



MINUTES OF THE 20TH PLENARY MEETING OF THE SCIENTIFIC PANEL ON ADDITIVES AND PRODUCTS OR SUBSTANCES USED IN ANIMAL FEED

(BRUSSELS, 25-26 MAY 2005)

ADOPTED ON 15 JUNE 2005

PARTICIPANTS

Panel Members:

Arturo Anadón, Georges Bories, Paul Brantom, Joaquim Brufau de Barberà, Andrew Chesson, Pier Sandro Cocconcelli, Noël Dierick, Gerhard Flachowsky, Anders Franklin, Jürgen Gropp, Ingrid Halle, Alberto Mantovani, Kimmo Peltonen, Guido Rychen, Pascal Sanders, Amadeu Soares and Wilhelm Windisch

Apologies

Margarita Arboix Arzo, Joop de Knecht, Anne-Katrine Lundebye Haldorsen and Pieter Wester

EFSA

Liisa Vahteristo, Claudia Roncancio, Jaume Galobart, Lucilla Gregoretti (scientific staff), Dominique Byron (administrative staff)

European Commission

Taina Säteri and Miguel Ángel Granero (2nd day) (DG Health and Consumer Protection)

1. WELCOME AND APOLOGIES FOR ABSENCE

The Chair opened the meeting and welcomed all the participants to the 20th 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 after the item on Bioprotein was removed.

4. ADOPTION OF THE DRAFT MINUTES OF THE 19TH PLENARY MEETING ON 12-14 April 2005

The minutes of the 19th Plenary meeting of the Scientific Panel held on 12-14 April 2005 were reviewed and adopted. The previously adopted minutes of the 18th plenary meeting were distributed to all the members.

5. GENERAL INFORMATION FROM EFSA

- Regarding the EFSA review the panel was informed that all the Chairs of the panels would be approached by the contractor chosen for the review.
- The Scientific Coordinator informed that the direct flight of Club Air between Brussels and Parma has been suspended, at least until October. On the other hand, other possibilities to improve the connections from Milan airports are under consideration.
- The move of the FEEDAP Secretariat to Parma is scheduled for 22 July 2005.
- EFSA official inauguration in Parma will be on 21 June.
- The first report from the Community Reference Laboratory regarding the methods of analysis for lasalocid sodium (Application under Regulation (EC) No 1831/2003) has been received by EFSA.
- The Scientific Coordinator informed that a page has been created on the EFSA website to host the information of the different applications received under Regulation (EC) No 1831/2003, including the summary of the dossier. This page can be reached at http://www.efsa.eu.int/science/feedap/an_applications/catindex_en.html.

6. WORK PROGRAM

6.1. Discussion and possible adoption of the following scientific opinions

- **Safety and efficacy of Hy•D (calcifediol) for chickens for fattening, turkeys and laying hens (EFSA-Q-2004-065)**

The Rapporteur of the Working Group (WG) introduced the new draft document, making special emphasis on the changes suggested by the members of the Panel in the previous meeting.

After an in-depth discussion on the approach taken for the evaluation of the safety for the consumer, the opinion was adopted by the Panel following some proposed editorial changes.

- **Safety and efficacy of Farmatan (tannin extract) for rabbits and piglets (EFSA-Q-2004-149)**

EFSA is requested to issue an opinion on the safety and the efficacy of this product, based on tannin, as a growth promoter intended for the target species piglets and rabbits for fattening. The Rapporteur of the Working Group (WG) introduced the question and the draft opinion. Each section of the document was discussed in detail. The panel had reservations regarding the efficacy and safety of the product based on the data provided by the applicant. This opinion was adopted after introducing minor editorial modifications.

- **Update on the criteria used in the assessment of bacteria for resistance to antibiotics of human or veterinary importance (EFSA-Q-2004-079)**

The Rapporteur of the WG informed the Panel that a new draft was prepared taking into account suggestions and/or comments received during the public consultation of this document. The public consultation lasted for two and a half months and was available on the website of EFSA for all interested parties.

Contributions were received from Universities, National Institutes/Centres, National Authorities, Scientific Societies, European Institutions and the Industry. Comments received could be classified into three groups:

- Definition and/or mechanisms of intrinsic *vs.* acquired resistance
- Methods for detection of MIC (Minimum Inhibitory Concentration) determination and
- Additional information on the microbiological breakpoints.

The Panel reviewed the revised document and after few editorial changes the opinion was adopted by the Panel.

- **Safety of the enzyme preparation Roxazyme G2 for ducks (EFSA-Q-2005-011)**

Not discussed due to lack of time.

- **Safety of the enzyme preparation Econase Wheat Plus for chickens for fattening (EFSA-Q-2005-010)**

Not discussed due to lack of time.

6.2. Discussion on the guidelines for silage additives (EFSA-Q-2004-088)

EFSA has been requested to give technical assistance to the Commission by producing a guideline regarding the safety and the efficacy of the silage additives. The Rapporteur of the Working Group on silage additives introduced the draft document.

The Panel reviewed the document and some modifications were introduced. The document was approved by the panel to be presented for public consultation. This consultation will be open for all and will be published on the EFSA website.

6.3. Discussion on tolerance studies for enzymes

The Working Group on Enzymes was requested by the Panel to review the scientific evidence for the tolerance studies that would be necessary/recommended for the different animal species/categories, in particular regarding the length of the studies for different target species and the necessary end-points. The Rapporteur from the Working Group on Enzymes presented the draft document. After discussion it was agreed to extend the scope of the document to cover not only enzyme preparations but also micro-organism products. Few members from the Working Group on Enzymes and the Working Group on Micro-organisms were identified as being in charge to address this issue and to draft a document for further discussion.

6.4. Progress reports 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 and efficacy of the enzyme preparation Phyzyme XP for chickens for fattening (EFSA-Q-2005-063)**

The Commission asks the European Food Safety Authority to deliver an opinion on the efficacy and the safety of the enzyme preparation of trade name "Phyzyme XP", a preparation of 6-phytase produced by *Schizosaccharomyces pombe* (ATCC 38399), for the consumer, the user, the workers and for the target animal category chickens for fattening and for the environment. The request will be dealt by the Working Group on Enzymes. The deadline proposed by the Commission is October 2005.

- **Question on the safety of the enzyme preparation Avizyme 1500 for ducks (EFSA-Q-2005-064)**

EFSA is requested to deliver an opinion on the safety of the enzyme preparation of trade name 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), polygalacturonase produced by *Aspergillus aculeatus* (CBS 589.94), for the target animal category ducks. The request will be dealt by the Working Group on Enzymes. The deadline proposed by the Commission is September 2005.

- **Question on the safety of the enzyme preparation Bio Feed Combi for chickens for fattening and piglets (EFSA-Q-2005-065)**

The Commission asks the European Food Safety Authority to deliver an opinion on the safety of the enzyme preparation of trade name Bio Feed Combi, which is a preparation of endo-1,3(4)-beta-glucanase produced by *Aspergillus aculeatus* (CBS 589.94) and xylanase produced by *Aspergillus oryzae* (DSM 10287), for the consumer, the user, the worker, for the target animal categories chickens for fattening and piglets, and for the environment. The request will be dealt by the Working Group on Enzymes. The deadline proposed by the Commission is October 2005.

- **Question on the safety of the enzyme preparation Bio-Feed Wheat for pigs for fattening and ducks for fattening (EFSA-Q-2005-066)**

The Commission asks the European Food Safety Authority to deliver an opinion on the safety of the enzyme preparation of trade name Bio-Feed Wheat, enzyme E 1607, which is a preparation of endo-1,4-beta-xylanase produced by *Aspergillus oryzae* (DSM 10287), for the target animal categories pigs for fattening and ducks for fattening. The deadline proposed by the Commission is September 2005. The Working Group on Enzymes is dealing with this request. Currently a request for more information has been sent to the applicant via the Member State Rapporteur.

- **Question on the safety of the new granulate formulation of the enzyme preparation Grindazym GP for chickens for fattening, turkeys for fattening and piglets (EFSA-Q-2005-067)**

The Commission asks the European Food Safety Authority to deliver an opinion on the safety of the new granulate form of the enzyme preparation of trade name Grindazym GP, enzyme E 1609, which is a preparation of endo-1,4-beta-xylanase and endo-1,4-beta-glucanase produced by *Aspergillus niger* (CBS 600.94), for the consumer, the user, the worker, for the target animal categories chickens for fattening, turkeys for fattening and piglets, and the environment.

- **Question on the safety of the enzyme preparation Grindazym GP for ducks for fattening (EFSA-Q-2005-068)**

The Commission asks the European Food Safety Authority to deliver an opinion on the safety of this enzyme preparation for the target species ducks for fattening. These last two questions will be addressed together by the Working Group on Enzymes. The deadline proposed by the Commission for the assessment is September 2005.

7.2. Valid applications under Regulation (EC) No 1831/2003

Applications considered valid for the start of the assessment:

- **Formi LHS (Potassium Diformate) (EFSA-Q-2004-173)**

The application and the particulars related to the question on Formi LHS for weaned piglets and pigs for fattening have been considered complete by EFSA since the 4th of May 2005.

The safety and efficacy of the product will need to be addressed as foreseen in Regulation (EC) No 1831/2003. A new WG has been established.

- **Amaferm (Extract of *Aspergillus oryzae*) (EFSA-Q-2004-175)**

The application and the particulars related to the question on Amaferm for dairy cows and beef cattle in growing-finishing stage have been considered complete by EFSA since the 20th of May 2005.

The safety and efficacy of the product will need to be addressed as foreseen in Regulation (EC) No 1831/2003. A new WG has been established, and the first meeting will take place at the beginning of June.

- **Biomin IMB 52 (*Enterococcus faecium* DSM 350) (EFSA-Q-2005-020)**

The application and the particulars related to the question on Biomin IMB 52 (*Enterococcus faecium* DSM 350) for chickens for fattening have been considered complete by EFSA since the 27th of April 2005.

The safety and efficacy of the product will need to be addressed as foreseen in Regulation (EC) No 1831/2003. The WG on Micro-organisms is dealing with this submission.

- **Toyocerin (*Bacillus cereus* var. *toyoi* NCIM 40112/CNCM I-1012) (EFSA-Q-2005-021)**

The application and the particulars related to the question on Toyocerin (*Bacillus cereus* var. *toyoi* NCIM 40112/CNCM I-1012) extension of use in chickens for fattening in feedingstuffs containing coccidiostats have been considered complete by EFSA since the 4th of May 2005. In particular the request is to assess the compatibility of the micro-organism product with the coccidiostats diclazuril, narasin-nicarbazin and maduramicin ammonium in

feed for chickens for fattening. The WG on Micro-organisms is dealing with this submission.

- **Coxidin (Monensin Sodium) (EFSA-Q-2005-024)**

The application and the particulars related to the question on Coxidin (Monensin sodium) for chickens for fattening and turkeys for fattening have been considered complete by EFSA since the 20th of April 2005.

The safety and efficacy of the product will need to be addressed as foreseen in Regulation (EC) No 1831/2003. A new WG has been established and the first meeting of this WG was held on 20th May, 2005.

- **Biosaf Sc 47 (*Saccharomyces cerevisiae* NCYC Sc 47) (EFSA-Q-2005-051)**

The application and the particulars related to the question on Biosaf Sc 47 (*Saccharomyces cerevisiae* NCYC Sc 47) for horses have been considered complete by EFSA since the 4th of May 2005.

The safety and efficacy of the product will need to be addressed as foreseen in Regulation (EC) No 1831/2003. The WG on Micro-organisms is dealing with this submission.

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

The Commission has forwarded to EFSA one new application of a feed additive seeking authorisation under Regulation (EC) No 1831/2003 since the last plenary meeting. This application is currently being checked for completeness:

- **Sel-Plex (Selenized yeast – selenium organic form) by *Saccharomyces cerevisiae* (CNCM I-3060) for dairy cows, calves, cattle for fattening, poultry and pigs (EFSA-Q-2005-071)**

Short discussion took place in order to provisionally identify any experts who could be involved in the assessment of this product once the application is considered complete for the start of the assessment.

8. FEEDBACK FROM THE SCIENTIFIC COMMITTEE HELD ON 14-15 APRIL 2005-06-14

The Chair of the Panel informed the other Panel Members about the outcome of some of the discussions in brief.

9. MISCELLANEOUS

EFSA is expecting a new task from the Commission on undesirable substances in animal feed on some persistent organic pollutants. The scientific coordinator invited the panel members to be involved in the identification of possible members to this working group of the Panel on contaminants in the food chain.