MINUTES OF THE 61ST PLENARY MEETING

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

(PARMA, 15-16 SEPTEMBER 2009)

(ADOPTED ON 13 OCTOBER 2009)

PARTICIPANTS

Panel Members

Gabriele Aquilina, Georges Bories, Paul Brantom, Francesca Caloni, Andrew Chesson, Pier Sandro Cocconcelli, Joop de Knecht, Mikolaj Antoni Gralak, Jürgen Gropp, Ingrid Halle (1st day), Nils-Gunnar Ilbäck, Reinhard Kroker, Peadar Lawlor, Lubomir Leng, Sven Lindgren (1st day), Anne-Katrine Lundebye Haldorsen, Alberto Mantovani, Miklós Mézes, Derek Renshaw and Maria Saarela.

Apologies

Noël Dierick, Ingrid Halle (2nd day) and Sven Lindgren (2nd day).

EFSA

Claudia Roncancio-Peña, Jaume Galobart, Lucilla Gregoretti, Rosella Brozzi (scientific staff), Ketty Antonelli (administrative staff).

European Commission

Marina Marini (DG SANCO), Christoph von Holst (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 61st 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 60TH PLENARY MEETING ON 7-9 JULY 2009

The minutes of the 60th Plenary meeting of the Scientific Panel held on 7-9 July 2009 were reviewed and adopted.[1]

5. WORK PROGRAM

5.1. Discussion and possible adoption of the following scientific opinions

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

  The Rapporteur from the Working Group (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 the re-evaluation of the use of this additive, based on potassium diformate, in sows.

  The draft opinion was already discussed in the July Plenary. The report from the Community Reference Laboratory has been received and verified. The Panel considers that the product Formi™ LHS is safe for the target species, the consumer and the environment. The risks for the user are basically restricted to its eye irritancy potential. The data provided in the dossier supports the efficacy of the additive at the highest inclusion rate in feed (1.2%) but not at the minimum dose proposed by the applicant (0.8%).

  The opinion was adopted.[2]

- ***Bacillus subtilis* PB6 (*Bacillus subtilis*) for chickens for fattening (EFSA-Q-2008-473)**

  The Chair of 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.

  The draft opinion was reviewed. The active agent is considered by EFSA to qualify for QPS status, and since its identity has been confirmed, the product is considered safe for the target species, consumer and the environment under the proposed conditions of use. The product is also considered safe for the users. The Panel also concluded that evidence of efficacy of the additive at the minimum recommended dose has been demonstrated in chickens for fattening. Additionally, the compatibility of *Bacillus subtilis* PB6 with the coccidiostats decoquinate, diclazuril, salinomycin sodium, narasin/nicarbazin and lasalocid A sodium has been demonstrated

  The opinion was adopted.[3]

- **Mintrex® Mn (manganese chelate of hydroxy analogue of methionine) for chickens for fattening (EFSA-Q-2009-00489)**

  The Rapporteur from the WG presented the question and the draft opinion. EFSA has been requested to deliver an opinion on the safety for the consumer of the product manganese chelate of hydroxyl analogue of methionine. In a previous opinion,[4] the FEEDAP Panel

[1] http://www.efsa.europa.eu/EFSA/Event_Meeting/feedap_minutes_60th_plenmeet_en.pdf?ssbinary=true
[2] http://www.efsa.europa.eu/EFSA/Scientific_Opinion/feedap_op_ej1315_formi_lhs_sw_en.pdf?ssbinary=true
[3] http://www.efsa.europa.eu/EFSA/Scientific_Opinion/feedap_op_ej1314_bacillus_subtilis_pb6_cff_en,3.pdf?ssbinary=true
[4] http://www.efsa.europa.eu/EFSA/Scientific_Opinion/feedap_op_ej692_mintrex_mn_en.pdf?ssbinary=true

could not conclude on the safety for the consumer due to the lack of data on Mn deposition in edible tissues.

The draft opinion was reviewed. The applicant has provided new data on the deposition of Mn in edible tissues of chickens for fattening. Based on the new data, the Panel concluded that Mintrex®Mn would not increase Mn deposition in edible tissues of chickens for fattening compared to other authorised inorganic Mn sources for which it would substitute. Consequently, the use of Mintrex®Mn as a feed additive for chickens for fattening is unlikely to present a safety concern to consumers.

The opinion was adopted.[5]

5.2. Discussion of the following scientific opinions

- **L-isoleucine for all animal species (EFSA-Q-2009-00456)**

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 nutritional additive for all animal species. L-isoleucine is produced by the genetically modified micro-organism *Escherichia coli* (K-12 3149 – FERM ABP-10641). The safety aspects of the genetic modification are being assessed by the GMO Panel.

The draft opinion was reviewed. A first discussion took place. However, due to lack of time, the discussion will continue in the next plenary meeting.

6. PROGRESS REPORT ON ONGOING WORK

Not discussed.

7. FEEDBACK FROM THE SCIENTIFIC COMMITTEE

Bernard Bottex, Scientific Officer from the Scientific Committee and Advisory Forum unit, gave a presentation to the Panel on the use of the benchmark dose approach in risk assessment, following the publication of the "Guidance of the Scientific Committee on Use of the benchmark dose approach in risk assessment".[6]

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 eight 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:

- **Formic acid.** Technological additives for all species (EFSA-Q-2009-00715)
- **Bactocell (*Pediococcus acidilactici*).** Zootechnical additive for laying hens (EFSA-Q-2009-00716)
- ***Pediococcus pentosaceus* (DSM 16244)**. Technological additive for all species (EFSA-Q-2009-00717)

[5] http://www.efsa.europa.eu/EFSA/Scientific_Opinion/feedap_op_ej1316_mintrex_mn_cff_en.pdf?ssbinary=true

[6] http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1211902629553.htm

- **Bactocell (*Pediococcus acidilactici*).** Zootechnical additives for piglets (weaned) (EFSA-Q-2009-00719)
- **Biosprint® (*Saccharomyces cerevisiae*).** Zootechnical additives for piglets (weaned) (EFSA-Q-2009-00720)
- **Sel-Plex (organic form of selenium produced by *Saccharomyces cerevisiae*).** Zootechnical additive for all animal species (EFSA-Q-2009-00752)
- **Biosprint® (*Saccharomyces cerevisiae*).** Zootechnical additives for horses (EFSA-Q-2009-00753)
- **Clinoptilolite of sedimentary origin.** Technological additive for all animal species (EFSA-Q-2009-00754)

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

Applications considered valid for the start of the assessment:

- **Soda ash (Sodium carbonate).** Technological additive for all animals (EFSA-Q-2008-694) Validated on 17 July 2009.
- **Animavit (*Bacillus subtilis*).** Zootechnical additive for piglets (weaned) and pigs for fattening (EFSA-Q-2008-771) Validated on 16 July 2009.
- **Monteban (Narasin).** Coccidiostat for chickens for fattening (EFSA-Q-2009-00502) Validated on 6 July 2009.
- **Natuphos (3-phytase).** Zootechnical additive for minor species (EFSA-Q-2009-00603) Validated on 7 September 2009.

8.3. Self-tasks of EFSA

- **Assessment of the use of cobalt compounds as additive in animal nutrition** (EFSA-Q-2009-00721)
- **Grant on a bibliographic review on the potential of micro-organisms, microbial products an enzymes to induce respiratory sensitisation** (EFSA-Q-2009-00789)

9. GENERAL INFORMATION FROM EFSA

- Davide Arcella, Scientific Officer of the DATEX unit of EFSA gave a presentation on the work of EFSA on food consumption data.
- Stef Bronzwaer, Senior Scientific officer of the SCO unit of EFSA, presented the new EFSA Journal and the new template for opinions.

10. PRESENTATION ON THE ACTIVITIES OF THE COMMUNITY REFERENCE LABORATORY FOR FEED ADDITIVES

Christoph von Holst, the Operating Manager of the CRL for Feed Additives, gave a presentation on the different activities of the CRL.

11. MISCELLANEOUS

- The Scientific Coordinator informed the Panel about the arrangements for the next Plenary meeting, which will take place on 13-15 October in Vienna, Austria.