

**MINUTES OF THE 65TH PLENARY MEETING
OF THE SCIENTIFIC PANEL ON ADDITIVES AND PRODUCTS OR SUBSTANCES USED IN
ANIMAL FEED (FEEDAP)**

(PARMA, 2-4 FEBRUARY 2010)

(AGREED ON 10 MARCH 2010)

PARTICIPANTS

Panel Members

Gabriele Aquilina, Georges Bories, Paul Brantom, Pier Sandro Cocconcelli, Joop de Knecht (1st day), Mikolaj Antoni Gralak, Jürgen Gropp, Ingrid Halle, Nils-Gunnar Ilbäck, Lubomir Leng, Sven Lindgren, Anne-Katrine Lundebye Haldorsen (1st day), Alberto Mantovani (2nd and 3rd days), Derek Renshaw and Maria Saarela.

Apologies

Andrew Chesson, Joop de Knecht (2nd and 3rd days), Noël Dierick, Reinhard Kroker, Anne-Katrine Lundebye Haldorsen (2nd and 3rd days), Alberto Mantovani (1st day), Miklós Mézes.

EFSA

Claudia Roncancio-Peña, Jaume Galobart, Rosella Brozzi, Gloria López-Gálvez, Maria Vittoria Vettori (scientific staff), Nicola Jane Reynolds (administrative staff).

European Commission

Marta Ponghellini, Marina Marini (DG SANCO), Giuseppe Simone, Piotr Robouch (DG JRC)

1. WELCOME AND APOLOGIES FOR ABSENCE

The Vice-Chair opened the meeting and welcomed the participants to the 65th Plenary meeting of the FEEDAP Panel.

The Vice-Chair informed that Dr. Francesca Caloni resigned from the FEEDAP Panel. He thanked her for her participation as expert in the Panel; the FEEDAP secretariat has started the procedure to replace Dr. Caloni with another expert.

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

2. ADOPTION OF THE AGENDA

The agenda was adopted after the deletion of the item on “Assessment of herbs, essential oils and other plant products as additives for use in animal nutrition (EFSA-Q-2004-064)”.

3. DECLARATIONS OF INTEREST

In accordance with EFSA's Policy on Declarations of Interests, EFSA screened the Annual Declaration of interest (ADoI) and the Specific Declaration of interest (SDoI) filled in by the experts invited for the present meeting. For further details on the outcome of the screening of the ADoI and SDoI, please refer to the Annex.

4. ADOPTION OF THE DRAFT MINUTES OF THE 64TH PLENARY MEETING

The minutes of the 64th Plenary meeting of the Scientific Panel held on 8-10 December 2009 were reviewed and agreed.¹

5. WORK PROGRAM

5.1. Discussion and possible adoption of the following scientific opinions

- **Maxiban[®] G160 (narsin/nicarbazin) for chickens for fattening (EFSA-Q-2008-474)**

The Chair from the Working Group (WG) presented the question and the draft opinion. EFSA has been requested to deliver an opinion on the safety and efficacy of Maxiban[®] G160 when used as a feed additive for chickens for fattening.

Due to lack of time, only an initial discussion took place on the environmental risk assessment.

- **Avatec[®] 150G (lasalocid sodium) for chickens for fattening, chickens reared for laying, turkeys and all other poultry (pheasant, partridges, quails, guinea fowl, ducks and geese) (EFSA-Q-2008-080)**

Not discussed due to lack of time.

- **Cylactin[®]/Cernivet[®] (*Enterococcus faecium*) for chickens for fattening (EFSA-Q-2008-422)**

The Chair of the WG presented the question and the draft opinion. This question refers to an application for the re-evaluation of a feed additive under Article 10(2) of Regulation (EC) No 1831/2003.

The draft opinion was thoroughly discussed. Following a technical hearing with the applicant (see under 10), the Panel decided to stop the assessment and request the applicant to provide additional data within an agreed deadline before concluding on the safety of the product.

- **Koffogran (nicarbazin) for chickens for fattening (EFSA-Q-2009-00225)**

The Rapporteur of the WG presented the question and the draft opinion. EFSA has been requested to deliver an opinion on the safety and efficacy of Koffogran when used as a coccidiostat for chickens for fattening.

The draft opinion was discussed, focussing on the characterisation of the additive and the safety for the consumer and the environment. The remaining parts of the opinion (i.e., user safety and efficacy) will be discussed at the next plenary meeting.

- ***Pediococcus pentosaceus* (DSM 16244) for all species (EFSA-Q-2009-00717)**

¹ http://www.efsa.europa.eu/EFSA/Event_Meeting/feedap091111m.pdf?ssbinary=true

A member of the WG presented the question and the draft opinion. This question refers to an application for the authorisation under Article 4(1) of Regulation (EC) No 1831/2003. The applicant is seeking authorisation of this product as silage additive for all species.

The draft opinion was discussed. The FEEDAP Panel concluded that the active agent fulfils the requirements to be considered as a QPS micro-organism and therefore it is safe for the target species, the consumer and the environment. The product is not an irritant and due to the lack of specific studies it should be considered as a potential sensitiser. The Panel also concluded that the additive is efficacious in improving the ensiling process.

The opinion was adopted.²

6. PROGRESS REPORT ON ONGOING WORK

Not discussed

7. FEEDBACK FROM THE SCIENTIFIC COMMITTEE

Not discussed

8. NEW REQUESTS TO EFSA

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

The Commission has forwarded to EFSA the following 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:

Additive	EFSA-Q-Number
Clinacox 0.5 % (diclazuril) for guinea-fowl	EFSA-Q-2009-00968
Fecinor and Fecinor Plus (<i>Enterococcus faecium</i>) for chickens for fattening	EFSA-Q-2009-00969
GalliPro [®] Tect (<i>Bacillus licheniformis</i>) for chickens for fattening	EFSA-Q-2009-00970
Cylactin [®] /Cernivet [®] (<i>Enterococcus faecium</i>) for calves, lambs and kids for rearing and fattening	EFSA-Q-2010-00009
AveMix [®] XG 10 (endo-1,3(4)-beta-glucanase and endo-1,4-beta-xylanase) for weaned piglets	EFSA-Q-2010-00018
Hostazym [®] X (endo-1,4-beta xylanase) for chickens for fattening, turkeys for fattening, laying hens, weaned piglets, fattening pigs and other birds for fattening or laying	EFSA-Q-2010-00036

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

Subject	EFSA-Q-Number
Evaluation of the safety of hemp used as animal feed	EFSA-Q-2010-00016

A specific WG was created to deal with this question.

² <http://www.efsa.europa.eu/en/scdocs/scdoc/1502.htm>

8.3. Self-tasks

Subject	EFSA-Q-Number
Update of the “Guidance for the preparation of dossiers for technological additives” to include the new functional group “substances for reduction of the contamination of feed by mycotoxins”	EFSA-Q-2010-00017

8.4. Other questions

Subject	EFSA-Q-Number
Update of the “Administrative guidance to applicants on the preparation and presentation of applications for authorisation of additives for use in animal nutrition”	EFSA-Q-2009-00981

The “Administrative guidance to applicants on the preparation and presentation of applications for authorisation of additives for use in animal nutrition” was updated by the secretariat and has already been published on the website.³

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

Applications considered valid for the start of the assessment:

#	Additive	EFSA-Q-Number	Valid on
1	SelenoSource AF 2000 (Selenomethionine) for all species	EFSA-Q-2009-00524	14-Jan-10
2	Ronozyme [®] P (6-phytase) for salmonids	EFSA-Q-2009-00535	11-Dec-09
3	Bactocell (<i>Pediococcus acidilactici</i>) for laying hens	EFSA-Q-2009-00716	08-Jan-10
4	Bactocell (<i>Pediococcus acidilactici</i>) for weaned piglets	EFSA-Q-2009-00719	08-Jan-10
5	Biosprint [®] (<i>Saccharomyces cerevisiae</i>) for dairy cows	EFSA-Q-2009-00824	17-Dec-09
6	KemTRACE Zn (Zinc propionate) for all species	EFSA-Q-2009-00855	12-Jan-10
7	Fresta [®] F (Carvone) for weaned piglets	EFSA-Q-2009-00939	14-Jan-10
8	Cassia gum for cats and dogs	EFSA-Q-2009-00948	21-Jan-10
9	PepSoyGen (<i>Bacillus subtilis</i> and <i>Aspergillus oryzae</i>), for piglets, chicken for fattening, calves for fattening and rearing, fish (salmonidae and other fish), lambs and goats for rearing and fattening, dogs	EFSA-Q-2009-00525	29-Jan-10

These applications were assigned to the working group on Trace elements (#1 and 6), Micro-organisms (#3, 4, 5 and 9), Enzymes (#2), Feed flavourings (#7) and Technological additives (#8).

9. GENERAL INFORMATION FROM EFSA

- The Scientific Coordinator (SC) presented the main changes to the “Decision concerning

³ <http://www.efsa.europa.eu/en/feedapguidance/feedapadminguidance.htm>

the establishment and operations of the Scientific Committee, Scientific Panels and of their Working Groups”⁴ which was adopted by the Management Board on 17 December 2009.

- The Secretariat made a presentation on the report of the “External review of the quality of scientific outputs of the European Food Safety Authority”, which makes part of the “Scientific Advice by the Scientific Committee: Internal and External Review. Proposal for a Review System for EFSA’s Scientific Activities”.⁵ A preliminary exchange of views took place. It was agreed that experts should provide further comments. All suggestions are to be collected in the next Plenary meeting.

10. MISCELLANEOUS

- On the 2nd February, following the thorough discussion of the draft opinion on Cylactin/Cernivet for chickens for fattening by the FEEDAP Panel (see 5.1), and upon request from the European Commission (EC), a technical hearing with the applicant, involving some Panel experts, the secretariat and representatives from the EC, took place. The applicant indicated that new data to support the safety of the additive have been and are still being developed. Therefore, the applicant has been given the opportunity to submit additional information, within the shortest possible deadline. After the meeting, feedback was provided to the Plenary. Once the information will be received, it will be submitted again to the WG and to the Panel.
- Following a request from two applicants, the Panel discussed the data necessary to support efficacy for an additive intended to be administered either via feed or in water for drinking, and for an additive with direct effects on the environment.

⁴ <http://www.efsa.europa.eu/en/keydocs/doc/mba1209ax7.pdf>

⁵ <http://www.efsa.europa.eu/en/scdocs/scdoc/526.htm>

Annex

INTERESTS AND ACTIONS RESULTING FROM THE SCREENING OF ADOIs OR SDOIs

- In her SDoI, Dr Maria Saarela declared the following interest: the Institute where she works performed some research activities related to a competitor of the product Cylactin (*Enterococcus faecium*). In accordance with EFSA's Policy on Declarations of Interests and Implementing documents thereof, and taking into account the specific matters discussed at the meeting in question, the interest above was deemed to represent a conflict of Interest. Pursuant to EFSA's Procedure on Identifying and Handling Declarations of Interest, the said expert incurs in the limitations identified under point C.III.b,⁶ that is, to be excluded from participating in EFSA activities concerned by the potential conflict in question.
- In his ADoI, Dr Paul Brantom declared the following interest: he had done consultancy work for Elanco, producer of Maxiban (nicarbazin/narasin). The product Koffogran (nicarbazin) is produced by a competitor of Elanco. In accordance with EFSA's Policy on Declarations of Interests and Implementing documents thereof, and taking into account the specific matters discussed at the meeting in question, the interest above was deemed to represent a conflict of Interest. Pursuant to EFSA's Procedure on Identifying and Handling Declarations of Interest, the said expert incurs in the limitations identified under point C.III.b,⁷ that is, to be excluded from participating in EFSA activities concerned by the potential conflict in question.

⁶ Implementing act to the policy on declaration of interests procedure for identifying and handling potential conflicts of interest.
http://www.efsa.europa.eu/cs/BlobServer/General/mb_annex_procedure_doi_en%20221008,0.pdf?ssbinary=true

⁷ Implementing act to the policy on declaration of interests procedure for identifying and handling potential conflicts of interest.
http://www.efsa.europa.eu/cs/BlobServer/General/mb_annex_procedure_doi_en%20221008,0.pdf?ssbinary=true