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

Minutes of the 132nd Plenary meeting

Held on 17-19 April 2018, Parma (Italy)

Meeting open to Observers

(Open session: 17 April 2018, 14:00-18:00h

18 April 2018, 9:00-12:00h)

(Agreed by written procedure on 26 April 2018)

Participants

- **Panel Members**
  Gabriele Aquilina, Giovanna Azimonti, Vasileios Bampidis, Maria de Lourdes Bastos, Georges Bories[1], Andrew Chesson, Pier Sandro Cocconcelli[2], Gerhard Flachowsky, Jürgen Gropp, Boris Kolar, Maryline Kouba, Marta López-Alonso, Secundino López Puente[3], Alberto Mantovani[4], 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: Montserrat Anguita, Rosella Brozzi, Jaume Galobart, Lucilla Gregoretti, Orsolya Holczknecht, Matteo Lorenzo Innocenti, Gloria López-Gálvez, Niovi Kordali, Paola Manini, Konstantinos Sofianidis, Jordi Tarrés-Call, Manuela Tiramani and Maria Vittoria Vettori.

1 Participated via webconference on 19 April 2018.
2 Participated on 17 AM, 18 and 19 April 2018
3 Participated via webconference
4 Participated on 17 and 19 April 2018.

AMU Unit: Laura Martino[5]

DATA Unit: Bruno Dujardin[6]

APDESK Unit: Karine Lheureux[7] and Margherita Guidi[7]

- **Observers[8]:**
  - **Attending physically in Parma:** Yara Antonissen (FEFANA), Ludovic Arnaud (Lallemand), Gerard Bertin (ERAWAN CONSULTING), Juan Luis Cerezuela (Lidervet, S.L.), Didier Jans (SERRPA), Alicia Juárez (FEFANA), Alexia Lepont (NOR-FEED), Manfred Lützow (saqual GmbH), Elinor McCartney (Association of Veterinary Consultants), Laurence Millot (ADISSEO), Johanna Nurmi-legat (Biomin Holding GmbH), Manfred Peisker (ADM), Miroslava Piskorikova (Elanco Animal Health), Anna Radawska (Pen & Tec Consulting), Valerie Ravidat (ERAWAN CONSULTING), Ron Roet (RM Associates Ltd), Regine Schreiner (Feed and Additives GmbH), Davy Van Gaver (Huvepharma NV)
  - **Attending via webstreaming:** Almudena Rodríguez (European Commission), Arnaud Bouxin (FEFAC), Audrey Kelly (Elanco Animal Health, Eli Lilly and Company Limited), Bas Verhagen (Puratos), Bettina Wagner (German Federal Institute for Risk Assessment), Daniel Bülichen (Glycomer GmbH), Daniela Rabe (Evonik Nutrition & Care GmbH), Edward Youngman (Pathway Intermediates Limited), Eva Duque (Trouw Nutrition), Garikai Midzi (Probiotics International Limited), Heinrich Schrage (Heinrich Schrage), Helena Oliveira (Nutreco), Inga Shahin (DuPont), Iris Van Dosselaer (Kemin Europa N.V.), Jean-Michel REPERANT (ANSES), Juliane Dohms (Phytobiotics Futterzusatzstoffe GmbH), Katherine Niederberger (Leveret GmbH), Katrin Grothaus (Biochem Zusatzstoffe Handels- und Produktionsges GmbH), Marie-Eve Martin (TECHNA), Marie-Julie Hannoun (AEL), Marie-Louise Simony (Chr. Hansen A/S), Mohammed Boularas (ZOETIS BELGIUM S.A.), Renato Ribeiro da Silva (Christian Hansen A/S), Sabina Díaz (Novus Spain, S.A.), Shea Beasley (Vetcare Ltd), Simon Duke (Simon Duke), Susann Richert (Evonik Nutrition & Care GmbH), Susanne Pippig (LANXESS Distribution GmbH), Tania Soenens (Eastman), Typhaine Morisset (Mixscience) and Zoltán Balázs (Leveret GmbH)

1. Welcome and apologies for absence

The Chair welcomed the participants. No apologies were received.

[5] Participated on 17 April 2018 for item 9.1
[6] Participated on 18 April 2018 for item 12.1.
[7] Participated on 18 April 2018 for item 11.1.1.
[8] http://www.efsa.europa.eu/en/stakeholders/observers.html

2. Adoption of agenda

The agenda was adopted.

3. Declarations of Interest of Scientific Panel members

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes[9] and the Decision of the Executive Director on Declarations of Interest[10], 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 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. Report on the written procedures since 131st Plenary meeting

The minutes of the 131st Plenary meeting held on 5-6 March 2018 were agreed by written procedure on 12 March 2018.[11]

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

5.1. Vitamin B_{12} (cyanocobalamin) for all animal species (EFSA-Q-2012-00456)

Not discussed due to lack of time.

5.2. KELFORCE (L-glutamic acid, N,N-diacetic acid, tetrasodium salt (GLDA-Na_4)) for chickens for fattening (EFSA-Q-2013-00434)

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 Kelforce (L-glutamic acid, N,N-diacetic acid, tetrasodium salt (GLDA-Na4)) as a zootechnical additive for chickens for fattening.

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

9 http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf
10 http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf
11 http://www.efsa.europa.eu/sites/default/files/event/180306-m.pdf

5.3. *Cumin cyminum* L. (Cumin tincture) for all animal species (EFSA-Q-2014-00909)

The Chair of the working group (WG) presented the question and the draft opinion. This question refers to the authorisation under Article 4 of Regulation (EC) No 1831/2003 of *Cumin cyminum* L. (Cumin tincture) as a sensory additive for all animal species.

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

5.4. Hemicell® L (endo-1,4-beta-d-mannanase) for chickens for fattening or reared for laying, turkeys for fattening or reared for breeding and minor poultry species (EFSA-Q-2016-00087 and EFSA-Q-2016-00181)

The rapporteur presented the questions and the draft opinion. These questions refer to the authorisation under Article 4 and the modification of the terms of the authorisation under Article 13 of Regulation (EC) No 1831/2003 of Hemicell® L (endo-1,4-β-mannanase) as a zootechnical additive for poultry species.

The draft opinion was discussed. The Panel decided to inform the applicant on issues that required clarification.

5.5. *Bacillus subtilis* GR-101 and *Aspergillus oryzae* GB-107 for all animal species (EFSA-Q-2016-00220)

The rapporteur presented the question and the draft opinion. EFSA has been asked to deliver an opinion on the safety and efficacy of *Bacillus subtilis* GR-101 and *Aspergillus oryzae* GB-107 as a technological additive for all animal species based on the additional information provided by the applicant.

The draft opinion was discussed. Discussion focussed mainly on the safety for the target species and consumer and on its efficacy. The Panel unanimously adopted the opinion.

5.6. Taminizer D (dimethylglycine sodium salt) for chickens for fattening (EFSA-Q-2016-00818)

The rapporteur presented the question and the draft opinion. This question refers to the authorisation under Article 13 of Regulation (EC) No 1831/2003 of Taminizer D (dimethylglycine sodium salt) as zootechnical additive for chickens for fattening.

The draft opinion was partly discussed in the previous plenary meeting. Discussion focussed mainly on the safety for the target animals, the consumer and users. The Panel unanimously adopted the opinion.

5.7. FUMzyme® (fumonisin esterase) for pigs and all avian species (EFSA-Q-2017-00073)

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 fumonisin esterase as a technological additive for pigs and avian species.

The draft opinion was discussed. Discussion focussed mainly on the characterisation of the additive and its safety for the target animals and users and on its efficacy. The Panel unanimously adopted the opinion.

5.8. L- Arginine (not less than 98% expressed on dry matter basis) produced by *Escherichia coli* (NITE BP-02186) for all animal species (EFSA-Q-2017-00480)

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-arginine produced by *Escherichia coli* (NITE BP-02186) as a nutritional and sensory additive for all animal species.

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

5.9. L-Arginine for all animal species (EFSA-Q-2017-00484)

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-arginine as nutritional additive for all animal species.

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

5.10. *Lactobacillus acidophilus* D2/CSL (CECT 4529) for cats and dogs (EFSA-Q-2017-00536)

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 *Lactobacillus acidophilus* D2/CSL (CECT 4529) as zootechnical additive for cats and dogs.

The draft opinion was discussed. Discussion focussed mainly on the characterisation of the additive and its efficacy. The Panel unanimously adopted the opinion.

5.11. Amylofeed (endo-1,3(4)-beta-glucanase, endo-1,4-beta-xylanase and alpha-amylase) for piglets and minor growing porcine species (EFSA-Q-2018-00001)

The Chair of the WG presented the question and the draft opinion. EFSA has been asked to deliver and opinion on the safety and efficacy of Amylofeed® (endo-1,3(4)-beta-glucanase, endo-1,4-beta-xylanase and alpha-amylase) as zootechnical additive for piglets (weaned) and minor porcine species based on the additional information provided by the applicant.

The draft opinion was discussed, focusing mainly on the efficacy of the additive. The Panel unanimously adopted the opinion.

5.12. Natural mixture of dolomite plus magnesite and magnesium-phyllosilicates for all animal species (EFSA-Q-2018-00010)

The rapporteur presented the question and the draft opinion. EFSA has been asked to deliver an opinion on the safety of natural mixture of dolomite plus magnesite and magnesium-phyllosilicates when used as technological additive for all animal species based on the additional information provided by the applicant.

The draft opinion was discussed, focusing mainly on the safety of the additive for the target species. The Panel unanimously adopted the opinion.

5.13. Hemicell® HT, Hemicell® HT-L (endo-1,4-beta-mannanase) for chickens for fattening, chickens reared for laying, turkey for fattening, turkeys reared for breeding, weaned piglets, pigs for fattening and minor poultry/porcine species (EFSA-Q-2018-00050)

The rapporteur and EFSA presented the question and the draft opinion. EFSA has been asked to deliver an opinion on the safety and efficacy of Hemicell® HT, Hemicell® HT-L (endo-1,4-beta-mannanase) when used as a zootechnical additive for chickens for fattening, chickens reared for laying, turkeys for fattening, turkeys reared for breeding, weaned piglets, pigs for fattening and minor poultry/porcine species based on the additional information provided by the applicant.

The draft opinion was discussed. Discussion focussed mainly on the safety for the environment and the efficacy. The Panel unanimously adopted the opinion.

OPEN SESSION

17 April 2018, 14:00-18:00h
18 April 2018, 9:00-12:00h

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 efficacy of feed additives (EFSA-Q-2017-00246)

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 efficacy of feed additives.

The draft guidance was endorsed by the FEEDAP Panel for public consultation on 28 November 2017. Discussion focussed on the modifications introduced in the guidance following the comments received in the public consultation. The Panel unanimously adopted the guidance.

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:

EFSA-Q-Number	Subject
EFSA-Q-2018-00268	*Pediococcus acidilactici* DSM 13943, *Lactobacillus plantarum* DSM 8862 and *Lactobacillus plantarum* DSM 8866 for minks (*Neovison vison*)
EFSA-Q-2018-00253	Endo-1,4-beta-xylanase produced by *Bacillus subtilis* (LMG S-15136) for sows in order to have benefit in piglets and all porcine species and life stages
EFSA-Q-2018-00254	Manganese chelates of lysine and glutamic acid for all animal species
EFSA-Q-2018-00255	Iron chelates of lysine and glutamic acid for all animal species
EFSA-Q-2018-00276	Benzoic acid for piglets (weaned)
EFSA-Q-2018-00266	L-lysine monohydrochloride and concentrated liquid L-lysine (base) for all animal species
EFSA-Q-2018-00287	*Lactobacillus hilgardii* CNCM I-4785 and *Lactobacillus buchneri* CNCM I-4323 for all animal species

10.2. 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
EFSA-Q-2018-00120	Butyric acid for dogs and cats	07/03/2018
EFSA-Q-2018-00122	Oregano oil for all animal species	07/03/2018
EFSA-Q-2010-01517	Botanically defined flavourings from Botanical Group 08 – Sapindales for all animal species and categories	19/03/2018
EFSA-Q-2018-00123	Chemically defined flavourings for use in cats and dogs from different chemical groups for dogs and cats	19/03/2018
EFSA-Q-2018-00121	Oil of *Origanum vulgare* L. subsp. Hirtum for poultry	07/03/2018
EFSA-Q-2017-00542	L-Tryptophan produced by fermentation with *Escherichia coli* K12 KCCM80135 for all animal species	15/03/2018
EFSA-Q-2017-00743	Tocopheryl phosphate mixture for all animal species	04/04/2018
EFSA-Q-2018-00011	Copper chelates of lysine and glutamic acid for all animal species	28/03/2018

These applications were assigned to the respective working groups.

10.3. New questions under Regulation (EC) No 178/2002 since the previous meeting

EFSA-Q-Number	Subject
EFSA-Q-2018-00267	Ethyl ester of beta-apo-8'-carotenoic acid for poultry for fattening and poultry for laying

This question was assigned to the respective working group.

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

11.1. EFSA

11.1.1. Guidance on processing of applications for regulated products

The Head of the Apdesk Unit presented the new guidance on the processing of applications for regulated products[12]. The discussion focused on the aspects of relevance for the current activities of the FEEDAP Panel and of the FEED Unit, namely the request of additional information to the applicants and the approach to follow for confidentiality issues raised by the applicants depending on the specific legal framework applicable.

11.2. Scientific Committee

The Panel was informed about the request of the Scientific Committee meeting to collect proposals on what the experts consider to be the next big challenge in food safety for the coming 10 years that needs prioritising for research funding. An ad hoc template was provided.

11.3. Working Groups[13]

The WG on trace elements requested the advice of the Panel regarding the assessment of a feed additive currently under discussion in the WG.

12. Other scientific topics for information and/or discussion

12.1. Presentation of the Feed Additives Consumer Exposure (FACE) tool

A member of the DATA Unit presented the Feed Additives Consumer Exposure calculator that will be used by the risk assessors to

[12] http://onlinelibrary.wiley.com/doi/10.2903/sp.efsa.2018.EN-1362/epdf
[13] This item was discussed during the closed session since it was related to a specific dossier.

estimate the exposure of consumers to residues of feed additives or their metabolites. This tool will be available online in the coming weeks.

12.2. Approach for the assessment of botanical preparations

The WG on Feed Flavourings made a presentation to update the Panel on the approach for the assessment of botanical preparations. The discussion focussed on aspects related to the methods for the assessment of chemical mixtures, currently under discussion in EFSA, and their applicability to assess the safety for target species of botanical preparations as feed additives. The principles, the data requirement, the methods and some examples were presented and discussed.

13. Answers to questions from Observers

Questions related to the Guidance on efficacy

Q1. My question concerns the draft guidance on the assessment of the efficacy of feed additives: Why, for lactating animals, the starting point for any trial has been considered at 4 weeks after calving or kidding? Some feed additives should be given just at the calving/kidding time to have their main impact on the peak. (Gerard Bertin – Erawan Consulting)

A1. The Panel considers that studies in dairy cows should not start before 4 weeks after calving in order to include in the study the peak of lactation and to allow milk production as a blocking factor in study design. The applicant may choose a different design for instance in the case in which the conditions of use justify it.

Q2. If I understood well, there is no split up between vitamins, provitamins on one hand and substances with similar effect on the other hand. Have you identified which substances should be on the separate list of "substances having similar effect as vitamins, pro-vitamins", since some may have already be re-authorized under the unified sub-classification on "vitamins, pro-vitamins and chemically well-defined chemical substances having similar effect". We would need to know of (at least of) the existing registrations which substances are under that split list and to understand why they would need to have different requirements for efficacy testing? Can you clarify?

To make my first question more concrete: are choline chloride (formerly referred to as vitamin B4), betaine, and other well-known substances, etc. vitamins or not? (Tania Soenens – Eastman)

A2. Substances having similar effect are not in a separate list, and the requirements for efficacy testing, if needed, are the same as for vitamins and provitamins.

Q3. Crustaceans are considered minor species? How long would have to last tolerance and efficacy studies in crustaceans? (Helena Oliveira – Nutreco)

A3. Crustaceans are considered minor species. The duration of the efficacy studies should be 42 days if growing and 56 days for adults.

Q4. About coccidiostat efficacy: virulence titration for species that do not cause typical lesions? *E. mitis* and *E. preacox* have known pathogenicity but do not cause measurable lesions... and for minor species like guinea fowl, partridge and pheasant? There is no scoring scale for coccidia of these bird species. Coccidiosis is mostly subclinical in the field. Why consider weight gain and FCR secondary? Indeed, some species of coccidia do not cause lesions but are pathogenic (*E. mitis* for example), and do not cause mortality or clinical signs, but only reduction of growth and increased FCR. (Jean-Michel REPERANT – ANSES)

A4. Coccidiostats are not intended for growth promotion but for prevention of coccidiosis. The assessment should be done based on disease-related end-points. An improved growth is not a primary end-point for coccidiostat efficacy assessment. Growth or feed gain is accepted if the primary end-points (e.g., lesion score, oocysts excretion) are affected.

Q5. Regarding the used feed in the trials, is it allowed to use feed that can be expected to be less than optimal for the control, if the addition of the additive is supposed to make the feed more optimal? (Bas Verhagen – Puratos)

A5. As mentioned in the guidance (see section 4.1.3) "where studies are required to demonstrate that the additive contributes to the animals' nutritional requirements, the feed of the control group should contain the nutrient at concentrations marginally below the animals' requirements". For enzymes, the diet should contain the substrate against which the enzyme is active.

Q6. Sorry, is this correct: young animals having completed the suckling period, and the trial should start at or before 7 days of age? Normally, the suckling period of period last until day 21, in specific raising systems at day 14. Could you check this again, please? (Juliane Dohms - Phytobiotics Futterzusatzstoffe GmbH)

A6. The study should start not more than 7 days after weaning, not at 7 days of age.

Q7. Would you please be so kind to explain what is meant by using the term "different feed"? Would it be okay if each of the 3 test facilities use the same kind of ingredients in the same amounts, but from different

suppliers? And, it would not be allowed to use one feed mill which would manufacture the test diets for all three requested efficacy trials? Thank you for clarification. (Susann Richert - Evonik Nutrition & Care GmbH)

A7. Yes, these would be considered as three different feeds, however, it is desirable that the composition is different. One feed mill could be used if the feeds are different.

Q8. Can 2 statistical significant experiments be combined with 2 non-significant experiments in a meta-analysis, and will the 2 sign test and the combined meta-analysis be sufficient, or can the experiments in the meta-analysis not also be submitted as one of the 3 significant studies? (Bas Verhagen – Puratos)

A8. The studies used in the pooling assessment cannot be used as individual evidence.

Q9. Regarding the use of EU commercial standards in mortality rate, it is recommended that mortality should be assessed on a case by case and a higher mortality could be justified. (Anna Radawska – Pen & Tec Consulting).

A9. An unusually high mortality raises a concern that animals are not in good health. The assessment of the studies is normally done on a case by case. Applicants should provide explanations of high mortalities.

Q10. Would a demonstration of efficacy for all pigs, all poultry, all ruminants and all fin fish cover also pets? (Ludovic Arnaud – Lallemand)

A10. No, these provisions would allow a conclusion on efficacy for all food producing animals. The effects claimed for additives in pets are normally different from those of food-producing animals.

Q11. For all fin fish, it is stated that 3 studies should be done in salmonids and three in other fish. Does it mean that the latter should be in three different fish species? (Ludovic Arnaud – Lallemand)

A11. Yes, three studies should be performed in salmonids (salmon or trout) and the other three in three different fish species (one study in each additional species).

Q12. Is there a requirement for all efficacy studies to follow good clinical practices? Will studies not following good clinical practices not be considered? (Miroslava Piskorikova – Elanco Animal Health)

A12. Trials should follow the criteria of external quality criteria schemes. The guidance provides examples of externally audited quality criteria schemes, but these are not mandatory requirements.

Q13. Blinding is necessary in cases where end-points are gained by expert judgement. Is the blinding only for the expert or all across the experiment? (Miroslava Piskorikova – Elanco Animal Health)

A13. The minimum requirement is that at least the assessor has no access to the treatment groups.

Q14. Does the requirement for bioequivalence mean that there is a need for comparative assessment? (Didier Jans – SERRPA)

A14. Please note that there is not a mandatory requirement for bioequivalence testing. If bioavailability data (e.g., plasma levels) is sufficient to support the efficacy of the additive there is no need for bioequivalence.

Q15. Why for all ruminants it is not enough to have one study in calves, one in cattle for fattening and one in cows? (Yara Antonissen – FEFANA)

A15. The Panel considers that for all ruminants, all pigs or all poultry efficacy should be demonstrated separately for growing and for reproductive animals.

Questions related to Feed Additives Consumer Exposure (FACE) calculator

Q16. Has there been a verification of the new exposure model using existing additives in the web-based tool to check whether the outcome is more or less conservative than the approach previously applied? (Yara Antonissen – FEFANA)

A16. Before concluding on the new model some indicative exposure calculations were carried out using some data available. This helped the WG and Panel to take some decisions on how to use the data available as well as to figure out how the outcome of the assessment would look like. Moving to the new methodology was not a question of being more or less conservative but obtaining a better estimate of the actual exposure to a substance. It was therefore proposed to no longer use a unique summary statistic for the consumption of each of the food items considered, but the actual consumption of each individual within a given food consumption survey and age class. Not only will this increase the accuracy of the exposure estimates per country and age class, it will also better reflect the variability of exposure within and among those population groups.

Q17. How will EFSA evaluate the human exposure of additives that are used in all animal species? In a recent discussed example, consumers of guinea fowl meat eat 31.2 grams per day on average, whereas they represent only 0.6% of the study population. Does the exposure model takes then account of consumption of duck meat, pigeon meat, boar meat, etc, and are these added to the food basket? Or is the exposure

calculated based on the meat that is consumed the most and by most of the consumers? (Yara Antonissen – FEFANA)

A17. For additives used in multispecies the exposure takes into account the origin of the food commodities, three species groups will be considered: poultry, mammals and fish. The exposure is not calculated based on the meat that is consumed the most. Within one group of species (e.g., poultry) and for a given food commodity (e.g., meat) the consumption will consider the consumption of any poultry species (chicken, turkey, guinea fowl…). For the time being the consumption data will not be disaggregated further to consider single species consumption. Within each species group (e.g., poultry) and for each food commodity (e.g., meat) the occurrence value for the species with the highest concentration of residues in a commodity (e.g., meat from guinea fowl) will be retained for the calculation.

Q18. How does the new exposure model deal with transformed products (e.g. pâtés, meatloaf, dairy products, egg-based products…)? Are these also included in the web-based tool? (Yara Antonissen – FEFANA)

A18. While the exposure calculations are based on the raw primary commodities (e.g., milk), consumption of all food is incorporated in the assessment, including composite food (e.g., pizza) or other single ingredients (e.g., cheese). To this purpose, all consumption data for composite foods have been disaggregated into single ingredients by estimating the content of each ingredient within the composite foods. Single ingredients were subsequently converted to the raw primary commodities by using where relevant a reverse yield factor. The consumption values expressed as raw primary commodity are the ones that will be used by the web tool.

Q19. Have all age groups been considered in the model for chronic exposure? (i.e. not only adults and elderly but also toddlers) (Yara Antonissen – FEFANA)

A19. Yes, in fact in point 4.3.1. of the Guidance on consumer safety it is reported the seven groups of age that will be considered.

Q20. A one day high value for an ingredient can increase the average of that ingredient significantly, especially if only data is entered on a few days. This can happen for different ingredients. Has the database been assessed to verify that the total average consumption of a person per day is within reasonable amounts? (Bas Verhagen – Puratos)

A20. Upon reception of the consumption data by EFSA, an analysis of outliers is carried out at the level of eating occasions and consumption days. The average consumption of a subject is not subject to this outlier analysis.

It is confirmed that consumption surveys with a low number of consumption days per subject may lead to overestimation of the high percentile exposures (EFSA, 2011). However, the minimum requirement for number of consumption days per subjects was carefully considered in the framework of EFSA's EU Menu Projects (EFSA, 2014). In this context it was considered that food consumption data collected over two non-consecutive days are sufficient for the assessment of chronic exposure.

Q21. Does the model consider that all food contains the residue at the average plus 2 standard deviations, and that this may represent an overestimation of exposure? (Manfred Lützow – saqual GmbH)

A21. This is indeed a conservative approach and we are aware that this may represent an overestimation of the exposure, since some variability in residue deposition will occur. However, in order to consider the variability in residue deposition, more data on residues in food products would be required.

Q22. When will this tool be applied? Is there a reference table with the relation of between the age groups and the body weights? (Didier Jans – SERRPA)

A22. The new consumer exposure calculation will be implemented as of 1st of May, in which also the tool will be made available online. The Guidance on selected default values to be used by the EFSA Scientific Committee, Scientific Panels and Units in the absence of actual measured data contains default values for the different population groups. However, it should be noted that default values for body weight are not needed anymore, since the tool uses the individual weight and calculates the individual exposure in terms of mg/kg body weight.

Questions related to the guidance on the processing of applications for regulated products

Q23. Who is responsible of the management of the extension of the deadlines for completeness check and during the scientific assessment? In case of a delay in the decision of the European Commission regarding the confidentiality of an application, will the summary be published as until now or will a different approach be taken? (Ludovic Arnaud – Lallemand)

A23. The management of the deadlines has not changed, i.e., Apdesk will deal with the deadlines regarding completeness check while the Feed Unit will deal with the deadlines regarding the scientific assessment.

The blackening of confidential information in the opinions will start with the opinions adopted in this plenary. If the EC decision on confidentiality has not been received, EFSA will publish the blackened opinion according to the confidentiality claims made by the applicant. Once the EC decision on confidentiality is received, the blackened opinion will be revised according to the EC decision.

Q24. When will the FEEDAP start following the new guidance, including publishing "blackened out" versions? (Bas Verhagen – Puratos)

A24. The blackening of confidential information in the opinions will start with the opinions adopted in this plenary.

Q25. If the applicant identifies an error in the opinion during the pre-notification period before publication, how should this be addressed? (Manfred Lützow – saqual GmbH)

A25. The applicant should notify EFSA immediately, and corrective measures will be taken, depending on the nature of the error.

14. Any other business

Not discussed.