FEED UNIT

SCIENTIFIC PANEL ON ADDITIVES AND PRODUCTS OR SUBSTANCES USED IN ANIMAL FEED

MINUTES OF THE 158th FEEDAP PLENARY MEETING

Webconference, 10-11 November 2021

Meeting open to observers

(Open session: 11 November 2021, 09:00-13:00)

(Agreed by written procedure on 19 November 2021)

Participants

- **Panel Members**

  Giovanna Azimonti, Vasileios Bampidis, Maria de Lourdes Bastos, Henrik Christensen, Birgit Dusemund, Mojca Fašmon Durjava, Maryline Kouba, Marta López-Alonso, Secundino López Puente, Francesca Marcon, Baltasar Mayo, Alena Pechová, Mariana Petkova, Fernando Ramos, Yolanda Sanz, Roberto Edoardo Villa and Ruud Woutersen.

- **Hearing Experts**

  Not applicable

- **European Commission**

  Marta Ponghellini (DG SANTE)

- **EFSA**

  Feed Unit: Angelica Amaduzzi, Montserrat Anguita, Rosella Brozzi, Jaume Galobart, Lucilla Gregoretti, Davide Guerra, Orsolya Holczknecht, Matteo Lorenzo Innocenti, Paola Manini, Jordi Ortuño, Elisa Pettenati, Fabiola Pizzo, Daniel Plaza, Anita Radovnikovic, Martina Reitano, Joana Revez, Jordi Tarrés-Call, Frank Verdonck and Maria Vittoria Vettori.

  APDESK Unit: Karine Lheureux[1] and Patricia Romero Fernández[1]

- **Observers (in application of the guidelines for Observers)[2]**

  Alexia Lepont (Nor-Feed SAS), Ludovic Arnaud (Lallemand), Gerard Bertin (Erawan Consulting), Nathalie Boulho MiXscience), Ruud Bremmers, Sergi Carné (Industrial Técnica Pecuaria, S.A.), Fatma Celik (Parma University), Gemma Choi (CJ Europe GmbH), Laure Clasadonte (Herbonis Animal Health), Lisa Conboy-schmidt (Nestlé Purina), Sabina Diaz (NOVUS Spain), Juliane Dohms

[1] Present on 11 November only for item 10.4
[2] http://www.efsa.europa.eu/en/stakeholders/observers.html

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- **Others**

  Not applicable

1. Welcome and apologies for absence

The Chair welcomed the participants. No apologies were received.

2. Adoption of agenda

The agenda was adopted after the inclusion of the item "Allura Red for small mammals and ornamental birds (EFSA-Q-2020-00290)".

3. Declarations of Interest of Panel members

In accordance with EFSA's Policy on Independence[3] and the Decision of the Executive Director on Competing Interest Management[4], EFSA screened the Annual Declarations of Interest filled out by the Panel members invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

4. Report on written procedures since the 157th FEEDAP Plenary meeting

The minutes of the 157th FEEDAP Plenary meeting were agreed by written procedure on 6 October 2021.[5]

[3] Policy on Independence
[4] Competing Interest Management
[5] https://www.efsa.europa.eu/sites/default/files/2021-10/157th-plenary-meeting-feedap-panel-minutes.pdf

5. Scientific topics for discussion

5.1. Botanically defined flavourings from Botanical Group 06 - Laurales, Magnoliales, Piperales: cinnamon tincture for all animal species and categories (EFSA-Q-2010-01296, EFSA-Q-2021-00133)

This question refers to the authorisation under Article 4 and re-evaluation under Article 10 of Regulation (EC) No 1831/2003 of cinnamon tincture as a sensory additive for all animal species and categories.

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

5.2. Botanically defined flavourings from Botanical Group 06 - Laurales, Magnoliales, Piperales for all animal species and categories: camphor white oil (EFSA-Q-2010-01296, EFSA-Q-2021-00514)

This question refers to the authorisation under Article 4 and re-evaluation under Article 10 of Regulation (EC) No 1831/2003 of camphor white oil as a sensory additive for all animal species and categories.

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

5.3. Botanically defined flavourings from Botanical Group 06 - Laurales, Magnoliales, Piperales: ylang ylang oil (EFSA-Q-2010-01296, EFSA-Q-2021-00596)

This question refers to the authorisation under Article 4 and re-evaluation under Article 10 of Regulation (EC) No 1831/2003 of ylang ylang oil as a sensory additive for all animal species and categories.

The draft opinion was discussed and the Panel identified the need for further discussion. The opinion will be tabled in the next plenary for possible adoption.

5.4. Botanically defined flavourings from Botanical Group 08 - Sapindales for all animal species and categories: Buchu leaves oil (EFSA-Q-2010-01517, EFSA-Q-2021-00597)

This question refers to the authorisation under Article 4 and re-evaluation under Article 10 of Regulation (EC) No 1831/2003 of Buchu leaves oil as a sensory additive for all animal species and categories.

The draft opinion was discussed and the Panel identified the need for further discussion. The opinion will be tabled in the next plenary for possible adoption.

5.5. Sodium aluminosilicate, synthetic for all animal species (EFSA-Q-2019-00661)

This question refers to the re-evaluation under Article 10 of Regulation (EC) No 1831/2003 of sodium aluminosilicate, synthetic as a technological additive for all animal species.

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

5.6. L-Isoleucine produced by fermentation with *Corynebacterium glutamicum* KCCM 80185 for all animal species (EFSA-Q-2020-00007)

This question refers to the authorisation under Article 4 of Regulation (EC) No 1831/2003 of L-isoleucine produced by fermentation with *Corynebacterium glutamicum* KCCM 80185 as a nutritional additive for all animal species.

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

5.7. MSG (monosodium L-glutamate) produced by fermentation with *Corynebacterium glutamicum* KCCM 80187 for all animal species (EFSA-Q-2020-00155)

This question refers to the authorisation under Article 4 of Regulation (EC) No 1831/2003 of MSG (monosodium L-glutamate) produced by fermentation with *Corynebacterium glutamicum* KCCM 80187 as a sensory additive for all animal species.

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

5.8. Allura Red for small mammals and ornamental birds (EFSA-Q-2020-00290)

This question refers to the authorisation under Article 4 of Regulation (EC) No 1831/2003 of Allura red as a sensory additive for small non-food producing mammals and ornamental birds.

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

5.9. Selenised yeast *Saccharomyces cerevisiae* CNCM I-3060, inactivated (SEL-PLEX) for all animal species (EFSA-Q-2020-00495)

This question refers to the modification of the conditions of the authorisation under Article 13 of Regulation (EC) No 1831/2003 of selenised yeast *Saccharomyces cerevisiae* CNCM I-3060, inactivated (SEL-PLEX) as a nutritional additive for all animal species.

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

5.10. Amaferm (fermentation product of *Aspergillus oryzae* NRRL 458) for dairy cows (EFSA-Q-2020-00574)

EFSA was requested to deliver an opinion on the safety of Amaferm (fermentation product of *Aspergillus oryzae* NRRL 458) as a zootechnical additive for dairy cows based on the additional information provided by the applicant.

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

5.11. L-Lysine monohydrochloride and L-lysine sulphate for all animal species (EFSA-Q-2020-00636)

This question refers to the authorisation under Article 4 of Regulation (EC) No 1831/2003 of L-lysine monohydrochloride and L-lysine sulphate as a nutritional additive for all animal species.

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

5.12. Rosemary extract for cats and dogs (EFSA-Q-2020-00728)

This question refers to the authorisation under Article 4 of Regulation (EC) No 1831/2003 of rosemary extract as a technological additive for cats and dogs.

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

5.13. Vitamin E/all-rac-α-tocopheryl acetate for all animal species (EFSA-Q-2020-00841)

This question refers to the renewal of the authorisation under Article 14 of Regulation (EC) No 1831/2003 of all-rac-α-tocopheryl acetate as a nutritional additive for all animal species.

The draft opinion was discussed focusing on the characterisation and safety of the additive. The Panel unanimously adopted the opinion.

5.14. *Lactococcus lactis* NCIMB 30160 for all animal species (EFSA-Q-2021-00082)

This question refers to the renewal of the authorisation under Article 14 of Regulation (EC) No 1831/2003 of *Lactococcus lactis* NCIMB 30160 as a technological additive for all animal species.

The draft opinion was discussed focusing on the characterisation and safety of the additive. The Panel unanimously adopted the opinion.

5.15. Capsozyme SB Plus (endo-1,4-beta-xylanase and alpha-galactosidase) for chickens for fattening, chickens reared for laying and minor poultry species for fattening and reared for laying (EFSA-Q-2021-00174)

EFSA was requested to deliver an opinion on the safety and efficacy of Capsozyme SB Plus (endo-1,4-beta-xylanase and alpha-galactosidase) as a zootechnical additive for chickens for fattening, chickens reared for laying and minor poultry species for fattening and reared for laying based on the additional information provided by the applicant.

The draft opinion was discussed focusing on the safety and efficacy of the additive. The Panel unanimously adopted the opinion.

5.16. Calsporin® (preparation of *Bacillus velezensis* (formerly *Bacillus subtilis*) DSM 15544) for dairy cows for milk production and other dairy ruminants (EFSA-Q-2021-00206)

This question refers to the authorisation under Article 4 of Regulation (EC) No 1831/2003 of Calsporin® (preparation of *Bacillus velezensis* (formerly *Bacillus subtilis*) DSM 15544) as a zootechnical additive for dairy cows for milk production and other dairy ruminants.

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

OPEN SESSION

11 November 2021, 09:00-13:00

6. Welcome

The Chair welcomed all the observers who attended the open session of the plenary.

7. Brief introduction of Panel members

The Panel Chair invited the Panel members and the staff of the FEED Unit 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 meeting.

9. New mandates

9.1. New Applications under Regulation (EC) 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-2021-00494	L-Arginine produced by *Corynebacterium glutamicum* CGMCC 20516 for all animal species
EFSA-Q-2021-00530	*Pediococcus pentosaceus* DSM 32292 for all animal species
EFSA-Q-2021-00544	ProAct 360 (subtilisin protease produced by *Bacillus Licheniformis* (DSM 33099)) for all growing poultry species
EFSA-Q-2021-00547	Dicopper chloride trihydroxide for all animal species
EFSA-Q-2021-00548	Zinc chloride hydroxide monohydrate for all animal species
EFSA-Q-2021-00549	Nutrixtend Optim (beta-mannanase (EC 3.2.1.78) produced by *Aspergillus niger* (CBS 120604)) for chickens for fattening
EFSA-Q-2021-00571	Vitamin B12/cyanocobalamin produced by *Ensifer adhaerens* CGMCC 19596 for all animal species
EFSA-Q-2021-00573	MM (chlorophyllins) for chickens for fattening, turkeys for fattening and minor poultry species
EFSA-Q-2021-00635	Kofasil Lac (*Lactiplantbacillus plantarum* DSM 3676 and *Lactiplantbacillus plantarum* DSM 3677) and Kofasil S (*Lentilactobacillus buchneri* DSM 13573) for all animal species

9.2. 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-2021-00309	Plexomin® Se 3000/Plexomin® Se 3000 micro (Selenised yeast *Saccharomyces cerevisiae* Y03-0 inactivated) for all animal species	20/10/2021
EFSA-Q-2021-00310	MAGNI-PHI® (*Quiliaja saponaria* and *Yucca schidigera*) for poultry	08/10/2021
EFSA-Q-2021-00341	25-Hydroxycholecalciferol for ruminants	15/10/2021
EFSA-Q-2021-00428	QUINOX® (Decoquinate) for chickens for fattening and chickens reared for laying	15/10/2021
EFSA-Q-2021-00442	VTR-xylanase liquid, VTR-xylanase powder (endo-beta-1,4-xylanase) for all avian species including ornamental, exotic and game birds	15/10/2021
EFSA-Q-2021-00448	Naringin for all animal species	20/10/2021
EFSA-Q-2021-00462	L-lysine monohydrochloride, Concentrated Liquid L-lysine, Concentrated Liquid L-lysine monohydrochloride for all animal species	22/10/2021
EFSA-Q-2021-00464	Pan-Zoot (pancreatin of porcine pancreas glands) for dogs	29/10/2021
EFSA-Q-2021-00470	Free Yeast® F (Fumonisin B1 esterase (3.1.1.87) produced by Komagataella phaffii NCAIM (P) Y001485) for piglets (suckling and weaned), pigs for fattening, sows for reproduction and sows in order to have benefit in piglets	22/10/2021

These applications were assigned to the respective working groups, where relevant.

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

EFSA-Q-Number	Subject
EFSA-Q-2021-00520	β-Damascone [07.083] and (E)-β-damascone [07.224] for all animal species
EFSA-Q-2021-00523	Ethoxyquin for all animal species
EFSA-Q-2021-00527	Levucell® SC (*Saccharomyces cerevisiae* CNCM I-1077) for dairy cows, cattle for fattening, minor ruminant species and camelids
EFSA-Q-2021-00528	Sodium saccharin for piglets, pigs for fattening, calves for rearing and calves for fattening
EFSA-Q-2021-00534	*Lactobacillus reuteri* DSM 32203 for dogs
EFSA-Q-2021-00535	Sorbiflore® ADVANCE (*Lactobacillus rhamnosus* CNCM I-3698 and *Lactobacillus farciminis* CNCM I-3699) for weaned piglets

EFSA-Q-Number	Subject
EFSA-Q-2021-00536	Sorbiflore® ADVANCE (*Lactobacillus rhamnosus* CNCM I-3698 and *Lactobacillus farciminis* CNCM I-3699) for chickens for fattening
EFSA-Q-2021-00537	ELANCOBAN® G200 (monensin sodium produced by *Streptomyces cinnamonensis* or mutants) for chickens for fattening, chickens reared for laying, turkeys
EFSA-Q-2021-00538	6-phytase (Nutrase P) for chickens for fattening, other poultry for fattening, reared for laying and ornamental birds
EFSA-Q-2021-00539	*Lactobacillus rhamnosus* CNCM I-3698 and *Lactobacillus farciminis* CNCM I-3699 for all animal species
EFSA-Q-2021-00582	Microcrystalline Cellulose E 460 and Carboxymethyl Cellulose E 466 for all animal species
EFSA-Q-2021-00583	Natugrain® TS (endo-1,4-beta-xylanase and endo-1,4-beta-glucanase) for chickens for fattening
EFSA-Q-2021-00585	Hydroxypropyl Cellulose E 463 for all animal species
EFSA-Q-2021-00594	Follow-up opinion linked to EFSA-Q-2013-00421 - *Lactobacillus plantarum* ATCC 55058 and ATCC 55942 for all animal species
EFSA-Q-2021-00633	Follow-up opinion linked to EFSA-Q-2017-00050 *Lactobacillus reuteri* NBF-2 (DSM 32264) as a feed additive for cats
EFSA-Q-2021-00634	Follow-up opinion linked to EFSA-Q-2012-00080 *Enterococcus faecium* (NCIMB 10415, DSM 22502, ATCC 53519 and ATCC 55593) as silage additives for all animal species

These questions were assigned to the respective working groups, where relevant.

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

10.1. Feedback from the Scientific Committee/Scientific Panels

The Chair of the Panel provided information on some recent opinions published by the Scientific Committee of EFSA, including the Guidance on risk assessment of nanomaterials to be applied in the food and feed chain: human and animal health[6], the Guidance on technical requirements for regulated food and feed product applications to establish the presence of small particles including nanoparticles[7], Guidance on aneugenicity assessment[8] and the one on Maximum levels of cross-contamination for 24 antimicrobial active substances in non-target feed[9], adopted by the BIOHAZ Panel, and on which the FEEDAP Panel contributed substantially.

10.2. Frequently asked questions to applicants during the assessment of feed additives

[6] https://efsa.onlinelibrary.wiley.com/doi/full/10.2903/j.efsa.2021.6768
[7] https://efsa.onlinelibrary.wiley.com/doi/full/10.2903/j.efsa.2021.6769
[8] https://efsa.onlinelibrary.wiley.com/doi/full/10.2903/j.efsa.2021.6770
[9] https://efsa.onlinelibrary.wiley.com/doi/toc/10.1002/(ISSN)1831-4732.cross-contamination

A member of the FEED Unit presented the document which summarises the topics for which questions are most frequently asked to applicants during the risk assessment.[10]

10.3. Experience on the application of the updated guidance on renewal

The updated Guidance on the renewal of authorisation of feed additives[11] was adopted by the FEEDAP Panel in November 2020 and implemented since March 2021. An overview was given on the experience gained during the 6 months since its implementation. Emphasis was given on the assessment of genotoxicity potential of the additives, the environmental risk assessment and the extensive literature searches as the basis for provision of evidence of safety.[12]

10.4. General update on the work related to feed additive dossiers

The Panel was informed on the ongoing activities by the APDESK and the FEED Units with regards the pre-submission activities, the number of applications received, the impact of the Transparency regulation, the opinions adopted by the Panel and other ongoing activities.

11. Other scientific topics for information/or discussion

11.1. Criteria for the assessment of efficacy of hygiene condition enhancers

The FEEDAP Panel endorsed in its 153rd Plenary meeting the criteria for the assessment of efficacy of feed additives from the functional group of hygiene condition enhancers (HCE).[13] An overview of the main criteria for the assessment of these products was given.

12. Answers to questions from Observers

Q: In case of hygiene condition enhancer feed additive, particularly concerning the pathogenic enterobacteria (*Salmonella*) for which we have several serovars (e.g. *enterica*, Enteritidis, Gallinarium) how many strains we have to test to cover all *Salmonella*? Same question for any other enterobacteria (G. Bertin, ERAWAN CONSULTING)

A: The mechanism of action and the use conditions of the additive need to be considered in the study design in order to identify a representative number of strains. For *Salmonella enterica*, several unrelated strains from different serovars (both field and reference strains) should be tested. For other microorganisms it should be checked on a case-by-case.

Q: For this functionality, several types of feeds are used: mash feed, liquid feed (soup) or milk (pigs, dogs, cats). Some of these feeds are given along animal's life, other are prepared extemporaneously. Would you confirm that the design should strictly follow the recommendations of use to prove the efficacy of the feed additive? (G. Bertin, ERAWAN CONSULTING)

[10] https://www.efsa.europa.eu/sites/default/files/2021-05/frequently-asked-questions-applicants-assessment-feed%20additives.pdf

[11] https://efsa.onlinelibrary.wiley.com/doi/full/10.2903/j.efsa.2021.6340

[12] The webinar on application procedure for feed additives and intended renewal applications available on EFSA's website provides useful practical tips for applicants https://www.efsa.europa.eu/en/events/webinar-application-procedure-feed-additives-and-intended-renewal-applications

[13] https://www.efsa.europa.eu/sites/default/files/2021-05/criteria-assessment-hygiene-condition-enhancers.pdf

A: As mentioned in the guidance for the assessment of efficacy, the efficacy should be demonstrated under practical condition of use. Therefore, the design of the study should consider in which type of feeds and under which conditions the feed additive will be used.

Q: Although the criteria for the assessment of hygiene condition enhancer makes sense and are scientifically sound, the requirements seem to be much higher than for other technological additives (e.g., preservatives). (L. Arnaud, Lallemand)

A: The scope of preservatives is to prevent the growth of spoilage microorganisms while that for HCE is the reduction of contamination with specific microorganism(s) relevant to feed safety. The requirements are not different from other technological additives, in the sense that efficacy should be assessed against the proposed conditions of use in a range of representative feed materials, the duration should reflect the period for which an effect is claimed.

Q: The criteria for HCE states that a difference of 2 logs is needed to support efficacy. Shouldn't lower levels of efficacy be accepted with a qualification so as to allow the use of products which have some effect on pathogenic microorganisms? (D. Jans, EMFEMA)

A: According to the criteria published, differences below 0.5 log are considered within the normal variation and would not support efficacy. Differences above 1 log may be considered indicative of an effect.

Q: The range of dry matter (DM) mentioned in the criteria for HCE (10-80%) is considered limiting, as for example, contamination with *Salmonella* in soybean with 90% DM content might happen. (H. Van Dam, Nutreco)

A: The DM range included in the criteria is indicative and applicants may propose different conditions, if properly justified, according to the conditions of use.

Q: For naturally contaminated feed would it be possible not to identify the target microorganisms, as this might prove difficult? (L. Arnaud, Lallemand)

A: In order to support efficacy, there is the need detect and quantify the presence of the target microorganism(s) in the feed sample, therefore, identification is fundamental. Applicants should consider that it might be easier to use artificially contaminated feed for which there is control over the inoculated microbial strains in the test feed.

Q: I have a question concerning the criteria for the assessment of efficacy of the new functional group "physiological condition stabilisers" in the category of zootechnical additives. As this functional group is recent and there is not yet feed additives registered in this group, the criteria of assessment of efficacy are not clear, and I would like to know if you work on a note or guidance to give details on the criteria that you would take into accompt to assess the efficacy of such feed additives. And if yes, when it will be available please? (T. Perrot, ALL4FEED)

A: The Panel in the last plenary meeting (29-30 September) agreed to request the Executive Director of EFSA a self-task to update some of the guidance documents, including the guidance on efficacy to cover the assessment of efficacy for physiological condition stabilisers. It is the aim that this work will be completed before the end of the mandate of this Panel in June 2024. This timeframe takes into account the current revision of the feed additives Regulations which should be finalised before the FEEDAP guidance can be adopted. A public consultation of the draft guidance document will be launched.

Q: On the feed area, it has so far been accepted that the Authorization Regulations only state a recommended maximum dose instead of maximum limits for (synthetic) flavourings, (based on safety aspects). However, more botanical aromas can contain a safety aspect, which could lead to many of these being given a maximum limit. Is there a set of clear wordings in EFSA's assessment reports that can give the risk manager

clarity about when there is an actual risk to the animals, requiring the setting of clear maximum limit for flavourings? Examples to talk from could be EFSA's reports on mandarin oil (EFSA journal 2021; 19(6):6625), lemon aromas (EFSA J. 2021; 19(4):6548) and Tincture from Gentiana Lutea (EFSA J. 2021 2021; 19(4):6547). (K. Roerbo, Danish Veterinary and Food Administration)

A: The safety assessment is intended to establish whether or not the highest proposed use level is safe for the target species. It is not originally intended to establish if higher doses are still safe.

With the data available in the technical dossier the Panel assesses whether there is enough evidence to conclude that the proposed levels are safe for the target species.

When the evidence does not support the levels proposed by the applicant, the Panel might conclude that the substances are safe at a lower level. In these circumstances, the Panel in the conclusions clearly establishes the levels which can be considered safe. However, this does not mean that higher levels cannot be safe if additional evidence, e.g., specific tolerance studies in target animals, are made available that support this claim.

When substances of concern are present in botanical flavourings, they are addressed in the risk assessment based on the occurrence data provided. If there is evidence that these might not be safe for the target animals, the Panel states this in the opinion. If substances of concern are present at concentrations that are considered not to be of concern for the target species, the Panel states that the conclusions of the assessment are applicable only to preparations with the concentrations of substances of concern that have been assessed. A recommendation is added to ensure that the levels assessed will not be exceeded.

In some cases, it is not possible to reach a conclusion with the information available and additional data would be required.

Q: What will be the approach of the test material is digested/not absorbed and therefore *in vivo* testing does not show exposure? The hazard identification may be inconclusive but the risk assessment would be "not genotoxic *in vivo*". Do you agree? (M. Lutzow, saqual GmbH)

A: A case-by-case evaluation should be done. The whole dataset available (including ADME data and *in vitro* genotoxicity battery) for a substance should be considered in the context of a weight of evidence approach. For substances that are not absorbed, the potential genotoxicity at the site of contact should be assessed.

Q: In the context of the refit of Regulation (EC) No 1831/2003, there is an ongoing discussion on the period of authorisation of feed additives, which is currently 10 years. In the food area, the authorisations are without time limits. With the development of new assessment methods there is the possibility that new studies are requested for feed additives but not for food. (K. Roerbo, Danish Veterinary and Food Administration)

A: In the context of the renewal of the authorisation there is the need to ensure that the additive remains safe. In case concerns are identified for an additive which is also authorised in food, EFSA has in place a cross-cutting task force to alert the food area of the concerns identified. In case of need, EFSA can start a self-task to assess potential risks for consumers.

Q: When performing extensive literature searches (ELS), using general keywords may lead to 500+ hits, using further keywords (or other criteria) limit the number of hits, but may lead to different references from different applicants (based upon the used criteria). How to deal with this? (R. Bremmers)

A: Although it is expected that some differences might exist when comparing ELS performed by different applicants on a given feed additive, those should not be major. The search strategy and search strings are the key to obtain a proper balance between sensitivity and specificity in the

ELS. They must be refined in an iterative process with the available resources (Boolean operators, truncation, synonyms...). Identifying *a priori* a few scientific papers that should be retrieved in the search may help in adjusting the search strategy.

Q: Could EFSA provide a list of "national copyright authorities"? (R. Schreiner, Feed and Additives GmbH)

A: EFSA is not in a position to provide such list.

Q: Is there any control on who can download the non-confidential data regarding dossiers that has been uploaded to the EFSA website? (L. Arnaud, Lallemand)

A: Public data that are uploaded in the EFSA website are available to anyone who is registered in the OpenEFSA Portal.

Q: When transferring the data from the Register of Questions (RoQ) to the new OpenEFSA environment, how far back in time were the old applications transferred? (H. van Dam, Nutreco)

A: All ongoing applications at the beginning of January 2021 were transferred to the OpenEFSA. Closed applications at that time are available in the extracts of the RoQ published on the EFSA website.[14]

Q: I thought the confidentiality requests for feed additives were to pass through the E submission platform- so Portalino is not relevant for confidentiality requests for feed additives. Can you confirm that? (T. Erbs, Novozymes)

A: New applications should be submitted using the E-submission platform, including the request for confidential information. Portalino should be used to indicate confidential requests for follow up dossiers following an inconclusive opinion.

Q: How can we know that a republication of an opinion has taken place after the confidentiality decision from the EC has been received? (D. Jans, EMFEMA)

A: In case the redaction of the opinion needs to be modified following the confidentiality decision, the applicant is pre-notified of the republication. The opinion maintains its output number.

Q: What are the rules to decide if an application falls under the provisions of the transparency regulation (TR) or not? (M. Lützow, saqual GmbH)

A: Regular applications submitted before the entry into force of the TR (27 March 2021) do not fall under the remit of the TR, while those submitted at or after 27 March 2021 do. For requests following inconclusive opinions, the date of receipt of the mandate from the EC to EFSA is what defines the application of the TR provisions. For follow-up opinions for which the mandate was received after 27 March 2021 the TR applies, even if the original dossier was submitted before that date.

Q: During the October 4th meeting of EU Member States, Switzerland, Norway, EFSA, the European Commission, and the EURL on the regulatory and technical aspects of ethylene oxide it was stated that the limit of 0.1 mg/kg "prevails for food and feed additives" and "it is the intention to update Regulation (EU) 231/2012 with the inclusion of a specific maximum level, i.e. 0.1 mg/kg" which will apply to all food additives. Is there a similar intention to revise Directive 2002/32/EC on undesirable substances in animal feed? (K. Mylona, Intertek)

A: Question not related to the assessment of feed additives. The question was brought to the attention of the European Commission.

[14] https://www.efsa.europa.eu/en/register-of-questions

13. Any other business

The Chair closed the session by thanking all the participants to the Open Session.