MINUTES OF THE 40TH PLENARY MEETING

OF THE SCIENTIFIC PANEL ON ADDITIVES AND PRODUCTS OR SUBSTANCES USED IN ANIMAL FEED

(PARMA, 12-14 JUNE 2007)

(ADOPTED ON 10 JULY 2007)

PARTICIPANTS

Panel Members

Georges Bories, Paul Brantom, Joaquim Brufau de Barberà, Andrew Chesson, Pier Sandro Cocconcelli, Joop de Knecht (3rd day), Noël Dierick, Anders Franklin, Jürgen Gropp, Ingrid Halle, Christer Hogstrand, Lubomir Leng, Anne Katrine Lundebye-Haldorsen, Alberto Mantovani (2nd and 3rd day), Miklós Mézes, Carlo Stefano Nebbia (1st and 2nd day), Walter Rambeck, Atte von Wright, Pieter Wester (1st and 2nd day).

Apologies

Joop de Knecht (1st and 2nd day), Bogdan Debski, Alberto Mantovani (1st day), Carlo Stefano Nebbia (3rd day), Guido Rychen, Pieter Wester (3rd day)

EFSA

Claudia Roncancio-Peña, Jaume Galobart, Lucilla Gregoretti (scientific staff), Caroline Baltus, Ketty Antonelli (administrative staff)

European Commission

Marta Ponghellini, Taina Säteri (1st and 2nd day) (DG SANCO), Christoph von Holst (2nd and 3rd day) (DG Joint Research Centre)

---

1. WELCOME AND APOLOGIES FOR ABSENCE

The Chair opened the meeting and welcomed the participants to the 40th Plenary meeting of the FEEDAP Panel.

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

2. ADOPTION OF THE AGENDA

The agenda was adopted.

3. DECLARATIONS OF INTEREST

No interests were declared relevant to the items of the agenda.

4. ADOPTION OF THE DRAFT MINUTES OF THE 39TH PLENARY MEETING ON 17-19 APRIL 2007

The minutes of the 39th plenary meeting of the Scientific Panel held on 17-19 April 2007 were reviewed and adopted.[1]

5. WORK PROGRAM

5.1. Discussion and possible adoption of the following scientific opinions

- **Maximum Residue Limits (MRLs) for canthaxanthin (EFSA-Q-2003-113)**

  The Rapporteur of the Working Group (WG) introduced the question and the draft opinion. EFSA was requested to deliver an opinion on the MRLs in foodstuffs coming from animals fed canthaxanthin as a feed additive in accordance with Directive 70/524/EEC.

  The FEEDAP Panel considers canthaxanthin only as the residue of concern and therefore retains it as the marker residue. The following MRL values are proposed: egg yolk 30 mg kg^{-1}, liver as target tissue for poultry 15 mg kg^{-1}, skin/fat as target tissue for poultry 2.5 mg kg^{-1}, salmon 10 mg kg^{-1} flesh and for trout 5 mg kg^{-1} flesh. Adopting these MRL values, the consumption of animal products from canthaxanthin-treated poultry and salmonids would result in a total canthaxanthin intake below the ADI.

  The opinion was adopted after some editorial changes.[2]

- **Safety and efficacy of Clinacox 0.5 % (diclazuril) for rabbits for fattening and breeding (EFSA-Q-2004-147)**

  The Rapporteur of the WG introduced the question and the draft opinion. The European Commission requested EFSA to deliver an opinion on the efficacy and safety of this product for the target species, the consumer, the user and the environment.

  The data presented showed that Clinacox protected rabbits for fattening and breeding at least as effectively as other coccidiostats tested. However, due to lack of recent data it is not possible to make a conclusive assessment of present day efficacy, particularly relating to resistance of rabbit-specific *Eimeria*. The product is considered safe for rabbits under the proposed conditions of use. For consumer safety assessment, the liver is considered the target tissue and diclazuril the marker residue. A diclazuril impurity/metabolite has been identified in the rabbit which was not identified in the rat. The FEEDAP Panel cannot reach a conclusion on the safety of Clinacox for the consumer until reassurance on the lack of genotoxic potential of this impurity/metabolite is provided. Clinacox is considered to be safe for the user and the environment.

  The opinion was adopted after some editorial modifications.[3]

- **Maximum Residue Limits for Clinacox 0.5% (diclazuril) for turkeys for fattening, chickens for fattening and chickens reared for laying (EFSA-Q-2006-134)**

  The Rapporteur of the WG introduced the question and the draft opinion. EFSA has been asked to set MRLs for diclazuril from Clinacox 0.5% in chickens and turkey tissues.

  Since a major diclazuril impurity/metabolite has been identified in the rabbit which was not identified in laboratory animals (see EFSA-Q-2004-147 above), it cannot be ruled out that

[1] http://www.efsa.europa.eu/en/science/feedap/feedap_meetings/feedap_39th_meeting.html
[2] http://www.efsa.europa.eu/en/science/feedap/feedap_opinions/ej507_canthaxanthin.html
[3] http://www.efsa.europa.eu/en/science/feedap/feedap_opinions/ej506_clinacox_rabbits.html

this compound can accumulate in fat of turkeys or chickens. Therefore, the FEEDAP Panel considers that until the safety issues related to this compound are not clarified, an MRL for diclazuril cannot be set for tissues from turkeys and chickens.

The opinion was adopted after some editorial modifications. [4]

- **Safety and efficacy of VitaLys® (L-lysine sulphate) for all species (EFSA-Q-2007-049)**

  The Rapporteur of the WG introduced the question and the draft opinion. This question refers to an application for authorisation of a feed additive under Article 4(1) of Regulation (EC) No 1831/2003. The applicant is seeking authorisation of the product VitaLys® to be used as a nutritional additive (functional group: amino acids, their salts and analogues) for all animal species.

  Some discussion took place regarding the characterisation of the product, the efficacy and the safety. The Panel proposed major changes in the structure of the opinion, and asked the WG to revise the draft opinion according to the discussion.

  The draft opinion will be reviewed by the WG and presented at the next Plenary meeting.

- **Use of feedingstuffs with high calcium content for the reduction of risk of milk fever in dairy cows (EFSA-Q-2007-017)**

  A member of the WG introduced the question and the draft opinion. EFSA has been requested to deliver an opinion on the safety for the target species, the consumer and the environment of the use of feedingstuffs with high calcium content for the reduction of risk of milk fever in dairy cows.

  The FEEDAP Panel considers that the use of feedingstuffs with high calcium poses a limited risk for the dairy cows, does not pose a risk to the consumer of milk from treated cows and to the environment.

  The opinion was adopted.[5]

5.2. Discussion of the following scientific opinions

- **Safety and efficacy of Ronozyme P (6-phytase) for ducks for fattening (EFSA-Q-2006-060)**

  The Rapporteur of the WG introduced the question and the draft opinion. This question refers to a feed additive application under Article 4(1) of Regulation (EC) No 1831/2003. The applicant is seeking authorisation of the product Ronozyme P to be used as a zootechnical feed additive (functional group: digestibility enhancers and additives which favourably affect the environment) in ducks. This product is already authorised for chickens for fattening, turkeys for fattening, laying hens, piglets, pigs for fattening and sows, and provisionally authorised for salmonids. An initial discussion took place on the draft presented.

- **Safety and efficacy of Panaferd-AX (sterilised dried cells of astaxanthin-rich *Paracoccus carotinifaciens*) for salmon and trout (EFSA-Q-2006-173)**

[4] http://www.efsa.europa.eu/en/science/feedap/feedap_opinions/ej505_clinacox_mrl.html
[5] http://www.efsa.europa.eu/en/science/feedap/feedap_opinions/ej504_high_calcium.html

The Rapporteur of the WG introduced the question. Some discussion took place on the safety of this product for the consumer. The WG will finalise the draft opinion according to the indications of the Panel.

- **Efficacy of Coxidin® 25% (monensin sodium) for turkeys for fattening. (EFSA-Q-2007-067)**

  The Rapporteur of the WG introduced the question. EFSA has been requested to deliver an opinion on the proposal made by the applicant for reducing the minimum content of Mo-Na from Coxidin® 25% in complete feedingstuffs for turkeys from the current 90 mg kg^{-1} to 60 mg kg^{-1}. An initial discussion took place on the efficacy trials provided.

6. PROGRESS REPORT ON ONGOING WORK

Not discussed

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 ten 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:

- **Toyocerin® (*B. cereus* var. *toyoi*).** Zootechnical additive for turkeys for fattening (EFSA-Q-2007-090)
- **Mintrex® Mn (Manganese chelate of hydroxy analogue of methionine).** Nutritional additive for all species (EFSA-Q-2007-094)
- **Mintrex® Cu (Copper chelate of hydroxy analogue of methionine).** Nutritional additive for all species (EFSA-Q-2007-097)
- **Mintrex® Zn (Zinc chelate of hydroxy analogue of methionine).** Nutritional additive for all species (EFSA-Q-2007-098)
- **Polysaccharide complex of iron.** Nutritional additive for ruminants, non-ruminants and, poultry (EFSA-Q-2007-100)
- **Polysaccharide complex of manganese.** Nutritional additive for ruminants, non-ruminants, and poultry (EFSA-Q-2007-101)
- **Polysaccharide complex of zinc.** Nutritional additive for ruminants, non-ruminants, and poultry (EFSA-Q-2007-102)
- **L-valine Feed Grade (L-valine).** Nutritional additive for all species (EFSA-Q-2007-103)
- **Biosaf® Sc47 (*Saccharomyces cerevisiae*).** Zootechnical additive for pigs for fattening (EFSA-Q-2007-104)
- **Polysaccharide complex of copper.** Nutritional additive for ruminants, non-ruminants, and poultry (EFSA-Q-2007-106)

7.2. Valid applications under Regulation (EC) No 1831/2003 since the previous meeting

Applications considered valid for the start of the assessment:

- **Coxidin® 25%.** Coccidiostat for turkeys for fattening **(EFSA-Q-2007-067)**

  The application and the particulars related to the question on Coxidin® 25% have been considered valid by EFSA on the 2nd May 2007.

EFSA shall deliver an opinion on the proposal made by the applicant for reducing the minimum content of Mo-Na from Coxidin® 25% in complete feedingstuffs for turkeys from the current 90 mg kg^{-1} to 60 mg kg^{-1}.

- **Natuphos® (3-phytase).** Zootechnical additive for ducks **(EFSA-Q-2007-041)**

  The application and the particulars related to the question on Natuphos® have been considered valid by EFSA on the 10th May 2007.

  The safety and efficacy of this product will need to be addressed as foreseen in Regulation (EC) No 1831/2003.

- **Carophyll® Stay-Pink (Astaxanthin dimethylsuccinate).** Sensory additive for salmon and trout **(EFSA-Q-2007-018)**

  The application and the particulars related to the question on Carophyll® Stay-Pink have been considered valid by EFSA on the 16th May 2007.

  The safety and efficacy of this product will need to be addressed as foreseen in Regulation (EC) No 1831/2003.

7.3. New questions under Regulation (EC) No 178/2002

- **Kokcisan 120G (salinomycin sodium) for chickens for fattening (EFSA-Q-2007-099).**

  The FEEDAP Panel delivered two opinions on 7 May 2004 and on 11 July 2006 on the safety and efficacy of this product when used as an additive for chickens for fattening.[6,7] In these opinions, the FEEDAP Panel was not able to reach a conclusion on the safety for the consumer. The applicant has now provided new data to support the safety for the consumer.

  The deadline proposed by the European Commission is end of July 2007.

8. GENERAL INFORMATION FROM EFSA

- The Scientific Committee has set a new WG on emerging risks. The Scientific Co-ordinator asked for volunteers from the Panel to attend this WG.
- Several members of the Panel reported back on the various meetings they attended in EMEA, other Panels and/or in the Scientific Committee.
- A WG of the Standing Committee on Animal Health and Food Chain took place on 7th June to discuss the new guidelines for the assessment of feed additives. A member of the Scientific Secretariat of EFSA attended to this meeting and reported back to the Panel.
- Two new scientific staff have been recruited in the FEEDAP Team: Irene Bustos Sepúlveda and Rosella Brozzi.

9. MISCELLANEOUS

- Guidelines/Guidance for the assessment of additives for use in animal nutrition.

  Some editorial modifications were introduced in the "Specific guidance for the assessment of nutritional additives". The Panel agreed on the changes proposed, and this new version

[6] http://www.efsa.europa.eu/en/science/feedap/feedap_opinions/466.html
[7] http://www.efsa.europa.eu/en/science/feedap/feedap_opinions/feedap_op_ej378_kokcisan.html

will be sent to the EC to be considered during the discussion on the establishment of the new Guidelines for the assessment of feed additives.