

**MINUTES OF THE 66TH PLENARY MEETING
OF THE SCIENTIFIC PANEL ON ADDITIVES AND PRODUCTS OR SUBSTANCES USED IN
ANIMAL FEED (FEEDAP)**

(PARMA, 10-11 MARCH 2010)

(AGREED ON 7 APRIL 2010)

PARTICIPANTS

Panel Members

Gabriele Aquilina, Georges Bories, Paul Brantom, Pier Sandro Cocconcetti, Noël Dierick, Mikolaj Antoni Gralak, Jürgen Gropp, Ingrid Halle, Reinhard Kroker, Lubomir Leng, Sven Lindgren, Anne-Katrine Lundebye Haldorsen (1st day), Alberto Mantovani, Miklós Mézes (1st day), Derek Renshaw and Maria Saarela.

Apologies

Andrew Chesson, Joop de Knecht, Anne-Katrine Lundebye Haldorsen (2nd day) and Miklós Mézes (2nd day).

EFSA

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

European Commission

Marina Marini, Willem Penning (1st day) (DG SANCO), Giuseppe Simone (DG JRC).

1. WELCOME AND APOLOGIES FOR ABSENCE

The Vice-Chair opened the meeting and welcomed the participants to the 66th Plenary meeting of the FEEDAP Panel.

The Vice-Chair informed that Dr. Nils-Gunnar Ilbäck resigned from the FEEDAP Panel. He thanked him for his participation as expert in the Panel; the FEEDAP secretariat has started the procedure to replace Dr. Ilbäck 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.

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 65TH PLENARY MEETING

The minutes of the 65th Plenary meeting of the Scientific Panel held on 2-4 February 2010 were reviewed and agreed.¹

5. WORK PROGRAM

5.1. Discussion and possible adoption of the following scientific opinions

- **Avatec[®] 150G (lasalocid sodium) pheasant, partridges, quails, guinea fowl, ducks and geese (poultry) (EFSA-Q-2008-080)**

Not discussed due to lack of time.

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

The Rapporteur 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.

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

- **Avatec[®] 150G (lasalocid sodium) for turkeys (EFSA-Q-2008-751)**

Not discussed due to lack of time.

- **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. The sections dealing with the characterisation of the additive and the safety for the consumer and the environment were discussed already in the previous plenary meeting. The discussion focused on the sections dealing with consumer safety, user safety and efficacy. The Panel concluded that nicarbazin at the recommended maximum use level is considered safe for the target species, consumers and users. No safety concerns for soil or, groundwater compartments or by secondary poisoning were identified. However, in the absence of raw toxicity data for algae the risk for surface water cannot be assessed.

The Panel also concluded that nicarbazin at the maximum dose proposed is effective in controlling coccidiosis in chickens for fattening. A series of recommendations were also made.

The opinion was adopted.²

¹ <http://www.efsa.europa.eu/en/events/event/feedap100202.htm>

² <http://www.efsa.europa.eu/en/scdocs/scdoc/1551.htm>

- **Monteban[®] G100 (narasin) for chickens for fattening (EFSA-Q-2009-00502)**

The Rapporteur of the WG presented the question and the draft opinion. This question refers to an application for the modification of the terms of authorisation under Article 13(3) of Regulation (EC) No 1831/2003. The applicant is seeking authorisation for a modification of the withdrawal time from one- to zero-day.

This draft opinion was already discussed during the 62nd Plenary (October 2009). The Panel concluded that applying a zero-day withdrawal period (considered equal to the experimental 0.25-day withdrawal) for Monteban[®] G100 when fed to chickens for fattening at the maximum dose of 70 mg/kg feed is considered safe for consumers.

The opinion was adopted.³

- **Compatibility of the microbial product 035 (*Bacillus subtilis*) with lasalocid sodium, maduramycin ammonium, monensin sodium, narasin, salinomycin sodium and semduramicin sodium (EFSA-Q-2009-00803)**

The Chair of the WG presented the question and the draft opinion. EFSA has been requested to deliver an opinion on the compatibility of microbial feed additive 035 based on *Bacillus subtilis* (DSM 17299) with the coccidiostats lasalocid sodium, maduramycin ammonium, monensin sodium, narasin, salinomycin sodium and semduramicin sodium.

The draft opinion was discussed. Based on the data available, the Panel concluded that *Bacillus subtilis* (DSM 17299) is compatible with the coccidiostats above mentioned.

The opinion was adopted.⁴

- **Quantum (6-phytase) for laying hens (EFSA-Q-2009-00804)**

The Rapporteur of the WG presented the question and the draft opinion. This question refers to an application for the modification of the terms of authorisation under Article 13(3) of Regulation (EC) No 1831/2003. The applicant is seeking authorisation for a modification of the minimum recommended dose from 2000 FTU/kg to 250 FTU/kg.

The draft opinion was already discussed in the 64th Plenary (December 2009). Comments from Member States were received and considered. The Panel considers that there is evidence of the efficacy of the product in laying hens at the minimum recommended dose proposed by the applicant.

The opinion was adopted.⁵

- **Finase EC (6-phytase) for turkeys (EFSA-Q-2010-0069)**

The Rapporteur of the WG presented the question and the draft opinion. EFSA has been requested to deliver an opinion on the safety of Finase[®] EC (6-phytase) for turkeys for fattening. In a previous opinion,⁶ the Panel could not conclude on the safety of this enzyme preparation for turkeys. The applicant has now provided a new tolerance study.

The draft opinion was discussed. Based on the new tolerance trial provided, the Panel concluded that Finase EC is safe for turkeys for fattening and reared for breeding.

³ <http://www.efsa.europa.eu/en/scdocs/scdoc/1549.htm>

⁴ <http://www.efsa.europa.eu/en/scdocs/scdoc/1552.htm>

⁵ <http://www.efsa.europa.eu/en/scdocs/scdoc/1550.htm>

⁶ <http://www.efsa.europa.eu/en/scdocs/scdoc/1380.htm>

The opinion was adopted.⁷

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 were briefly presented to the Panel and are currently being checked for completeness:

Additive	EFSA-Q-Number
Ronozyme [®] RumiStar (L/CT) (α -amylase) for dairy cows	EFSA-Q-2010-00139
Miya-Gold [®] EU (<i>Clostridium butyricum</i> MYYAIRI 588) for weaned piglets, minor porcine (relevant) and minor avian species	EFSA-Q-2010-00140
Danisco Glycosidase (TPT/L) (endo-1,4-beta-xylanase and endo-1,3(4)-beta-glucanase) in poultry, piglets (weaned) and pigs for fattening	EFSA-Q-2010-00141
Econase XT (endo-1,4-beta xylanase) for laying hens, pigs for fattening and minor species, including ducks, geese, quails, pheasants, pigeons	EFSA-Q-2010-00142
Optiphos [®] (6 phytase) for chickens and turkeys for fattening, chickens reared for laying, turkeys reared for breeding, other birds for fattening and laying, weaned piglets, pigs for fattening and sows	EFSA-Q-2010-00152

8.2. 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	Bioimin [®] IMB 52 (<i>Enterococcus faecium</i>) for piglets	EFSA-Q-2008-471	24/02/2010
2	Formic acid for all species	EFSA-Q-2009-00715	24/02/2010
3	Biosprint [®] (<i>Saccharomyces cerevisiae</i>) for cattle for fattening	EFSA-Q-2009-00818	02/02/2010
4	Bioimin [®] C3 (<i>Enterococcus faecium</i> , <i>Bifidobacterium animalis</i> ssp. <i>animalis</i> and <i>Lactobacillus salivarius</i> ssp. <i>salivarius</i>) for chickens for fattening	EFSA-Q-2009-00823	11/02/2010
5	SBS (sodium bisulphate) for all species (as preservative and silage additive); for pets and other non food producing animals (as acidity regulator) and for pets (as flavouring)	EFSA-Q-2009-00868	05/02/2010
6	Taminizer D (dimethylglycine sodium salt) for chickens for fattening	EFSA-Q-2009-00881	24/02/2010

⁷ <http://www.efsa.europa.eu/en/scdocs/scdoc/1553.htm>

7	Chemically defined flavourings. Group 25 - Phenol derivatives containing ringalkyl, ring-alkoxy, and side-chains with an oxygenated functional group for all species and categories	EFSA-Q-2009-00882	02/02/2010
8	Vitamin B6 for all species and categories	EFSA-Q-2009-00883	22/02/2010

These applications were assigned to the working group on Micro-organisms (#1, 3 and 4), Organic acids (#2), Technological additives (#5), Taminizer D (#6), Feed flavourings (#7) and Vitamins (#8).

9. GENERAL INFORMATION FROM EFSA

- The Scientific Coordinator (SC) informed the panel experts that a short biography of the panel members will be published on the EFSA website.
- The SC also informed the panel on the current status of the selection of experts for the replacement of experts who have resigned from the panel.
- The Secretariat informed the panel that all documents related to the Plenary and working group meetings will not be sent by e-mail but using the electronic platform ScienceNet.

10. MISCELLANEOUS

- Vice-chairs for the WG on Enzymes and Micro-organisms were appointed.
- The SC reminded the experts to submit comments to the recommendations from the external review report.
- The Panel was informed about the public consultation by the Scientific Committee on the “draft opinion on the human health risk/benefit assessment of foods”.⁸ The deadline to submit comments is 15 April.
- The Panel was informed about the request from the EC concerning technical assistance in reviewing the MRLs for narasin in cattle and pig, which are subject of a Codex Commission discussion.

⁸ <http://www.efsa.europa.eu/en/consultations/call/sc100226.htm>

Annex

INTERESTS AND ACTIONS RESULTING FROM THE SCREENING OF ADOIs OR SDOIs

- In his ADoI, Dr Paul Brantom declared the following interest: he had done consultancy work for Elanco, producer of Maxiban[®] G160 (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,⁹ that is, to be excluded from participating in EFSA activities concerned by the potential conflict in question.
- In his SDoI, Dr Sven Lindgren declared the following interest: he had done consultancy work for Chr Hansen, the producer of the product 035. 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, that is, to be excluded from participating in EFSA activities concerned by the potential conflict in question.

⁹ 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