MINUTES OF THE 63RD PLENARY MEETING

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

(PARMA, 11-12 NOVEMBER 2009)

(ADOPTED ON 9 DECEMBER 2009)

PARTICIPANTS

Panel Members

Gabriele Aquilina, Georges Bories, Paul Brantom, Francesca Caloni, Andrew Chesson, Pier Sandro Cocconcelli, Joop de Knecht, 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, Derek Renshaw and Maria Saarela.

Apologies

Nils-Gunnar Ilbäck and Anne-Katrine Lundebye Haldorsen (2nd day)

EFSA

Claudia Roncancio-Peña, Jaume Galobart, Gloria López-Gálvez, Rosella Brozzi, Matteo Lorenzo Innocenti (scientific staff), Ketty Antonelli (administrative staff).

European Commission

Marta Ponghellini, Marina Marini (DG SANCO), Giuseppe Simone (DG JRC, 2nd day)

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1. WELCOME AND APOLOGIES FOR ABSENCE

The Chair opened the meeting and welcomed the participants to the 63rd 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 without modifications.

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 62ND PLENARY MEETING ON 13-15 OCTOBER 2009

The minutes of the 62nd Plenary meeting of the Scientific Panel held on 13-15 October 2009 were reviewed and adopted.[1]

5. WORK PROGRAM

5.1. Discussion and possible adoption of the following scientific opinions

- **Bonvital (*Enterococcus faecium*) for dogs (EFSA-Q-2006-318)**

  The Rapporteur from the Working Group (WG) presented the question and the draft opinion. This question refers to an application for the authorisation of a feed additive under Article 4(1) of Regulation (EC) No 1831/2003. The applicant is requesting the authorisation of this product for use in dogs.

  The draft opinion was reviewed. The safety for the user and environment were considered in previous opinions. Based on the data provided in the dossier, the Panel was not able to draw a conclusion on the safety and the efficacy of this additive in dogs.

  The opinion was adopted.[2]

- **Finase® EC (6-phytase) as feed additive for chickens for fattening and reared for laying, laying hens, turkeys for fattening and reared for breeding, ducks and other minor poultry species, piglets (weaned), pigs for fattening and sows (EFSA-Q-2008-748 and EFSA-Q-2009-00676)**

  The Rapporteur from the WG presented the question and the draft opinion. This question refers to an application for the authorisation of a feed additive under Article 4(1) of Regulation (EC) No 1831/2003. The applicant is seeking the authorisation of this product as a zootechnical additive for chickens for fattening and reared for laying, laying hens, turkeys for fattening and reared for breeding, ducks and other poultry minor species (i.e., geese, quails, pigeons, pheasants and other game birds), piglets (weaned), pigs for fattening and sows. This enzyme preparation is produced by a genetically modified strain of *Trichoderma reesei* (CBS 122001). The safety aspects of the genetic modification have been assessed by the GMO Panel.[3]

  The draft opinion was discussed. The additive is considered to be safe for chickens for fattening, laying hens, minor poultry species, piglets and pigs for fattening. A conclusion on the safety for turkeys for fattening and for sows was not possible. The product is also considered safe for the consumers, users and the environment. The additive is considered to be efficacious in the different species/categories of target species.

  The opinion was adopted.[4]

- **Mintrex® Cu (copper chelate of hydroxy analogue of methionine) for all animal species (EFSA-Q-2009-00628)**

  The Rapporteur from the WG presented the question and the draft opinion. EFSA has been requested to deliver an opinion on the safety for consumers and for the target animals of the

[1] http://www.efsa.europa.eu/EFSA/Event_Meeting/feedap091013m.pdf?ssbinary=true
[2] http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1211903077634.htm
[3] GMO assessment adopted on 21 October 2009
[4] http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1211903077839.htm

product copper chelate of hydroxyl analogue of methionine when used as a feed additive for all animal species. In an opinion adopted in 2008,[5] the FEEDAP Panel could not conclude on the safety for the target animals (except chickens for fattening); the conclusions on the safety for the consumer included a reservation due to the limited data. The applicant has provided new data on the safety of the product for all species, and for the further support of the safety for consumer.

The draft opinion was reviewed. Based on the new data provided, the FEEDAP concludes that the use of Mintrex®Cu up to the maximum authorised copper content in feed is safe for all species and for consumers.

The opinion was adopted.[6]

- **Mintrex® Mn (manganese chelate of hydroxy analogue of methionine) for all animal species (EFSA-Q-2009-00630)**

  Not discussed due to lack of time.

- **Zinc chelate of hydroxy analogue of methionine (Mintrex® Zn) for all animal species (EFSA-Q-2009-00667)**

  The Rapporteur from the WG presented the question and the draft opinion. EFSA has been requested to deliver an opinion on the safety for consumers and for the target animals of the product zinc chelate of hydroxyl analogue of methionine when used as a feed additive for all animal species. In an opinion adopted in 2008,[7] the FEEDAP Panel could not assess the safety for the target animals due to the lack of data; despite the limited data supplied by the applicant, the safety for the consumers could be derived. In a recent opinion,[8] the FEEDAP Panel has concluded on the safety of the product for chickens for fattening. The applicant has provided new data to support the safety of the product for all species, and for the further support of the safety for consumer.

  The draft opinion was reviewed. Based on the new data provided, the FEEDAP concludes that the use of Mintrex®Zn up to the maximum authorised zinc content in feed is safe for all species and for consumers.

  The opinion was adopted.[9]

- **Assessment of the use of cobalt compounds as additive in animal nutrition (EFSA-Q-2009-00721)**

  The Rapporteur from the WG presented the question and the draft opinion. The FEEDAP Panel established a self-task to evaluate the safety for the consumer and the user related to cobalt compounds used as feed additives as well as on the potential impact on target animal health in view of the given genotoxic and carcinogenic properties of inorganic cobalt (II) compounds.

  The draft opinion was reviewed. In the opinion the Panel reviewed the necessity of use of cobalt for all animal species, its implications for consumer safety and for the safety of persons handling cobalt compounds. The Panel concluded that there is no necessity for

[5] http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1178706516653.htm
[6] http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1211903077851.htm
[7] http://www.efsa.europa.eu/EFSA/Scientific_Opinion/feedap_op_ej694_mintrex_zn_en.pdf?ssbinary=true
[8] http://www.efsa.europa.eu/cs/BlobServer/Scientific_Opinion/feedap_op_ej1042_mintrex_zn_en.pdf?ssbinary=true
[9] http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1211903076496.htm

cobalt supplementation of feed for animals other than ruminants, horses and rabbits. It is considered unlikely that cobalt toxicity in target animals could be a major problem in practice. The Panel also concluded that the potential cobalt intake of consumers from food of animal origin is not of safety concern. The Panel recommended limiting exposure of users to cobalt compounds. The Panel made several recommendations regarding the current authorization of cobalt in animal nutrition.

The opinion was adopted.[10]

6. PROGRESS REPORT ON ONGOING WORK

The Secretariat informed the Panel on the status of the two calls for proposals under Article 36 of Regulation (EC) No 178/2002 that are currently in process.

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 six 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
Beta-carotene. Nutritional additive for all species and categories	EFSA-Q-2009-00884
Vitamin B6. Nutritional additive for all species and categories	EFSA-Q-2009-00883
Chemically defined flavourings. Group 25 - Phenol derivatives containing ring-alkyl, ring-alkoxy, and side-chains with an oxygenated functional group. Sensory additive for all species and categories	EFSA-Q-2009-00882
Taminizer D (dimethylglycine sodium salt). Zootechnical additive for chickens for fattening	EFSA-Q-2009-00881
SBS (sodium bisulphate). Technological, sensory and zootechnical additive 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
KemTRACE Zn (zinc propionate). Nutritional additive for all species	EFSA-Q-2009-00855

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
Vitamin E. Nutritional additive for all species and categories	EFSA-Q-2009-00816	30 Oct 2009
Biosprint® (*Saccharomyces cerevisiae*). Zootechnical additive for piglets (weaned)	EFSA-Q-2009-00720	04 Nov 2009

[10] http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1211903081132.htm

Canthaxanthin. Sensory additive for chickens for fattening, chickens reared for laying; laying hens, salmon and trout, other poultry, other fish, petfood and other non-food producing animals.	EFSA-Q-2009-00486	04 Nov 2009

8.3. New applications under Regulation (EC) No 1829/2003

Product	EFSA-Q-Number
Genetically modified NOVO Yeast Cream (pAK1214) as feed for pigs	EFSA-Q-2009-00867

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

The Commission has sent two new questions on feed additives under Regulation (EC) No 178/2002 since the last Plenary meeting.

Mandate	EFSA-Q-Number
Question on specific guidelines for the authorisation of additives belonging to the new functional group of substance for reduction of the contamination of feed by mycotoxins	EFSA-Q-2009-00894
Technical assistance to assess the draft Codex MRLs for Narasin in cattle and pigs tissue	EFSA-Q-2009-00878

9. GENERAL INFORMATION FROM EFSA

- The CEF Panel has opened a public consultation on "Guidance on the data required for the risk assessment of flavourings". The consultation is open on the EFSA website until 7th December.[11]
- The Scientific Coordinator (SC) informed the Panel about the EFSA Workshop on Systematic Review and Risk Assessment in food and feed safety that will take place in February at EFSA.

10. MISCELLANEOUS

- A working group has been set to deal with the question on the development of specific guidelines for the authorisation of additives belonging to the new functional group of substances for reduction of the contamination of feed by mycotoxins.
- The dates for the Plenary meeting in December have been changed. The meeting will take place on 9-10 December.
- The SC informed the Panel about an amendment needed in Table 1 of the guidance for the preparation of dossiers on sensory additives[12] adopted in the last plenary, since a miscalculation was detected. The SC proposed to modify the table to remove the data that was miscalculated. The Panel agreed on the proposal and a working group meeting was set in order to allow the working group to revise and propose an amended version at the next Plenary meeting.

[11] http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1211902971427.htm
[12] http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1211902967516.htm

Annex

INTERESTS AND ACTIONS RESULTING FROM THE SCREENING OF SDOIs

In her SDoI Dr Maria Saarela declared the following interest: the Institute where she works performed some research activities related to the product Bonvital (*Enterococcus faecium*) for dogs 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,[13] that is to be excluded from participating in EFSA activities concerned by the potential conflict in question.

[13] 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