

**MINUTES OF THE 60<sup>TH</sup> PLENARY MEETING  
OF THE SCIENTIFIC PANEL ON ADDITIVES AND PRODUCTS OR SUBSTANCES USED IN  
ANIMAL FEED**

**(PARMA, 7-9 JULY 2009)**

**(ADOPTED ON 15 SEPTEMBER 2009)**

**PARTICIPANTS**

Panel Members

Gabriele Aquilina, Georges Bories, Paul Brantom, Francesca Caloni, Andrew Chesson (1<sup>st</sup> and 2<sup>nd</sup> day), Pier Sandro Cocconcelli, Noël Dierick, Mikolaj Antoni Gralak, Jürgen Gropp, Ingrid Halle (1<sup>st</sup> and 2<sup>nd</sup> day), Nils-Gunnar Ilbäck, Reinhard Kroker, Lubomir Leng, Sven Lindgren, Anne-Katrine Lundebye Haldorsen, Alberto Mantovani (2<sup>nd</sup> and 3<sup>rd</sup> days), Miklós Mézes, Derek Renshaw and Maria Saarela.

Apologies

Andrew Chesson (3<sup>rd</sup> day), Ingrid Halle (3<sup>rd</sup> day), Joop de Knecht, Peadar Lawlor and Alberto Mantovani (1st day).

EFSA

Claudia Roncancio-Peña, Jaume Galobart, Montserrat Anguita, Matteo Innocenti (scientific staff), Nicola Reynolds (administrative staff).

European Commission

Marta Ponghellini, Marina Marini (DG SANCO).

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**1. WELCOME AND APOLOGIES FOR ABSENCE**

The Chair opened the meeting and welcomed the participants to the 60<sup>th</sup> 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**

In accordance with EFSA's Policy on Declarations of Interests, EFSA screened the Annual Declaration of interest (ADoI) and Specific Declaration of interest (SDoI) filled in by the experts invited for the present meeting. No conflicts of interests related to the issues discussed

in this meeting have been identified during the screening process or at the beginning of this meeting.

#### 4. ADOPTION OF THE DRAFT MINUTES OF THE 59<sup>TH</sup> PLENARY MEETING ON 16-17 JUNE 2009

The minutes of the 59<sup>th</sup> Plenary meeting of the Scientific Panel held on 16-17 June 2009 were reviewed and adopted.<sup>1</sup>

#### 5. WORK PROGRAM

##### 5.1. Discussion and possible adoption of the following scientific opinions

###### - **Ronozyme<sup>®</sup> ProAct (serine protease) for chickens for fattening (EFSA-Q-2008-431)**

The Chair of 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 seeking the authorisation of this product as a zootechnical additive for chickens for fattening. This enzyme is produced by a genetically modified micro-organism. The safety of the genetic modification has been assessed by the GMO Panel.<sup>2</sup>

The draft opinion was reviewed. The Panel concluded that the additive is safe for the target species, consumer and the environment under the proposed conditions of use. The product is a skin irritant and it is considered a potential skin and respiratory sensitizer. The Panel also considered that the potential efficacy of the additive has been demonstrated in chickens for fattening.

The opinion was adopted.<sup>3</sup>

###### - **AveMix<sup>®</sup> 02 CS (endo-1,3(4)-beta-glucanase and endo-1,4-beta-xylanase and pectinase) for weaned piglets (EFSA-Q-2008-432)**

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 weaned piglets.

The draft opinion was reviewed. The product is considered safe for the target species at the recommended use level, the consumer and the environment. The product is considered a non-irritant to eyes and skin but it is considered a dermal and respiratory sensitizer. The Panel could not conclude on the efficacy of the additive for piglets.

The opinion was adopted.<sup>4</sup>

###### - **Natuphos<sup>®</sup> (3-phytase) for pigs for fattening (EFSA-Q-2008-692)**

The Rapporteur from the WG presented the question and the draft opinion. This question refers to an application for the change of terms of authorisation of a feed additive under Article 13(3) of Regulation (EC) No 1831/2003. The additive is currently authorised for use

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<sup>1</sup> [http://www.efsa.europa.eu/EFSA/Event\\_Meeting/feedap\\_minutes\\_59th\\_plenmeet.pdf?ssbinary=true](http://www.efsa.europa.eu/EFSA/Event_Meeting/feedap_minutes_59th_plenmeet.pdf?ssbinary=true)

<sup>2</sup> Adopted by the GMO Panel on 2 July 2009.

<sup>3</sup> [http://www.efsa.europa.eu/EFSA/efsa\\_locale-1178620753812\\_1211902706995.htm](http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1211902706995.htm)

<sup>4</sup> [http://www.efsa.europa.eu/EFSA/efsa\\_locale-1178620753812\\_1211902700890.htm](http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1211902700890.htm)

in pigs for fattening at a minimum dose of 280 FTU kg<sup>-1</sup> feed. The applicant is seeking the authorisation to reduce the minimum dose to 100 FTU kg<sup>-1</sup> feed.

The draft opinion was reviewed. The Panel considers that there is sufficient evidence to support the efficacy of Natuphos at the minimum dose proposed of 100 FTU kg<sup>-1</sup> feed.

The opinion was adopted.<sup>5</sup>

## 5.2. Discussion of the following scientific opinions

### - **Formi™ LHS (potassium diformate) for sows (EFSA-Q-2008-693)**

The Rapporteur from 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 applicant is requesting authorisation for the use of this additive, based on potassium diformate, in sows.

The draft opinion was reviewed and discussion took place. The opinion will be presented in the September plenary for adoption, once the report from the Community Reference Laboratory is available.

## 6. PROGRESS REPORT ON ONGOING WORK

Not discussed.

## 7. FEEDBACK FROM THE SCIENTIFIC COMMITTEE

Daniela Maurici, scientific officer from the Scientific Committee and Advisory Forum unit, gave a presentation to the Panel on two recent opinions adopted by the Scientific Committee: “Existing approaches incorporating replacement, reduction and refinement of animal testing: applicability in food and feed risk assessment”<sup>6</sup> and “Guidance of the Scientific Committee on Transparency in the Scientific Aspects of Risk Assessments carried out by EFSA. Part 2: General Principles”.<sup>7</sup>

## 8. NEW REQUESTS TO EFSA RECEIVED FROM THE EUROPEAN COMMISSION

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

The Commission has forwarded to EFSA two 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:

- **Lactiferm® (*Enterococcus faecium*)**. Zootechnical additive for piglets and calves (EFSA-Q-2009-00679)
- **BioPlus 2B® (*Bacillus licheniformis* and *Bacillus subtilis*)**. Zootechnical additives for piglets, pigs for fattening, sows, turkeys for fattening and calves (EFSA-Q-2009-00680)

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

Applications considered valid for the start of the assessment:

- **Lactiferm® (*Enterococcus faecium*)**. Zootechnical additive for chickens for fattening. (EFSA-Q-2009-00202) Validated on 02/07/2009.

<sup>5</sup> [http://www.efsa.europa.eu/EFSA/Scientific\\_Opinion/feedap\\_op\\_ej1184\\_Natuphos\\_en.pdf?ssbinary=true](http://www.efsa.europa.eu/EFSA/Scientific_Opinion/feedap_op_ej1184_Natuphos_en.pdf?ssbinary=true)

<sup>6</sup> [http://www.efsa.europa.eu/EFSA/efsa\\_locale-1178620753812\\_1211902559349.htm](http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1211902559349.htm)

<sup>7</sup> [http://www.efsa.europa.eu/EFSA/efsa\\_locale-1178620753812\\_1211902597244.htm](http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1211902597244.htm)

- **Protural (sodium benzoate)**. Zootechnical additive for piglets. (EFSA-Q-2009-00446)  
Validated on 24/06/2009.

## 9. GENERAL INFORMATION FROM EFSA

Not discussed

## 10. MISCELLANEOUS

- Following the appointment of the new FEEDAP Panel, working groups were established.
- The Chair of the WG on trace elements presented a proposal for 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 request for the self-task will now be sent to the Executive Director for endorsement.
- A discussion took place, based on an expert report provided by an industry association, on the potential of micro-organisms used as feed additive to induce respiratory sensitisation. The Panel decided to establish a self-task to address this issue.
- A discussion took place on the evaluation of the worker/user inhalatory exposure to coccidiostats, considering a new model proposed by the WG. After discussion the Panel has agreed to use this exposure model in evaluating inhalatory exposure and agreed to modify the guidance document on the worker/user safety accordingly.
- The dates for the Plenary meetings of the FEEDAP Panel for 2010 were decided: 2-4 February, 10-11 March, 7-8 April, 25-27 May, 22-24 June, 13-15 July, 7-9 September, 5-7 October, 9-11 November and 7-9 December.