Scientific Panel on Additives and Products or Substances Used in Animal Feed (FEEDAP)

Minutes of the 95th Plenary Meeting

Held on 16-18 April 2013, Parma

(Agreed on 18 June 2013)

Participants

- **Panel Members**

  Gabriele Aquilina, Vasileios Bampidis, Maria De Lourdes Bastos, Mikolaj Antoni Gralak, Christer Hogstrand, Lubomir Leng, Secundino López-Puente, Giovanna Martelli, Baltasar Mayo, Derek Renshaw, Guido Rychen,[1] Maria Saarela, Kristen Sejrsen, Patrick van Beelen and Johannes Westendorf.

- **Hearing Experts**

  Andrew Chesson[2] (for item 5.10)

- **European Commission**

  N/A

- **EFSA**

  - **FEED Unit:** Claudia Roncancio-Peña, Jaume Galobart, Montserrat Anguita, Gloria López-Gálvez, Rosella Brozzi, Lucilla Gregoretti, Paola Manini, Nicola Jane Reynolds and Cecilia Lloyd.
  - **SCISTRAT Directorate:** Andras Szoradi[3]

- **Observers**

  N/A

1. Welcome and apologies for absence

The Chair welcomed the participants.

Apologies were received from Alex Bach, Lucio Guido Costa, Gerhard Flachowsky, Fernando Ramos and John Wallace.

The Chair informed that Lucio Guido Costa and Fernando Ramos have been appointed by the Management Board as members of the Panel.

The Chair welcomed Cecilia Lloyd who has recently joined the FEED unit.

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1 Present only on 16 and 17 April.
2 Present only on 16 April.
3 Present only on 17 April.

2. Adoption of agenda

The agenda was adopted after the deletion of the item "Iron amino acid chelate hydrate (Availa® Fe) for all animal species (EFSA-Q-2012-00490)".

3. Declarations of interest

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes[4] and the Decision of the Executive Director implementing this Policy regarding Declarations of Interests,[5] EFSA screened the Annual Declaration of Interest and the Specific Declaration of Interest 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 Oral Declaration of Interest at the beginning of this meeting.

4. Agreement of the minutes of the 94th Plenary meeting held on 12-14 March 2013

The minutes of the 94th Plenary meeting were reviewed and agreed.[6]

5. Scientific outputs submitted for discussion and possible adoption[7]

5.1. Chemically defined flavourings from Flavouring Group 20 - Aliphatic and aromatic mono- and di- thiols and mono-, di-, tri-, and polysulfides with or without additional oxygenated functional groups for all animal species and categories (EFSA-Q-2010-00998)

The rapporteur presented the question and the draft opinion. This question refers to the re-evaluation under Article 10 and the authorisation under Article 4 of Regulation (EC) No 1831/2003 of the chemically defined flavourings from Chemical Group 20[8] as sensory additives for all animal species.

The draft opinion was discussed. The Panel was unable to perform an assessment on six compounds (methanethiol, methyl propyl disulphide, dipropyl trisulphide, 3-mercaptobutan-2-one, 3-(methylthio)butanal and 3-methyl-1,2,4-trithiane) because of lack of data on their purity. The Panel concluded that, when used at the maximum proposed level (0.05 mg/kg complete feed), the remaining 25 compounds are safe for the target species, the consumer (except allyl isothiocyanate, for which the exposure is higher than the acceptable daily intake) and the environment (except for 2-methylpropane-1-thiol, where 0.04 mg/kg is expected to be safe). All compounds should be considered as irritants to skin, eyes and respiratory tract, and as skin sensitisers. Since all 25 compounds are used in food as flavourings, no further demonstration of efficacy is necessary.

The opinion was adopted.[9]

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4 http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf
5 http://www.efsa.europa.eu/en/keydocs/docs/independencerules.pdf
6 http://www.efsa.europa.eu/en/events/event/130312-m.pdf
7 During the scientific risk assessment process of each output, the relevant guidelines and guidance documents have been followed.
8 During the assessment, the applicant withdrew the application for dimethyl tetrasulphide. The compounds 8-mercapto-p-menthan-3-one and p-menth-1-ene-8-thiol will be assessed in a separate opinion.
9 http://www.efsa.europa.eu/en/efsajournal/pub/3208.htm

5.2. Hostazym C (endo-1,4-beta-glucanase) for chickens for fattening all other birds for fattening except turkeys and weaned piglets (EFSA-Q-2010-01025)

The rapporteur presented the question and the draft opinion. This question refers to the re-evaluation under Article 10 and the authorisation under Article 4 of Regulation (EC) No 1831/2003 of the product Hostazym C (endo-1,4-beta-glucanase) as a zootechnical additive for chickens for fattening, all other birds for fattening except turkeys and weaned piglets.

The draft opinion was discussed. The Panel could not conclude on the safety of the product for the target species nor on the safety for the consumers of products obtained from animals receiving the additive due to the presence in the fermentation product of genotoxic activity. Moreover it was concluded that any level of exposure of users to the additive is hazardous. The additive has the potential to be efficacious in the target species at the corresponding recommended dose.

The opinion was adopted.

5.3. Sodium saccharin for pigs, piglets (suckling and weaned), pigs for fattening, calves for rearing, calves for fattening (EFSA-Q-2010-01228)

Not discussed due to lack of time

5.4. Betaine anhydrous for all animal species (EFSA-Q-2011-00258)

The rapporteur presented the question and the draft opinion. This question refers to the re-evaluation under Article 10 and the authorisation under Article 4 of Regulation (EC) No 1831/2003 of betaine anhydrous as a nutritional additive for all animal species.

The draft opinion was discussed. The Panel concluded that betaine anhydrous at the maximum supplementation rate of 2 000 mg/kg complete feed is safe for the target species, the consumer and the environment. Betaine anhydrous should be considered as an irritant to skin, eyes and mucous membranes, and as a skin sensitiser. The Panel also concluded that betaine has the potential to become efficacious in all animal species and categories when administered via feed or water for drinking. The FEEDAP Panel recommended the introduction of a maximum content for supplemental betaine in complete feed and water for drinking.

The opinion was adopted.[10]

5.5. Betaine in the form of betaine anhydrous and betaine hydrochloride for all animal species (EFSA-Q-2011-00259)

A member of the working group presented the question and the draft opinion. This question refers to the re-evaluation under Article 10 and the authorisation under Article 4 of Regulation (EC) No 1831/2003 of betaine anhydrous and betaine hydrochloride as nutritional additives for all animal species.

The draft opinion was discussed. The Panel concluded that betaine at the maximum supplementation rate of 2 000 mg/kg complete feed is safe for the target species, the consumer and the environment. Both should be considered as hazardous by inhalation, as irritants to skin and eyes and mucous membranes, and as skin sensitisers. The Panel also concluded that both compounds are regarded as effective sources of betaine and that betaine has the potential to become efficacious in all animal species

[10] http://www.efsa.europa.eu/en/efsajournal/pub/3209.htm

and categories when administered via feed or water for drinking. The FEEDAP Panel recommended the introduction of a maximum content for supplemental betaine in complete feed and water for drinking.

The opinion was adopted.[11]

5.6. Betaine anhydrous for all animal species (EFSA-Q-2011-00260)

A member of the working group presented the question and the draft opinion. This question refers to the re-evaluation under Article 10 and the authorisation under Article 4 of Regulation (EC) No 1831/2003 of betaine anhydrous as a nutritional additive for all animal species.

The draft opinion was discussed. The Panel concluded that betaine anhydrous at the maximum supplementation rate of 2 000 mg/kg complete feed is safe for the target species, the consumer and the environment. Betaine anhydrous should be considered as an irritant to skin, eyes and mucous membranes, and as a skin sensitiser. The Panel also concluded that betaine has the potential to become efficacious in all animal species and categories when administered via feed or water for drinking. The FEEDAP Panel recommended the introduction of a maximum content for supplemental betaine in complete feed and water for drinking.

The opinion was adopted.[12]

5.7. *Lactobacillus plantarum* (NCIMB 40027) for all animal species (EFSA-Q-2011-00944)

The Chair of the working group presented the question and the draft opinion. This question refers to the re-evaluation under Article 10 of Regulation (EC) No 1831/2003 of *Lactobacillus plantarum* (NCIMB 40027) as a silage additive for all animal species.

The draft opinion was discussed. The Panel concluded that the additive is presumed safe for livestock species, consumers and the environment. The Panel considered it prudent to treat this additive as respiratory a sensitiser. The additive has the potential to improve the ensiling process in all forages.

The opinion was adopted.[13]

5.8. L-Selenomethionine for all animal species (EFSA-Q-2011-01109)

The rapporteur presented the question and the draft opinion. This question refers to the authorisation under Article 4 of Regulation (EC) No 1831/2003 of L-selenomethionine as a nutritional additive for all animal species.

The draft opinion was discussed. However, due to lack of quorum, the opinion will be submitted for written adoption.

5.9. Lancer (Lanthanide-citrate) for piglets (weaned) (EFSA-Q-2012-00287)

The rapporteur presented the question and the draft opinion. This question refers to the authorisation under Article 4 of Regulation (EC) No 1831/2003 of Lancer (lanthanide-citrate) as a zootechnical additive for weaned piglets.

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11 http://www.efsa.europa.eu/en/efsajournal/pub/3210.htm
12 http://www.efsa.europa.eu/en/efsajournal/pub/3211.htm
13 http://www.efsa.europa.eu/en/efsajournal/pub/3205.htm

The draft opinion was discussed. The Panel could not conclude on the safety of the additive for the target species, the consumer and the environment due to lack of data. The Panel concluded that the additive is not irritant to skin or eyes nor is a skin sensitizer, but that exposure by inhalation should be avoided. The additive has the potential to be efficacious in weaned piglets.

The opinion was adopted.[14]

5.10. Biomin® BBSH 797 - DSM 11798 Genus nov. (formerly *Eubacterium*) species nov. for pigs (EFSA-Q-2012-00719)

The rapporteur presented the question and the draft opinion. This question refers to the authorisation under Article 4 of Regulation (EC) No 1831/2003 of the microorganism DSM 11798 as a technological additive for pigs.

The draft opinion was discussed. The Panel concluded that the microbial strain needs probably to be allocated to a new taxonomic unit within the *Coriobacteriaceae* family. The additive is considered safe for weaned piglets and pigs for fattening, for consumers and the environment. Concerns for users are limited to respiratory sensitisation. The Panel concluded that the additive has the capacity to biotranform trichothecenes in pigs.

The opinion was adopted.[15]

5.11. Lenziaren (iron aqua carbonate hydroxy oxo starch sucrose complex) for cats (EFSA-Q-2012-00789)

The rapporteur presented the question and the draft opinion. This question refers to the authorisation under Article 4 of Regulation (EC) No 1831/2003 of Lenziaren (iron aqua carbonate hydroxy oxo starch sucrose complex) as a zootechnical additive for cats.

The draft opinion was discussed. The Panel concluded that the additive is safe for adult cats, but notes that the consequences of chronic exposure have not been investigated. No concerns for users/owners have been expressed. The additive has the potential to be efficacious in reducing phosphorus absorption, but the Panel has some reservations on the value of its long term use in healthy cats. The Panel considered that there is a need for a post-market monitoring plan.

The opinion was adopted.[16]

6. New Mandates

6.1. 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 presented to the Panel, who accepted them:

EFSA-Q-Number	Subject
EFSA-Q-2013-00325	Chemically defined flavourings from Chemical Group 20 - aliphatic and aromatic mono- and di-thiols and mono-, di-, tri-, and polysulphides with or without additional oxygenated functional groups

14 http://www.efsa.europa.eu/en/efsajournal/pub/3206.htm
15 http://www.efsa.europa.eu/en/efsajournal/pub/3203.htm
16 http://www.efsa.europa.eu/en/efsajournal/pub/3174.htm

	when used as flavourings: 8-mercapto-p-menthan-3-one and p-menth-1-ene-8-thiol for all animal species and categories

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

EFSA-Q-Number	Subject
EFSA-Q-2013-00278	Zinc amino acid chelate hydrate for all animal species

6.3. Self-tasks

EFSA-Q-Number	Subject
EFSA-Q-2013-00303	Update of Technical Guidance on the assessment of the toxigenic potential of *Bacillus* species used in animal nutrition

6.4. Other mandates

EFSA-Q-Number	Subject
EFSA-Q-2013-00094	Internal mandate proposed by EFSA to the FEED Unit for a procurement (Framework contract) on the preparatory work to support the re-evaluation of feed additives: technological additives (445 000 €).
EFSA-Q-2013-00297	Internal Mandate proposed by EFSA to the FEED Unit for a procurement (Direct Service contract) on the preparatory work to support the re-evaluation of feed additives: botanically defined feed flavouring additives (200 000 €)

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

Applications considered valid for the start of the assessment:

#	EFSA-Q-Number	Subject	Valid on
1	EFSA-Q-2012-00942	DL-Methionyl-DL-Methionine for all aquatic animals species	11/03/2013
2	EFSA-Q-2012-00947	Complexation products of sodium tartrates with iron(III) chloride for all animal species	02/04/2013

These applications were assigned to the working groups on Amino acids (#1) and Technological additives (#2).

7. Feedback from the Scientific Committee/the Scientific Panel, Working Groups, EFSA, the European Commission

- The Panel was informed that the Executive Director has accepted the proposed self-task on the “Update of Technical Guidance on the assessment of the toxigenic potential of *Bacillus* species used in animal nutrition” (EFSA-Q-2013-00303, see 6.3 above). A new working group has been created to address this mandate. The draft updated guidance will be subject to public consultation.
- The Chair of the Panel provided feedback from the last Scientific Committee meeting.

- The Panel was informed on the progress regarding the evaluation of Formaldehyde.
- The Panel was informed on the progress regarding the evaluation of Allura Red.
- The FEED Unit has launched two procurement calls to support the work of the Panel in the re-evaluation of feed additives (see 6.4 above).
- A member of the SCISTRAT Directorate made a presentation regarding the EFSA project for opening up Panel plenary meetings.

8. Other scientific topics for information and/or discussion

Not discussed

9. Any other business

The plenary meeting in May (14-16 May) has been cancelled. The next plenary will take place on 18-20 June, and will be partially open to observers.