MINUTES OF THE 23RD PLENARY MEETING OF THE SCIENTIFIC PANEL ON ADDITIVES AND PRODUCTS OR SUBSTANCES USED IN ANIMAL FEED

(BRUSSELS, 21-22 SEPTEMBER 2005)

(ADOPTED ON 19 OCTOBER 2005)

PARTICIPANTS

Panel Members:
Arturo Anadón (2nd day), Georges Bories, Paul Brantom, Joaquim Brufau de Barberà, Andrew Chesson, Pier Sandro Cocconcelli, Joop de Knecht, Noël Dierick (1st day), Gerhard Flachowsky, Anders Franklin, Jürgen Gropp, Anne-Katrine Lundebye Haldorsen (1st day), Ingrid Halle, Kimmo Peltonen, Guido Rychen, Pieter Wester, Wilhelm Windisch

Apologies
Arturo Anadón (1st day), Margarita Arboix Arzo, Noël Dierick (2nd day), Anne-Katrine Lundebye Haldorsen (2nd day), Alberto Mantovani, Pascal Sanders, Amadeu Soares

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

European Commission
Rosella Brozzi Bettio, Willem Penning (1st day), Rui Cavaleiro (1st day) and Marta Ponghellini (1st day) (DG Health and Consumer Protection), Christoph Von Holst (2nd day) (DG JRC, Community Reference Laboratory Feed Additives Authorisation)

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1. WELCOME AND APOLOGIES FOR ABSENCE

The Chair opened the meeting and welcomed all the participants to the 23rd Plenary meeting of the FEEDAP Panel. This is the last Plenary meeting of the FEEDAP Panel that is held in the Brussels premises.

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

2. DECLARATIONS OF INTEREST

Dr. Brufau informed that his institute has been involved in several experiments related to the product Phytase SP 1002, and he therefore withdrew from related discussions.

3. ADOPTION OF THE AGENDA

The agenda was adopted.

4. ADOPTION OF THE DRAFT MINUTES OF THE 22ND PLENARY MEETING ON 6-7 July 2005

The minutes of the 22nd plenary meeting of the Scientific Panel held on 6-7 July 2005 were reviewed and adopted. The previously adopted minutes of the 21st plenary meeting were distributed to all the members.

5. GENERAL INFORMATION FROM EFSA

- The Scientific Co-ordinator (SC) informed the Panel about the resignation of the Executive Director of EFSA, Mr. Geoffrey Podger, who will be taking up a new post as Chief Executive of the British Health and Safety Executive. The management Board agreed to nominate the Deputy Executive Director and Director of Science, Dr. Herman Koëter as acting Executive Director, until the new Executive Director is nominated. The tasks of the Deputy Executive Director will be delegated to other staff for this interim period. It is expected that the new Executive Director will be nominated early next year following the call for expressions of interest published on 30 August in the Official Journal of the EU.
- The SC also informed the Panel about several calls for expressions of interest for recruitment of scientific staff for several panel secretariats, including FEEDAP, and suggested to distribute this information for any interested parties.
- The panel members were reminded about the request for the Member States to nominate competent organisations in the fields of EFSA's mission for a scientific network according to Article 36 of Regulation 178/2002 and Commission Regulation 2230/2004. Letter informing about this has been sent to all Panel members, and a wide distribution of this request is desirable .
- The deadline for the consultation on the working document "Assessing the safety and efficacy of silage additives" has been extended until 21st September.
- The first preparations for the launch of the call for experts for the scientific committee and panels of EFSA have been started as the first three year term is coming to a close in next April. The SC promised to keep the Panel informed about the developments and the eventual publication of the call.

6. WORK PROGRAM

6.1. Discussion and possible adoption of the following scientific opinions

- **Safety of the enzyme preparation Finase for laying hens (EFSA-Q-2005-114)**

  A member of the working group (WG) on Enzymes introduced the draft document. EFSA is requested to deliver an opinion on the safety of this enzyme preparation of 3-phytase produced by *Trichoderma reesei* (CBS 528.94) for the laying hens. EFSA already issued an opinion on this product in 27 January 2004, in which, based on the data presented no conclusions on the safety for laying hens could be drawn. The applicant has now provided new data. After carefully reviewing the document, the FEEDAP Panel concluded that the use of Finase is safe for the laying hens. This opinion was adopted after some minor editorial changes.

- **Safety of the enzyme preparation Kemzyme W Dry for laying hens and turkeys for fattening (EFSA-Q-2005-028)**

  A member of the WG on Enzymes introduced the draft document. EFSA is requested to deliver an opinion on the safety of this product, 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.

Discussion on the draft opinion focused mainly on the tolerance data presented for laying hens. The experiment lasted only 28 days, and the Panel considers that this duration is not sufficient to demonstrate the safety of this preparation for the laying hens. Therefore the members of the Panel concluded that the safety for the laying hens cannot be assessed with the data presented. On the other hand, the tolerance study presented for turkeys for fattening demonstrated that the product was safe for this target species. The opinion was adopted after introducing some editorial changes.

- **Safety and efficacy of the enzyme preparation Phytase SP 1002 for piglets, pigs for fattening, sows, chickens for fattening, turkeys and laying hens (EFSA-Q-2005-030)**

  EFSA is requested 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 the efficacy. This enzyme preparation is produced by a genetically modified micro-organism (GMM), and the safety aspects of the genetic modification are being assessed by the GMO Panel of EFSA. Therefore, this opinion will be co-adopted by both Panels. SC informed the Panel that some clarification from the Applicant will be requested to allow full assessment of the safety of the product to be made.

  The draft opinion was tabled but due to lack of time it was not discussed besides some details in the section on user safety where the WG invited the Panel for some discussion.

- **Modification of terms of authorisation of the micro-organism product *Bacillus licheniformis* (DSM 5749) and *Bacillus subtilis* (DSM 5750) (BioPlus 2B) (EFSA-Q-2004-174)**

  The Rapporteur of the WG on Micro-organisms introduced the draft document. This question refers to an application under Article 4(1) of Regulation (EC) No 1831/2003. The applicant is seeking to modify the Annex entry of Directive 70/524/EEC to allow the use of the product BioPlus 2B in pig feed containing the growth promoter potassium diformate (Formi LHS) and in turkey feed containing the coccidiostat lasalocid sodium (Avatec 15%). The draft opinion was reviewed in detail. The Panel concluded that the experiments conducted did not allow reaching a conclusion on the compatibility of BioPlus 2B with either potassium diformate or lasalocid A sodium. The opinion was adopted after some editorial modifications.

6.2. Discussion on the draft opinion

- **Safety and efficacy of the coccidiostat Coxidin (EFSA-Q-2005-024)**

  This question refers to an application under Article 4(1) of Regulation (EC) No 1831/2003. The applicant is seeking authorisation of the product Coxidin®, a coccidiostat consisting of monensin sodium, to be used as a feed additive for chickens for fattening and turkeys for fattening. Therefore, EFSA shall deliver an opinion on the safety for the target animals, consumer, user, and the environment, and on the efficacy of this product.

  The Rapporteur of the WG introduced the draft document regarding sections where some lacks in the available dataset were identified. The working group could not conclude on the

safety of the product and after discussion during the meeting it was decided to request to the applicant for additional information and further clarification on some of the findings presented in the safety section.

According to the provisions of Article 8 of Regulation (EC) 1831/2003 when supplementary information is requested, the Authority will extend the time limit, after consultation with the Applicant.

6.3. Discussion on the draft implementing rules and guidelines/guidance for authorisation of additives for use in animal nutrition

Following the discussions during the last Plenary meeting, a WG on Guidelines was set to prepare a document which will include the comments and/or suggestions of the FEEDAP Panel on the consultation of the draft prepared by the European Commission on the "Implementing rules and specific guidelines for the authorisation of feed additives (Article 7 of Regulation 1831/2003).

In the meanwhile EFSA has received some comments from different stakeholders to the Commission document under consultation and also a small technical hearing was organised in August between industry association (FEFANA) and some members of the FEEDAP Panel.

The WG on Guidelines presented a draft document with the general guidelines for the assessment of additives for use in animal nutrition. The document was reviewed by the Panel, and some modifications were introduced in it. This document gives the general principles that are required by the Risk Manager for the assessment of additives to be used in animal nutrition.

The Chairman presented to the Commission representatives the approach of the Panel. The FEEDAP Panel and EFSA strongly support the structure of two sets of documents, namely guidelines and guidance(s). The guidelines would detail the requirements of the risk manager, setting the appropriate targets for the risk assessor. The guidance(s) would be the description of the requirements of the risk assessor. This approach would be in line with the spirit of Regulation (EC) No 178/2002 on Food law, which clearly separates risk assessment and risk management. Therefore the proposal from FEEDAP Panel and EFSA is to have a Commission Regulation with the implementing rules and three annexes containing the application form, the guidelines detailing the principles for the risk assessment and the third annex containing the definition of animal categories. On the other side, EFSA would propose a General (Common) Guidance with all the details on how to perform the risk assessment, and a set of specific guidance(s) for different categories/functional groups of feed additives as defined under Regulation (EC) No 1831/2003 (including also, extrapolation to minor species, requirements for additives already authorised in food, etc). This approach would offer flexibility to adapt the requirements of the assessment to the most recent scientific knowledge and appreciate the role of the risk assessor in defining its requirements for its assessment.

The Commission Representative expressed the concerns from the Commission. The first concern is that the final document(s) has to be a complete document when it enters into force, since at that moment the currently applicable guidelines (Annex to Directive 87/153/EEC) will be repealed. Therefore, the guidelines/guidance(s) adopted have to be at least as complete as the current guidelines. The second concern expressed was that the industry needs to have a stable framework in order to prepare a dossier.

Some members of the Panel explained that the current guidelines are only covering chemically defined substances (but not all, since Regulation (EC) No 1831/2003 introduced as feed additives e.g. amino-acids, for which there are no specific guidelines). Regarding the industry concerns on frequent changes, the Chairman acknowledged those concerns, but also

stressed that no "unnecessary" changes would be introduced, and that a mechanism to limit the rate of changes should be introduced in the guidelines in order to avoid too frequent modifications.

Some discussion took place in specific points of the guidelines.

Regarding the time frame for the development of the final documents, the Commission Representative said that Regulation (EC) No 1831/2003 does not fix any time limit to adopt the new guidelines and that in the meantime there is the Annex to Directive 87/153/EEC, the SCAN opinion on enzymes and micro-organisms and the FEEDAP draft proposal on the assessment of efficacy and safety of silage additives. The Chairman concluded that by the end of October, the FEEDAP Panel would have ready the comments on the Implementing rules and Annex I, and also a version for Annex II (general guidelines) and Annex III (animal categories definition). The General Guidance and one example of the specific guidance for one category of feed additive could eventually be ready by the end of the year, but that specific guidance(s) for some categories of feed additives (e.g. flavouring compounds) would take longer to be developed. At the same time, the Chairman asked the Commission for advice in which categories there is more need by the Commission to develop the specific guidance(s).

6.4. Progress reports on ongoing work

- A Restricted Call for Tender on the "Assessment of plants/herbs, plant herb extracts and their naturally or synthetically produced components as additives for use in animal nutrition" has been used by EFSA to identify a contractor to aid in the previously accepted selftask of the FEEDAP Panel in this field. The contract is due to be signed in the near future. The objective of this background study is to identify and highlight particular issues of importance in the risk assessment for this type of substances.

  Based on the results and recommendations of this study, EFSA, in consultation with different stakeholders, will produce guidance to companies seeking for authorisation for plant/herbal products and their constituents as feed additives.

7. NEW REQUESTS TO EFSA RECEIVED FROM THE EUROPEAN COMMISSION

7.1. New applications under Regulation (EC) No 1831/2003

The Commission has forwarded to EFSA seven new applications of feed additives seeking authorisation under Regulation (EC) No 1831/2003 since the last plenary meeting. These applications are currently being checked for completeness:

- **Biosaf Sc47. Zootechnical Additive for lambs (*Saccharomyces cerevisiae* NCYC Sc47) (EFSA-Q-2005-149)**
- **Calsporin (*Bacillus subtilis* C-3102). Zootechnical Additive for Chickens for fattening (EFSA-Q-2005-150)**
- **Colicure. (*Escherichia coli* E-101-88, LMG S-17146). Zootechnical Additive for horses (EFSA-Q-2005-167)**
- **Elancoban G200, 200, G100, 100, ELANCOGRAN 100. (Monensin Sodium A and B). Coccidiostat for calves for rearing and cattle for fattening (EFSA-Q-2005-168)**
- **Levucell SC20/Levucell SC10ME. (*Saccharomyces cerevisiae* CNCM I-1077). Zootechnical Additive for dairy goats and dairy ewes (EFSA-Q-2005-176)**
- **Biogalactosidase (α-Galactosidase). Zootechnical Additive for pigs for fattening (EFSA-Q-2005-224)**

- ***Haematococcus algae*** **meal (NatuRose, Natural Astaxanthin). Sensory Additive for salmon and trout (EFSA-Q-2005-225)**

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

Applications considered valid for the start of the assessment:

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

  The application and the particulars related to the question on Sel-Plex (Selenized yeast – selenium organic form) by *Saccaromyces cerevisiae* (CNCM I-3060) for dairy cows, calves, cattle for fattening, poultry and pigs have been considered complete by EFSA since the 8th of September 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 to deal with the evaluation of this submission.

- **Belfeed B 1100MP/ML for ducks for fattening (EFSA-Q-2005-080)**

  The application and the particulars related to the question on Belfeed B 1100MP/ML for ducks for fattening have been considered complete by EFSA since the 20th of September 2005.

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

- **Selenium enriched yeast (*Saccharomyces cerevisiae*) (Alkosel/Selsaf) (EFSA-Q-2005-117)**

  The application and the particulars related to the question on Selenium enriched yeast (Saccharomyces cerevisiae) (Alkosel/Selsaf) have been considered complete by EFSA since the 12th of September 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 to deal with this submission.

8. FEEDBACK FROM THE SCIENTIFIC COMMITTEE HELD ON 15-16 SEPTEMBER 2005

Discussed briefly under agenda item 5.

9. MISCELLANEOUS

- The following dates were agreed for plenary meetings until the end of the mandate of the current Panel: 25-26 January, 8-9 March and 19-20 April.
- A representative of the Community Reference Laboratory (CRL) for feed additives authorisation was present during the second day of the meeting and gave a short presentation on the evaluation of the methods of control of the feed additives according to Regulation (EC) No 1831/2003. Some discussion took place with regards on the tasks of the CRL and their suitability for FEEDAP assessment.
- Some panel members expressed dissatisfaction to the rate the meeting reimbursements are done. As a response the SC gave an update of the status related to pending plenary and

working group reimbursements and she also promised to forward these messages to the relevant persons in EFSA in order to improve the situation in the long term.

- The panel members were informed about two new requests to EFSA received from the European Commission on some botanical impurities (undesirable substances) and on cross-contamination of non target feedingstuffs by coccidiostats authorised for use as feed additive. Both questions are dealt by the CONTAM Panel and the SC invited the members to propose experts to take part in those tasks once the requests are formally accepted. These names will be forwarded to the SC of the CONTAM Panel.
- EFSA has received a request from the European Commission requesting to review scientific data on various aspects of iodine in animal nutrition, following the opinion of the FEEDAP Panel issued on 25th January 2005. Once the formal terms of reference have been agreed upon, the Panel will be informed and involved.