consumer Protection)

1. WELCOME AND APOLOGIES FOR ABSENCE

The Chair opened the meeting and welcomed all the participants to the 17th 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 slightly modified. The discussion of the draft opinions on Avizyme 1300 for ducks and Avizyme 1500 for laying hens were included in the agenda, and the discussion on the approach for future guidelines was removed from the agenda.

4. **ADOPTION OF THE DRAFT MINUTES OF THE 16TH PLENARY MEETING ON 8-9 December 2004**

The minutes of the 16th Plenary meeting of the Scientific Panel held on 8-9 December 2004 were reviewed. The minutes were adopted after the introduction of some minor editorial changes. The previously adopted minutes of the 15th plenary meeting were distributed to all the members.

5. **GENERAL INFORMATION FROM EFSA**

The Scientific Co-ordinator (SC) provided the Panel with information on several issues of interest to the Panel.

- Two new persons have joined the FEEDAP Team, Gloria López as Scientific Officer and Nathalie Conreur as an administrative support. Another person is joining soon in a short term basis to enhance the work with the Notifications.
- The Executive director of EFSA, Mr. G. Podger, has officially moved to Parma in January. Move of several work teams is currently underway. The FEEDAP secretariat is to move at the end of July.
- Industry has approached the FEEDAP secretariat on several issues, mostly linked to the requirements for efficacy under the new authorisation system, including categories and functional groups. A set of questions received from companies were distributed to the Panel members for discussion during the meeting.

6. **WORK PROGRAM**

6.1. **Discussion of the following scientific opinions**

Use of Iodine in Feedingstuffs (EFSA-Q-2003-058)

One member from the Working Group on Iodine introduced the new version of the draft opinion for discussion. EFSA is requested to evaluate the physiological requirements for iodine of the different animal species and to advise the Commission on the possible detrimental effects on human and animal health or the environment of iodine, when used at the current levels authorised under Directive 70/524/EC.

The discussion focused mainly on the different parts that were modified after the last Plenary discussion. The Panel concluded that with respect to animal safety the maximum dietary iodine levels should be limited below the current permitted levels under EU regulations for horses, laying hens, dogs and cats. The iodine tolerance of pigs and fish is far above the existing levels permitted. An upper safe level for dairy cows can not be determined, and no data is available for chickens for fattening, turkeys, rabbits, sheep and goats. Model calculations showed that reducing iodine to 4 mg kg⁻¹ for dairy cows and laying hens would result in a satisfactory margin of human consumers. The opinion was adopted with minor editorial changes.

Biomin BBSH 797 for piglets, pigs for fattening and chickens for fattening (EFSA-Q-2003-052)

The Rapporteur from the Working Group on Micro-organisms introduced the slightly modified version of the draft opinion for discussion. EFSA is requested to assess the safety of “Biomin BBSH 797” *Eubacterium* sp. DSM 11798 for the piglets, the pigs for fattening and the chickens for fattening, for the user, the consumer of animal products and the environment. This product is intended to be added to cereals contaminated with trichothecenes incorporated

into feed for animals to augment any existing detoxification capacity and so aid the protection of the target species. The safety for the target species was not fully demonstrated due to the experimental design. The Panel did not expect any negative effect on the user, consumer and the environment. Following the discussion, the opinion was adopted subject to some editorial changes.

BioCox 120G Update of Opinion (EFSA-Q-2004-156)

EFSA is requested to update the opinion on Biocox 120G adopted on 1st July 2004 taking into account the new data that has been provided by the Applicant. The Rapporteur of the Working Group introduced the draft opinion for discussion. The lack of genotoxic potential was now considered demonstrated and thus allowed the Panel to propose an Acceptable Daily Intake and Maximum Residue Limits. The Panel did not expect that salinomycin sodium is likely to pose a risk to the environment. After some editorial modifications the opinion was adopted by the Panel.

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

The Rapporteur of the Working Group introduced the draft opinion. EFSA is requested to issue an opinion on the safety for the target animals, the worker, the user, the consumer and the environment and the bioavailability of L-Histidine monohydrochloride monohydrate.

The panel reviewed the document in detail. The production strain and the degree of purity were considered as important determinants for the safety assessment. The discussion was broadened to the principle of a possible common approach for the toxicological assessment of chemically defined nutrients/endogenous metabolites that would consider the fact that these substances interfere metabolically with the experimental test systems used for their toxicological evaluation. The assessment should take into consideration only the accompanying impurities (intermediary chemicals of the synthesis, degradation products, side-products from the fermentation process), and possibly these requirements could be modulated on a case by case basis.

The document was referred back to the Working Group and the toxicologist of the Panel for finalisation and consequent presentation in the next Plenary.

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

The Rapporteur of the Working Group on MRL for Canthaxanthin introduced the draft. 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.

A first discussion on the approach taken in the working group was presented and discussed. After further refinement into the working group, the document could be presented during the next plenary.

Avizyme 1500 for Laying Hens (EFSA-Q-2005-008)

The Rapporteur of the Working Group on Enzymes introduced the draft opinion. EFSA is requested to assess the safety of this product for the laying hens. From the tolerance study provided by the notifier, the safety of Avizyme 1500 for the laying hens has been demonstrated.

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

Avizyme 1300 for Ducks (EFSA-Q-2005-009)

The Rapporteur of the Working Group on Enzymes introduced the draft opinion. EFSA is requested to assess the safety of this product for the ducks. The results of the tolerance study with ducks showed that this product is safe for this target species.

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

6.2. Progress reports on ongoing work

Not discussed.

6.3. Self Tasks - Progress made

- Self Task on Antimicrobial Resistance Criteria.

The document on criteria used in the assessment of bacteria for resistance to antibiotics of human or veterinary importance was placed on the EFSA website for public consultation. The deadline to submit comments ends on February 28.

- Self Task on Environmental Risk Assessment of additives, products and substances in animal feed.

The Chair of the Working Group described in short the progress and status of the self-task after the first two meetings, which have been discussing on the possible use of the FOCUS models for the assessment of feed additives. New experts will be invited to address the second part of the mandate of this Working Group.

- Self Task on Herbal Products.

The proposed self-task to prepare a background paper on the known biological effects of plant/herbal products and their constituents on livestock, and to make recommendations for follow-up work has been accepted by EFSA in December. The corresponding letter from Mr. Koëter was distributed to the members of the Panel. The initial discussion on how to proceed with this self-task took place and it was considered that at least a year would be needed for completion of this task.

7. NEW REQUESTS TO EFSA RECEIVED FROM THE EUROPEAN COMMISSION – AS APPLICATIONS UNDER DIRECTIVE 70/524/EEC

Question on the safety of “Reuteri”: preparation of *Lactobacillus reuteri* ATCC 55148, for chickens for fattening (EFSA-Q-2004-167).

The Commission requests the European Food Safety Authority to deliver an opinion on the safety of the micro-organism product "Reuteri", which is a preparation of *Lactobacillus reuteri* ATCC 55148, for the consumer, for the target animals (chickens for fattening), the user of the product and the environment. The request will be dealt by the Working Group on Micro-organisms. The deadline proposed by the Commission for the assessment is June 2005.

Question on the safety of BioProtein regarding effects on certain health parameters (EFSA-Q-2004-171).

The Commission asks the European Food Safety Authority to issue an opinion on the effects of BioProtein on health parameters (changes in white blood cell counts, lymph node weights, spleen and liver changes, histology changes, body weight depression). The assessment will be drafted by a new Working Group. The deadline proposed by the Commission for the assessment is June 2005.

Question on the safety of "Biacton" for chickens for fattening, turkeys and laying hens (EFSA-Q-2004-177).

EFSA is requested by the Commission to deliver an opinion on the safety of the micro-organism product "Biacton", which is a preparation of *Lactobacillus farciminis* CNCM MA 67/4R, for the target animals. The request will be dealt by the Working Group on Micro-organisms. The deadline proposed by the Commission for the assessment is June 2005.

Question on the safety of the enzymatic product Avizyme 1500 for use as feed additive for laying hens (EFSA-Q-2005-008).

The Commission asks 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), for the laying hens. This product has been assessed in the meanwhile and the opinion was adopted in the present Plenary meeting (see under 6.1).

Question on the safety of the enzymatic product Avizyme 1300 for use as feed additive for ducks (EFSA-Q-2005-009).

The Commission asks the European Food Safety Authority to deliver an opinion on the safety of the enzyme preparation "Avizyme 1300", which is a preparation of endo-1,4-beta-xylanase produced by *Trichoderma longibrachiatum* (ATCC 2105) and subtilisin produced by *Bacillus subtilis* (ATCC 2107), for the target animals ducks. This product has been assessed in the meanwhile and the opinion was adopted in the present Plenary meeting (see under 6.1).

Question on the safety of the enzymatic product Econase Wheat Plus for use as feed additive for chickens for fattening (EFSA-Q-2005-010).

The Commission asks the European Food Safety Authority to deliver an opinion on the safety of the enzyme preparation "Econase Wheat Plus L and P", which is a preparation of endo-1,4-beta-xylanase (IUB 3.2.1.8) from *Trichoderma reesei* CBS 529.94 and endo-1,3(4)-beta-glucanase (IUB 3.2.1.6) from *Trichoderma reesei* CBS 526.94, for the chickens for fattening. The request will be dealt by the Working Group on Enzymes. The deadline proposed by the Commission for the assessment is April 2005.

Question on the safety of the enzymatic product Roxazyme® G2 (liquid and granular) for use as feed additive for ducks (EFSA-Q-2005-011).

The Commission asks the European Food Safety Authority to deliver an opinion on the safety of the enzyme product "Roxazyme G2", which is a preparation of endo-1,4-beta-glucanase, endo-1,3(4)-beta-glucanase and endo-1,4-beta-xylanase produced from *Tricoderma*

longibranchiatum (ATCC 74 252), for the target animals ducks. The request will be dealt by the Working Group on Enzymes. The deadline proposed by the Commission for the assessment is April 2005.

8. MISCELLANEOUS

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 check by EFSA.

- Avatec 15%. Modification of terms of authorization (EFSA-Q-2004-172).
- FormiTM LHS for weaned piglets and pigs for fattening (EFSA-Q-2004-173).
- Bioplus 2B (*Bacillus licheniformis* DSM 749 and *Bacillus subtilis* DSM 5750). Modification of annex entries of Directive 70/527/EEC (EFSA-Q-2004-174).
- Amaferm for dairy cows and beef cattle in growing finishing stage (EFSA-Q-2004-175).
- Rosemary extract liquid of natural origin for pets (EFSA-Q-2004-176).