Scientific Panel on Additives and Products or Substances used in Animal Feed

Minutes of the 128th Plenary meeting

Held on 26-28 September 2017, Parma (Italy)

Meeting open to Observers
(Open session: 26 September 2017, 14:00-18:00h
27 September 2017, 9:00-18:00h)
(Agreed by written procedure on 9 October 2017)

Participants

Panel Members
Gabriele Aquilina, Giovanna Azimonti, Vasileios Bampidis, Maria de Lourdes Bastos, Andrew Chesson, Pier Sandro Cocconcelli1, Gerhard Flachowsky, Jürgen Gropp, Boris Kolar, Maryline Kouba, Marta López-Alonso, Secundino López Puente2, Alberto Mantovani, Baltasar Mayo, Fernando Ramos, Guido Rychen, Maria Saarela, Roberto Edoardo Villa, Robert John Wallace and Pieter Wester.

Hearing Experts:
N/A

European Commission and/or Member States representatives:
Marta Ponghellini (DG SANTE).

EFSA:

FEED Unit: Jaime Aguilera, Montserrat Anguita, Agnese Balzani, Rosella Brozzi, Jaume Galobart, Lucilla Gregoretti, Orsolya Holczknecht, Matteo Lorenzo Innocenti, Gloria López-Gálvez, Paola Manini, Jordi Tarrés-Call, Manuela Tiramani and Maria Vittoria Vettori.

DATA Unit: Bruno Dujardin3

1 Participated only on 26 September 2017.
2 Participated via tele-webconference only on 28 September 2017.
3 Participated only on 27 September 2017.
■ Observers

- **Attending physically in Parma:** Yara Antonissen (FEFANA), Pablo Arias Echeverria (Fertinagro), Maria Cambra (Universitat Politecnica de Valencia), Clémentine Hincelin (Adisseo), David John (IFAH-Europe), Manfred Kuhn (Glycomer GmbH), Manfred Luetzow (saqual GmbH), Elinor McCartney (Pen & Tec Consulting Group), Gilles Morelle (Puratos NV), Laura Payo Lewis (Pen & Tec Consulting SLU), Manfred Peisker (ADM Specialty Ingredients (Europe) B.V.), Xhilda Pepa (National Food Authority Albania), Mirka Piskorikova (Elanco), Susann Richert (Evonik Nutrition & Care GmbH), Regine Schreiner (Self-employed), Davy Van Gaver (Huvepharma NV)

- **Attending via webstreaming:** Alexandra Lensch (Evonik), Amparo de Benito (AINIA), Audrey Kelly (Elanco), Bas Verhagen (Puratos), Daniela Rabe (Evonik), Eeva Saarisalo (MAA-Ja Metsätalousministeriö, Finland), Francesca Irene Pietrantonio (Ministero della Salute, Italy), Gerry Dillon (Alltech), Heinrich Schrage (Lanxess), Helena Oliveira (Trouw Nutrition), Karin Schöndorfer (Biomin), Katrin Grothaus (Biochem), Marie-Julie Hannoun (Ajinomoto Eurolysine), Marta Isabel Gracia (Imasde), Martijn Sen (College ter Beoordeling van Geneesmiddelen), Pablo Belmar von Kretschmann (Intertek), Pauliina Halimaa (Biosafe), Quentin Royer (Diana petfood), Susanne Dr. Pippig (Lanxess) and Valeria Paganizza (Food-law.it)

1. **Welcome and apologies for absence**

The Chair welcomed the participants. Apologies were received from Georges Bories.

2. **Adoption of agenda**

The agenda was adopted without changes.

3. **Declarations of Interest of Scientific Panel members**

In accordance with EFSA’s Policy on Independence and Scientific Decision-Making Processes and the Decision of the Executive Director on Declarations of Interest, EFSA screened the Annual Declarations of Interest and the Specific Declarations of Interest filled in by the Scientific Panel Members invited for the present meeting. No Conflicts of Interest

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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 127th Plenary meeting held on 4-6 July 2017**

The minutes of the 127th Plenary meeting held on 4-6 July 2017 were agreed by written procedure on 13 July 2017.⁷

5. **Scientific outputs submitted for discussion and/or possible adoption**

   5.1 **ENZY CARBOPLUS®** (preparation of Xylanase (EC 3.2.1.8) and beta-glucanase (EC 3.2.1.6) for chickens for fattening, laying hens, turkeys for fattening, piglets (weaned), avian species (game birds, ducks, geese, pigeons, sporting and ornamental birds) including laying birds, chickens reared for laying and turkeys reared for breeding *(EFSA-Q-2013-00528)*

   Not discussed due to lack of time.

   5.2 **Natuphos® E** (6-phytase) for all pigs and all avian species *(EFSA-Q-2015-00054 and EFSA-Q-2015-00732)*

   The rapporteur presented the questions and the draft opinion. These question refer to the authorisation under Article 4 of Regulation (EC) No 1831/2003 of Natuphos® E (6-phytase) as a zootechnical additive for all pigs and all avian species.

   The draft opinion was discussed. Discussion focussed mainly on the characterisation, safety for the target species, consumer and user and the efficacy of the additive. The opinion was unanimously adopted.

   5.3 **Natural essential oil from Origanum vulgare L. ssp. hirtum var. Vulkan** (DOS 00001) *(EFSA-Q-2016-00112)*

   Not discussed due to lack of time.

   5.4 **Zinc-L-selenomethionine** for all animal species *(EFSA-Q-2016-00554)*

   Not discussed due to lack of time.

   5.5 **RONOZYME® WX** (endo-1,4-beta-xylanase) for laying hens *(EFSA-Q-2016-00842)*

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⁷ http://www.efsa.europa.eu/sites/default/files/event/170704-0-m.pdf
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 RONOZYME® WX (endo-1,4-beta-xylanase) as a zootechnical additive for laying hens.

The draft opinion was discussed. Discussion focussed on the characterisation, safety for the target species and the efficacy of the additive. The opinion was unanimously adopted.

5.6 Benzoic acid for suckling piglets, weaned piglets, pigs for fattening, sows for reproduction, sows in order to have benefit in piglets, minor porcine species, chickens for fattening, chickens reared for laying, laying hens, breeding hens, turkeys for fattening, turkeys for breeding purposes, turkeys reared for breeding, minor poultry species (EFSA-Q-2016-00858)

Not discussed due to lack of time.

5.7 Vevovitall® (benzoic acid) for minor porcine species (EFSA-Q-2016-00861)

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 Vevovitall® as a zootechnical additive for minor porcine species.

The draft opinion was discussed. Discussion focussed on the safety for the target species and the efficacy of the additive. The opinion was unanimously adopted.

5.8 AviMatrix® (benzoic acid, calcium formate and fumaric acid) for chickens for fattening, chickens reared for laying, minor avian species for fattening and to point of lay (EFSA-Q-2017-00047)

The rapporteur presented the question and the draft opinion. EFSA has been asked to deliver an opinion on the safety and efficacy of AviMatrix® (benzoic acid, calcium formate and fumaric acid) as a zootechnical additive for chickens for fattening, chickens reared for laying, minor avian species for fattening and to point of lay based on the additional information provided by the applicant.

The draft opinion was discussed. Discussion focused on the safety for the target species and the efficacy. The opinion was unanimously adopted.
6. Welcome
The Chair welcomed all observers who attended the open session of the plenary.

7. Brief introduction of Panel members and Observers
A tour de table followed the Chair’s welcome to enable all meeting participants to introduce themselves.

8. Presentation of the EFSA Guidelines for Observers
A member of the Feed Unit presented the guidelines for observers for open plenary meetings.

9. Scientific outputs submitted for discussion and/or possible adoption

9.1 Guidance on the assessment of the safety of feed additives for the environment (EFSA-Q-2016-00400)
The Chair of the working group (WG) presented the question and the draft guidance. This question refers to the self-task of the Panel on the revision of the guidance documents. This guidance document covers the assessment of the safety of feed additives for the environment.

The guidance was not discussed in detail, but the Chair of the WG gave an overview of the main changes with respect to the current guidance. A detailed discussion will take place in a next plenary.

9.2 Guidance on the assessment of the safety of feed additives for the target species (EFSA-Q-2016-00553)
The rapporteur presented the question and the draft guidance. This question refers to the self-task of the Panel on the revision of the guidance documents. This guidance document covers the assessment of the safety of feed additives for the target species.

The draft guidance was endorsed by the FEEDAP Panel for public consultation on 22 March 2017. Discussion focussed on the modifications introduced in the guidance following the comments received in the public consultation. The guidance was unanimously adopted.
The Panel also endorsed the technical report prepared by the FEED Unit regarding the outcome of the public consultation.

9.3 **Guidance on the assessment of the safety of feed additives for the consumer (EFSA-Q-2016-00822)**

The rapporteur presented the question and the draft guidance. This question refers to the self-task of the Panel on the revision of the guidance documents. This guidance document covers the assessment of the safety of feed additives for the consumer.

The draft guidance was endorsed by the FEEDAP Panel for public consultation on 17 May 2017. Discussion focussed on the modifications introduced in the guidance following the comments received in the public consultation. The guidance was unanimously adopted.

The Panel also endorsed the technical report prepared by the FEED Unit regarding the outcome of the public consultation.

9.4 **Guidance on the identity, characterisation and conditions of use of feed additives (EFSA-Q-2016-00823)**

The rapporteur presented the question and the draft guidance. This question refers to the self-task of the Panel on the revision of the guidance documents. This guidance document covers the requirements for the proper identification and characterisation of feed additives.

The draft guidance was endorsed by the FEEDAP Panel for public consultation on 16 May 2017. Discussion focussed on the modifications introduced in the guidance following the comments received in the public consultation. The guidance was unanimously adopted.

The Panel also endorsed the technical report prepared by the FEED Unit regarding the outcome of the public consultation.

10. **New Mandates**

10.1 **New applications under Regulation (EC) No 1831/2003 since the previous meeting**

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:
<table>
<thead>
<tr>
<th>EFSA-Q-Number</th>
<th>Subject</th>
</tr>
</thead>
<tbody>
<tr>
<td>EFSA-Q-2017-00661</td>
<td>Salinomycin sodium for rabbits for fattening</td>
</tr>
<tr>
<td>EFSA-Q-2017-000542</td>
<td>L-Tryptophan produced by fermentation with <em>Escherichia coli</em> K12 KCCM80135 for all animal species</td>
</tr>
<tr>
<td>EFSA-Q-2017-00609</td>
<td>L-threonine for all animal species</td>
</tr>
<tr>
<td>EFSA-Q-2017-00610</td>
<td>L-tryptophan for all animal species</td>
</tr>
<tr>
<td>EFSA-Q-2017-00650</td>
<td>Preparation of 3-phytase (EC 3.1.3.8) produced by <em>Komagataella pastoris</em> (CECT 13094) for chickens for fattening, chickens reared for laying and minor poultry species for fattening and reared for laying, laying hens and minor poultry species for laying, pigs for fattening and minor porcine species for growing</td>
</tr>
<tr>
<td>EFSA-Q-2017-00627</td>
<td>Mixture of ZnEDTA and Cu(NH$_4$)$_2$EDTA chelates, on chicory pulp carrier, supplemented with 3b E6 ZnO and 3b E4 CuO for pigs</td>
</tr>
<tr>
<td>EFSA-Q-2017-00644</td>
<td>Sodium selenite for ruminants</td>
</tr>
<tr>
<td>EFSA-Q-2017-00632</td>
<td>Muramidase produced by <em>Trichoderma reesei</em> DSM 32338 for chickens for fattening and minor poultry species</td>
</tr>
<tr>
<td>EFSA-Q-2017-00662</td>
<td>Extract from super critical carbon dioxide extraction of <em>Humulus Lupulus</em> L. flos containing 40% beta acids with propylene glycol (Beta Rich Hop Extract - BRHE) for all animal species</td>
</tr>
<tr>
<td>EFSA-Q-2017-00648</td>
<td>Benzoic acid for pigs for fattening</td>
</tr>
<tr>
<td>EFSA-Q-2017-00651</td>
<td>endo-1,4-β-xylanase, endo-1,4-β-glucanase for sows in order to have benefit in piglets</td>
</tr>
</tbody>
</table>

10.1 **Valid applications under Regulation (EC) No 1831/2003 since the previous meeting**

Applications considered valid for the start of the assessment:

<table>
<thead>
<tr>
<th>EFSA-Q-Number</th>
<th>Subject</th>
<th>Valid on</th>
</tr>
</thead>
<tbody>
<tr>
<td>EFSA-Q-2016-00712</td>
<td><em>Lactobacillus farciminis</em> CNCM MA67/4R for piglets (weaned)</td>
<td>31/07/2017</td>
</tr>
<tr>
<td>EFSA-Q-2017-00051</td>
<td><em>Enterococcus faecium</em> NBIMCC 8270, <em>Lactobacillus acidophilus</em> NBIMCC 8242, <em>Lactobacillus helveticus</em> NBIMCC 8269, <em>Lactobacillus delbrueckii</em> ssp. lactis NBIMCC 8250, <em>Lactobacillus delbrueckii</em> ssp. bulgaricus NBIMCC 8244 and <em>Streptococcus thermophilus</em> NBIMCC 8253 for chickens for fattening, rabbits (suckling and weaned)</td>
<td>06/07/2017</td>
</tr>
<tr>
<td>EFSA-Q-2017-00485</td>
<td>L-tryptophan, technically pure produced by <em>Escherichia coli</em> CGMCC 7248 for all animal species</td>
<td>19/07/2017</td>
</tr>
<tr>
<td>EFSA-Q-2017-00501</td>
<td>L-lysine monohydrochloride and concentrated liquid L-lysine for all animal species</td>
<td>28/07/2017</td>
</tr>
<tr>
<td>EFSA-Q-2017-00481</td>
<td>Ferric tyrosine chelate for all avian species</td>
<td>18/07/2017</td>
</tr>
<tr>
<td>EFSA-Q-2017-00480</td>
<td>L-Arginine (not less than 98% expressed on dry matter basis) produced by fermentation of <em>Escherichia coli</em> (deposition Number:NITE BP-</td>
<td>18/07/2017</td>
</tr>
</tbody>
</table>
These questions were assigned to the respective working groups.

11. Feedback from the Scientific Committee/Scientific Panels, EFSA, the European Commission

   a) The Head of Unit informed the Panel on the status of the renewal of the Panel. The mandate of the current Panel will end in June 2018. The call for expressions of interest closed on 8th September and the selection of the experts for the new Panel is ongoing.

   b) The Panel was informed that the public consultation on the guidance on the characterisation of microorganisms used as feed additives or as production organisms has been closed. The comments received will now be considered by the WG and the guidance modified as relevant.


12. Other scientific topics for information and/or discussion

   d) A member of the FEED Unit gave a presentation on the requirements for the assessment of applications for the renewal of the authorisation of feed additives under Article 14 of Regulation (EC) No 1831/2003.

13. Answers to questions from Observers

Questions related to the Guidance on target animals safety

Q1. To reduce animal testing, will EFSA accept TAS\(^8\) study designs following US FDA & Chinese guidance? (Laura Payo Lewis – Pen & Tec Consulting)

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\(^8\) Target animal safety
A1. EFSA may accept such studies if they comply with the requirements of the FEEDAP guidance, or in case they do not, if an appropriate justification is provided.

Q2. To reduce animal testing, will EFSA waive TAS studies for microorganisms supported by *in vitro* data (taxonomy, WGS\(^9\), AMR\(^10\) & toxins/virulence factors)? (Laura Payo Lewis – Pen & Tec Consulting)

A2. Tolerance studies are not required for microorganisms qualifying for the qualified presumption of safety (QPS) approach. For microorganisms not listed in the QPS list (or for those which biology is not sufficiently well known to allow pathogenic/toxigenic strains to be excluded by direct testing) the Panel considers that, at present it is not possible to accurately predict the potential for toxic metabolites or virulence factors based on the basis of whole genome sequencing. This may be revised in the future as annotation becomes complete.

Q3. To reduce animal testing, will EFSA accept safe-strain lineage concept supported by taxonomy, WGS, AMR, toxins/virulence data, & waive further consumer & TAS studies? (Laura Payo Lewis – Pen & Tec Consulting)

A3. See answer to question 2

Q4. Questions concerning the Guidance on the assessment of the safety of feed additives for the target species: Please clarify the significantly longer necropsy list (15 tissue samples per animal)! It appears that turkeys are not a major species anymore. What does it mean for the extrapolation between chickens and turkey? (Alexandra Lensch – Evonik)

A4. The previous guidance did not include details on the minimum parameters to be assessed in the necropsy. The FEEDAP Panel considers that these are the minimum requirements to allow a proper assessment.

Please note that the guidance does not state that turkeys are not major species. The current proposed guidance opens the possibility to use data from chickens to conclude on the safety of other poultry species (including turkeys).

Q5. The assessment of efficacy of additives in suckling piglets is very difficult if the additive is to be administered only to suckling piglets. The possibility to allow the use of the additive in sows and suckling piglets should be kept. (Elinor McCartney – Pen & Tech Consulting Group)

A5. There is a category “sows in order to have benefit in the piglets”.

Q6. For applications for all animal species, a tolerance study in dairy cows is required. According to the guidance, necropsy should be performed in these animals, which will have a significant impact on the cost of the

\(^9\) Whole genome sequence
\(^10\) Antimicrobial resistance
experiments. Would it be possible to substitute the cow with another animal, e.g., goat? (Yara Antonissen – FEFANA)

A6. Please note that the guidance already foresees the exception of performing necropsy in cows, sows and pets, among other animals. High producing dairy cows are considered as a more sensitive model to assess safety for the target animals than dairy goats.

Q7. If a study is performed following the new guidance before the date of application of the guidance, will that study be accepted? (Manfred Lützow – saqual)

A7. Yes, a study performed following the new guidance will be accepted if properly designed, conducted and reported.

Q8. According to the guidance on safety for target species, tolerance studies in trout should be done with a starting weight of 10g. Would it be possible to start with 90g fish? (Regine Schreiner)

A8. Yes, if properly justified.

Questions related to the Guidance on consumer safety

Q9. The new guidance on consumer safety proposes to introduce a new way to calculate consumer exposure by use of a web based tool. However, no information is available on this tool. Can the FEEDAP panel provide more information/examples on this tool? (Davy Van Gaver – Huvepharma)

A9. The tool will allow to input the data on residues for the different food commodities, make the calculations based on the food consumption data from the EFSA comprehensive database and show the outcome of consumer exposure. The tool for feed additives is currently being developed and will be made publicly available via the EFSA website before the entry into force of the guidance document. This tool will be similar to the one used for food additives, which will be released in the coming weeks.

Q10. The proposed new way to define MRLs using this web based tools differs fundamentally from the approach used in the past by EFSA. How will this impact substances for which MRLs were set previously by EFSA? (Davy Van Gaver – Huvepharma)

A10. Please note that the methodology to derive an MRL has not changed. The tool is used only to calculate exposure of consumers. It is not expected that the MRLs already set will be revised because of the tool.

Q11. The proposed new way to define MRLs using this web based tools differs fundamentally from the approach used by other EU scientific bodies (e.g. EMA). Can FEEDAP clarify on the consequence this may have
on MRLs set on the same molecules by these other bodies? (Davy Van Gaver – Huvepharma)

**A11.** For substances for which an MRL exist the approach to be followed is the one described in chapter 5.2. EFSA is not modifying the MRLs proposed by other bodies.

**Q12.** There are some differences in the assessment of enzymes used in food and in feed. (Laura Payo Lewis – Pen & Tec Consulting)

**A12.** EFSA is aware of some differences in the assessment of food and feed enzymes (e.g., safe strain lineage), and work is ongoing to harmonise the assessment.

**Q13.** Is the database used for the exposure of consumers open? (Manfred Lützow – saqual)

**A13.** At present it is not a fully open database due to issues of confidentiality of some parts of the database; however summary statistics are published on the EFSA website. The tool for exposure assessment to feed additives will be published on the EFSA website and available to the public.

**Questions related to the Guidance on the identity, characterisation and conditions of use of feed additives**

**Q14.** For Gram negative bacteria data on endotoxins should be provided. An official reference point for this requirement is missing. (Manfred Lützow – saqual)

**A14.** The experience gained by the FEEDAP Panel in the assessment of a number of applications on amino acids produced by genetically modified *Escherichia coli* indicated that there is a safety issue linked to these products.

**Other questions**

**Q15.** To reduce animal testing, will EFSA accept pragmatic safety measures to cover worker safety (use of standard protective clothing, safety glasses & face masks; & use of adequate/barrier ventilation systems)? (Laura Payo Lewis – Pen & Tec Consulting)

**A15.** The acceptance of protection measures to cover user safety is not under the remit of EFSA but of the risk managers. EFSA will assess the safety of the additives for the users based on the data on their physico-chemical characteristics and toxicological profile provided in the dossier. However, if the applicant submits information showing that protection measures reduce the exposure of the users, EFSA will consider it in its assessment.
Q16. How will EFSA take into account the changes incorporated into the feed additive regulation (after REFIT)? (Laura Payo Lewis – Pen & Tec Consulting)

A16. Once Regulation (EC) No 429/2008 will be revised and adopted, EFSA will carefully check any changes in it that may have an impact on the guidance documents, and proceed, if needed, to update them accordingly. The activity will be performed in collaboration with the EC.

Q17. In the update of the guidance on the environment risk assessment, which is the approach to follow when the additive is applied for all animal species and measurements of the residues in faeces and urine have to be performed? (Manfred Lützow – saqual)

A17. The option of selecting three target species as surrogates in which to perform the measurements is under discussion.

Q18. Why the meetings with the selected discussion groups for the update of the guidance documents on efficacy and on the environmental risk assessment have been delayed? (Yara Antonissen – FEFANA)

A18. The delays were caused by administrative issues which are now solved. The discussion groups will start in the next weeks.

14. Any other business

   Not discussed