FEED TEAM

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

MINUTES OF THE 164th FEEDAP PLENARY MEETING

Hybrid meeting, 22-24 November 2022

Meeting open to observers

(Open session: 24 November 2022, 09:00-13:00)

(Agreed by written procedure on 15 December 2022)

Participants

- **Panel Members**[1]

  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**

  N/A

- **European Commission**

  N/A

- **EFSA**

  FEEDCO Unit: Natalia Alija Novo, Angelica Amaduzzi, Arianna Angelini, Montserrat Anguita, Rosella Brozzi, Yvette Dirven, Joana Firmino, Stefani Fruk, Yolanda García Cazorla, Mary Gilsenan, Davide Guerra, Orsolya Holczknecht, Matteo Lorenzo Innocenti, Paola Manini, Alberto Navarro Villa, Jordi Ortuño, Daniel Pages Plaza, Elisa Pettenati, Fabiola Pizzo, Anita Radovnikovic, Joana Revez, Barbara Rossi, Jordi Tarrés-Call and Maria Vittoria Vettori.

  FDP Unit: Irene Baratto, Óscar González, Patricia Romero Fernández.

  LA Unit: Nicole Falessi, Simone Gabbi, Gunda Kriz, Andrea Martinello, Vasileios Migkos, Citlali Pintado.

[1] Giovanna Azimonti, Vasileios Bampidis, Maria de Lourdes Bastos, Henrik Christensen, Mojca Fašmon Durjava, Maryline Kouba, Marta López-Alonso, Baltasar Mayo, Alena Pechová, Mariana Petkova, Fernando Ramos and Roberto Edoardo Villa participated to the meeting from EFSA premises; Francesca Marcon participated from EFSA premises on the 24th of November

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

  Miguel Abad (United Animal Health), Rose-Aimee Bailly (METEX-NOOVISTAGO), Caroline Bertein (Phileo by Lesaffre), Gérard Bertin (Erawan Consulting), Ruud Bremmers (Regal B.V.), Levie Cequena (Landmark), Ilse Cleenwerck, Lisa Conboy-Schmidt (Nestlé Purina), Sabina Díaz (Novus Spain SA), Mari Eskola (Medfiles Ltd), Rossana Gastaldo (Mérieux NutriSciences), Katrin Grothaus (Biochem Zusatzstoffe Handels- und Produktionsges. mbH), Marie-Julie Hannoun (METEX NOOVISTAGO), Ruud Huibers (Elanco Deutschland GmbH), Didier Jans (EMFEMA), Alicia Juárez Pallarés (FEFANA), Dennis Kap (Baseclear BV), Katarzyna Kapusta (Adifeed), Nikolaos Katerelos (Hellenic Food Authority (EFET)), Verena Kiehne (Forschungsinstitut Futtermitteltechnik der IFF), Anouk Lanckriet (Huvepharma NV), Birgit Langwost (DSM Nutritional Products Ltd.), Manfred Lützow (saqual GmbH), Typhaine Morisset (MIXSCIENCE), Daniel Muñoz (Zinpro Animal Nutrition (Europe), Inc.), Johanna Nurmi-Legat (Biomin Holding GmbH), Regina Ohlmann, Francesca Peditto (Solvay), Tifenn Perrot (ALL4FEED), Susanne Pippig (LANXESS Deutschland GmbH), Valerie Ravidat (ERAWAN CONSULTING), Oriol Ribo (DSM Nutritional Products Ltd.), Fernando Rivero (CoGreen Consulting), Kristina Rørbo (Danish Veterinary and Food Administration), Jacek Sas (Grupa Azoty Zakłady Chemiczne "Police" S.A.), Regine Schreiner (Feed and Additives GmbH), Maria Tsakalidou (Prefecture of Western Macedonia – kozani), Anne Ukkonen (Biosafe Ltd), Petra Weindl (Feed and Additives), Christina Zantioti (Agricultural University of Athens).

- **Others**

  N/A

1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Baltasar Mayo for the 24th of November. Arianna Angelini was welcomed as a staff member to the FEEDCO Unit and Natalia Alija Novo, Yvette Dirven and Stefani Fruk were welcomed as trainees in the FEED Team.

2. Adoption of agenda

The agenda was adopted without modifications.

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.

[2] http://www.efsa.europa.eu/en/stakeholders/observers.html; attending on the 24th of November.
[3] Policy on Independence
[4] Competing Interest Management

4. Report on written procedures since the 163rd FEEDAP Plenary meeting

The minutes of the 163rd FEEDAP Plenary meeting were agreed by written procedure on 11 October 2022.[5]

5. Scientific topics for discussion

5.1. Botanically defined flavourings from Botanical Group 02 - Apiales and Austrobaileyales for all animal species and categories: *Ferula assa-foetida* oil (EFSA-Q-2010-01286, EFSA-Q-2022-00404)

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

The draft opinion had been discussed in previous meetings and the Panel unanimously adopted the opinion.

5.2. Botanically defined flavourings from Botanical Group 02 - Apiales and Austrobaileyales for all animal species and categories: Dill herb oil (EFSA-Q-2010-01286, EFSA-Q-2022-00405)

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

The draft opinion had been discussed in previous meetings and the Panel unanimously adopted the opinion.

5.3. Botanically defined flavourings from Botanical Group 02 - Apiales and Austrobaileyales for all animal species and categories: Cumin oil (EFSA-Q-2010-01286, EFSA-Q-2022-00566)

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

The draft opinion had been discussed in previous meetings and the Panel unanimously adopted the opinion.

5.4. Botanically defined flavourings from Botanical Group 02 - Apiales and Austrobaileyales for all animal species and categories: Dill tincture (EFSA-Q-2010-01286, EFSA-Q-2022-00567)

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

The draft opinion had been discussed in previous meetings and the Panel unanimously adopted the opinion.

[5] https://www.efsa.europa.eu/sites/default/files/2022-10/feedap20220927-28_m.pdf

5.5. Botanically defined flavourings from Botanical Group 02 - Apiales and Austrobaileyales for all animal species and categories: Dong quai tincture (EFSA-Q-2010-01286, EFSA-Q-2022-00568)

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

The draft opinion had been discussed in previous meetings and the Panel unanimously adopted the opinion.

5.6. Botanically defined flavourings from Botanical Group 02 - Apiales and Austrobaileyales for all animal species and categories: Fennel tincture (EFSA-Q-2010-01286, EFSA-Q-2022-00569)

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

The draft opinion had been discussed in previous meetings and the Panel unanimously adopted the opinion.

5.7. Botanically defined flavourings from Botanical Group 02 - Apiales and Austrobaileyales for all animal species and categories: Parsley tincture (EFSA-Q-2010-01286, EFSA-Q-2022-00570)

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

The draft opinion had been discussed in previous meetings and the Panel unanimously adopted the opinion.

5.8. Botanically defined flavourings from Botanical Group 02 - Apiales and Austrobaileyales for all animal species and categories: Star anise tincture (EFSA-Q-2010-01286, EFSA-Q-2022-00571)

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

The draft opinion had been discussed in previous meetings and the Panel unanimously adopted the opinion.

5.9. Botanically defined flavourings from Botanical Group 08 - Sapindales for all animal species and categories: Quebracho extract (EFSA-Q-2010-01517)

This question refers to the authorisation under Article 4 and re-evaluation under Article 10 of Regulation (EC) No 1831/2003 of quebracho extract 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.

5.10. RONOZYME® VP (CT) and RONOZYME® VP (L) (endo-1,3(4)-beta-glucanase (IUB No 3.2.1.6)) for weaned piglets and chickens for fattening (EFSA-Q-2019-00528)

This question refers to the re-evaluation under Article 10 of Regulation (EC) No 1831/2003 of RONOZYME® VP (CT) and RONOZYME® VP (L) (endo-1,3(4)-beta-glucanase) as a zootechnical additive for weaned piglets and chickens for fattening.

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

5.11. Axtra® XAP 104 TPT (endo-1,4-beta-xylanase, alpha-amylase and protease) for chickens for fattening, laying hens and all minor poultry species (EFSA-Q-2020-00620)

EFSA was requested to deliver an opinion on the safety and efficacy of Axtra® XAP 104 TPT (endo-1,4-beta-xylanase, alpha-amylase and protease) as a zootechnical additive for chickens for fattening, laying hens and all minor poultry species 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 endorsed the draft for adoption by written procedure after minor comments are addressed.

5.12. Vitamin B2 produced by *Bacillus subtilis* CGMCC 13326 for all animal species (EFSA-Q-2020-00637)

This question refers to the authorisation under Article 4 of Regulation (EC) No 1831/2003 of vitamin B2 produced by *Bacillus subtilis* CGMCC 13326 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 considers that further discussion is needed regarding the characterisation of the additive.

5.13. Amoklor™ (Ammonium Chloride) for all ruminants, sows for urinary health, cats and dogs (EFSA-Q-2020-00815)

This question refers to the authorisation under Article 4 and the renewal of the authorisation under Article 14 of Regulation (EC) No 1831/2003 of Amoklor™ (ammonium chloride) as a zootechnical additive for all ruminants, sows for urinary health, cats and dogs.

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

5.14. Zinc (II) - betaine complex for all animal species (EFSA-Q-2021-00280)

This question refers to the authorisation under Article 4 of Regulation (EC) No 1831/2003 of zinc (II) - betaine complex 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 endorsed the draft for adoption by written procedure pending the application of minor revision to the section on safety for the environment.

5.15. Huvezym neXo (endo-1,4-beta-xylanase, endo-1,4-beta-glucanase and xyloglucan-specific-endo-beta-1,4-glucanase) for poultry and pigs (EFSA-Q-2021-00308)

This question refers to the authorisation under Article 4 of Regulation (EC) No 1831/2003 of Huvezym neXo (endo-1,4-beta-xylanase, endo-1,4-beta-glucanase and xyloglucan-specific-endo-beta-1,4-glucanase) as a zootechnical additive for poultry and pigs.

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

5.16. RONOZYME® HiPhos (6-phytase) for poultry, pigs for fattening, piglets (weaned) and sows (EFSA-Q-2021-00342)

This question refers to the modification of the conditions of the authorisation under Article 13 and the renewal of the authorisation under Article 14 of Regulation (EC) No 1831/2003 of RONOZYME® HiPhos (6-phytase) as a zootechnical additive for poultry, pigs for fattening, piglets (weaned) and sows.

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

5.17. Miya-Gold® (Preparation of *Clostridium butyricum* FERM BP-2789) for chickens for fattening, chickens reared for laying and minor avian species (excluding laying birds) (EFSA-Q-2021-00384)

This question refers to the authorisation under Article 4 and the modification of the conditions of the authorisation under Article 13 of Regulation (EC) No 1831/2003 of Miya-Gold® (preparation of *Clostridium butyricum* FERM BP-2789) as a zootechnical additive for chickens for fattening, chickens reared for laying and minor avian species (excluding laying birds).

The draft opinion was discussed focusing on the characterisation, safety and efficacy of the additive. The Panel endorsed the draft and will be considered for written adoption after the outcome of the public consultation is addressed.

5.18. VTR-phytase liquid, VTR-phytase powder (6-phytase) for all avian species including ornamental, exotic and game birds (EFSA-Q-2021-00417)

This question refers to the authorisation under Article 4 of Regulation (EC) No 1831/2003 of VTR-phytase liquid, VTR-phytase powder (6-phytase) as a zootechnical additive for all avian species including ornamental, exotic and game birds.

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

5.19. Copper (II) - betaine complex for all animal species (EFSA-Q-2021-00419)

This question refers to the authorisation under Article 4 of Regulation (EC) No 1831/2003 of copper (II) - betaine complex 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 endorsed the draft for adoption by written procedure pending the application of a revision to the section on safety for the environment.

5.20. VTR-phytase liquid, VTR-phytase powder (6-phytase) for all pigs (EFSA-Q-2021-00425)

This question refers to the authorisation under Article 4 of Regulation (EC) No 1831/2003 of VTR-phytase liquid, VTR-phytase powder (6-phytase) as a zootechnical additive for all pigs.

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

5.21. BioStabil *Lactiplantibacillus* (previously *Lactobacillus*) *plantarum* DSM 19457 for all animal species (EFSA-Q-2021-00497)

This question refers to the renewal of the authorisation under Article 14 of Regulation (EC) No 1831/2003 of BioStabil *Lactiplantibacillus* (previously *Lactobacillus*) *plantarum* DSM 19457 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.

5.22. Sodium saccharin for piglets, pigs for fattening, calves for rearing and calves for fattening (EFSA-Q-2021-00528)

EFSA was requested to deliver an opinion on the safety of sodium saccharin as a sensory additive for piglets, pigs for fattening, calves for rearing and calves for fattening based on the additional information provided by the applicant.

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

5.23. *Lactobacillus diolivorans* DSM 33625 for all animal species (EFSA-Q-2021-00590)

This question refers to the authorisation under Article 4 of Regulation (EC) No 1831/2003 of *Lactobacillus diolivorans* DSM 33625 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 endorsed the draft and will be considered for written adoption after the outcome of the public consultation is addressed.

5.24. Urea (No 3d1) for ruminants (EFSA-Q-2021-00688)

This question refers to the renewal of the authorisation under Article 14 of Regulation (EC) No 1831/2003 of urea (No 3d1) as a nutritional additive for ruminants.

The draft opinion was discussed focusing on the characterisation, safety and efficacy of the additive. The Panel endorsed the draft and will be considered for written adoption after the outcome of the public consultation is addressed.

5.25. 27 flavouring compounds to provide a Milky-Vanilla flavour for all animal species and categories (EFSA-Q-2022-00158)

EFSA was requested to deliver an opinion on the safety of 27 flavouring compounds to provide a Milky-Vanilla flavour as a sensory additive for all animal species and categories based on the additional information provided by the applicant.

The draft opinion was discussed focusing on the safety of the compounds. The Panel unanimously adopted the opinion.

5.26. Stenorol® (halofuginone hydrobromide) for chickens for fattening and turkeys (EFSA-Q-2022-00182)

EFSA was requested to deliver an opinion on the safety of Stenorol® (halofuginone hydrobromide) as a coccidiostat for chickens for fattening and turkeys based on the additional information provided by the applicant.

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

5.27. Correlink™ (*Bacillus subtilis* ABS747) for chickens for fattening, turkeys for fattening, chickens reared for laying, turkeys reared for breeding, minor poultry species (EFSA-Q-2022-00233)

EFSA was requested to deliver an opinion on the efficacy of Correlink™ (*Bacillus subtilis* ABS747) as a zootechnical additive for chickens for fattening, turkeys for fattening, chickens reared for laying, turkeys reared for breeding, minor poultry species based on the additional information provided by the applicant.

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

5.28. Correlink™ (*Bacillus subtilis* ABS1781) for chickens for fattening, turkeys for fattening, chickens reared for laying, minor poultry species, turkeys reared for breeding (EFSA-Q-2022-00264)

EFSA was requested to deliver an opinion on the efficacy of Correlink™ (*Bacillus subtilis* ABS1781) as a zootechnical additive for chickens for fattening, turkeys for fattening, chickens reared for laying, minor poultry species, turkeys reared for breeding based on the additional information provided by the applicant.

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

5.29. Plexomin® L-Fe (Ferrous lysinate sulfate) for all animal species (EFSA-Q-2022-00372)

EFSA was requested to deliver an opinion on the efficacy of Plexomin® L-Fe (ferrous lysinate sulfate) as a nutritional additive for all animal species based on the additional information provided by the applicant.

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

5.30. Avatec® 150G (lasalocid A sodium) as a feed additive for chickens for fattening and chickens reared for laying (EFSA-Q-2022-00425)

EFSA was requested to deliver an opinion on the safety and efficacy of Avatec® 150G (lasalocid A sodium) as a coccidiostat for chickens for fattening and chickens 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.

OPEN SESSION

24 November 2022, 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 to introduce themselves.

8. Presentation of the EFSA Guidelines for Observers

A member of the FEED Team presented the guidelines for observers for open plenary meeting.

9. New mandates

9.1. New Applications under Regulation (EC) 1831/2003 since the 163rd Plenary meeting

The Commission has forwarded to EFSA the following new applications of feed additives seeking authorisation under Regulation (EC) No 1831/2003 since the 163rd Plenary meeting. These applications were presented to the Panel:

EFSA-Q-Number	**Subject**
EFSA-Q-2022-00624	Iron (II) - betaine complex for all animal species
EFSA-Q-2022-00745	Coated granulated cobalt (II) carbonate (3b304) for herbivore reptiles and zoo mammals, ruminants with functional rumen, lagomorphs, equidae, rodents
EFSA-Q-2022-00746	PB6 (*Bacillus velezensis* ATCC PTA-6737) for all growing poultry
EFSA-Q-2022-00778	*Lentilactobacillus* (*Lactobacillus*) *buchneri* LN4637 / ATCC PTA-2494 for all animal species
EFSA-Q-2022-00779	Tartrazine (2a102) for freshwater fish
EFSA-Q-2022-00780	*Lentilactobacillus* (*Lactobacillus*) *buchneri* LN40177 / ATCC PTA-6138 for all animal species
EFSA-Q-2022-00781	Ponceau 4R (2a124) for freshwater fish
EFSA-Q-2022-00789	*Lentilactobacillus buchneri* DSM 22501 (formerly *Lactobacillus buchneri*) for all animal species
EFSA-Q-2022-00791	L-Cystine (3c391) for all animal species

EFSA-Q-Number	Subject
EFSA-Q-2022-00792	Cobalt (compounds: cobalt(II) acetate tetrahydrate, cobalt(II) carbonate, cobalt(II) carbonate hydroxide (2:3) monohydrate, cobalt(II) sulphate heptahydrate) for bovines with a functional rumen, equidae, lagomorphs, rodents, herbivore reptiles and zoo mammals
EFSA-Q-2022-00793	BIOMIN® BBSH® 797 (microorganism strain DSM 11798) for pigs and all avian species
EFSA-Q-2022-00799	Bentonite for ruminants, poultry and pigs
EFSA-Q-2022-00800	AveMix XG 10 (endo-1,4-beta-xylanase and endo-1,4-beta-glucanase produced by *T. longibrachiatum* (MUCL 49755 and 49754)) for pigs for fattening, minor porcine species for fattening other than *Sus scrofa domesticus*, and turkeys for fattening
EFSA-Q-2022-00801	Bentonite (1m558i) for all animal species
EFSA-Q-2022-00810	Fumaric Acid for all animal species
EFSA-Q-2022-00811	NITTEN DFAIII (difructose anhydride III) for all female adult ruminants in the periparturient period, all neonatal ruminants fed colostrum and milk/milk replacer in early life

9.2. Valid applications under Regulation (EC) No 1831/2003 since the 163rd Plenary meeting

Applications considered valid to start the risk assessment:

EFSA-Q-Number	Subject	Valid on
EFSA-Q-2021-00130	Cannabidiol for cats and dogs	09/11/2022
EFSA-Q-2022-00318	Balancius® Muramidase (EC 3.2.1.17) for laying hens	21/10/2022
EFSA-Q-2022-00320	PB6 *Bacillus velezensis* ATCC PTA-6737 for all pigs	30/09/2022
EFSA-Q-2022-00325	GalliPro® Fit (*Bacillus subtilis* DSM 32324, *Bacillus subtilis* DSM 32325 and *Bacillus amyloliquefaciens* DSM 25840) for all poultry species for fattening or reared for laying or reared for breeding	16/11/2022
EFSA-Q-2022-00340	*Pediococcus acidilactici* CNCM I-4622 for all insect species and categories	30/09/2022
EFSA-Q-2022-00350	KemTRACE Chromium (Chromium propionate) for all growing birds	11/10/2022
EFSA-Q-2022-00375	Hydroxy-analogue of Selenomethionine (3b814) for all animal species	20/10/2022

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

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

10.1. Status of the Transparency Regulation implementation[6]

10.1.1. Pre-submission activities and completeness check: Challenges and achievements in the implementation of the Transparency Regulation

EFSA staff presented the services available for potential applicants before the submission of an application after the implementation of the Transparency regulation and the impact of the Transparency regulation provisions on the completeness check of the dossiers. The activities available to the applicants prior to the submission of an application may help in the preparation of the technical dossiers and applicants are encouraged to make best use of all of them. The presentation also provided some insights into the impact of the Transparency regulation on the activities undertaken during the completeness check. It was also presented the information that is available to the applicants for a better understanding of the overall process.

The questions received during the registration phase were answered and the Chair allowed further questions. All the questions received, and the corresponding answers are reproduced here below:

Q: Upon submission in the E-submission Food Chain Platform (ESFC), will it become possible in the future to fill in the notification number and that the information from the notification will be imported automatically, so that not all information needs to be filled in manually? (Regal B.V.)

A: ESFC communicates with some of EFSA's system as Connect.EFSA, however the current implementation requires the manual insertion of data in ESFC. European Commission (EC) is in charge of developing and updating the ESFC platform. EFSA took note of this comment and will pass this information to EC.

Q: We would appreciate to have a validation button on ESFC to know exactly the date of submission from the applicant side. Moreover, as we upload a lot of metadata in ESFC during the submission of a dossier, it would be very useful to make available to the applicants/consultants a record of these metadata uploaded. (R. Schreiner, Feed and Additives GmbH)

A: EFSA took note of this comment and will pass this information to the EC.

Q: I noticed EFSA can manage ESFC platform, even if it is a tool developed by EC. Why EFSA is not addressing the issues directly, if it is possible to manage the platform? (Saqual GmbH)

A: The EC is responsible for ESFC, and therefore EFSA needs to pass requests for improvements and feedback to the EC. Please note that EFSA collaborates with the EC for the development of the ESFC platform to make it better fit for purpose and in accordance with the needs of different stakeholders.

[6] All presentations are published in EFSA website.

Q: We are encountering issues when submitting Certificates of Analysis (CoA): sometimes EFSA communicates it has to be submitted as CoA, other times EFSA ask to submit it as study report. What should we do? (Elanco Deutschland GmbH)

A: The different requests arise from the attempt to overcome a temporary technical issue in ESFC with the submission of studies and CoA. Until this issue is solved, when the CoA is considered a study (i.e. includes data of the physical-chemical characterization of the test item subject of the dossier), we are asking the applicant to resubmit as a study report document type because this analysis falls into the definition of study. Currently in ESFC, the document type study report is the only one that allows the applicant to include NoS information (NoS-ID or a justification for non-notification). In the future, ESFC will allow the applicant to include a NoS-ID and a justification for non-notification also for CoA document type.

Q: Regarding the confidentiality assessment process, we are requested to sanitise some pages in some annexes, but not in some others. Some clarity would be needed at this regard. (Elanco Deutschland GmbH)

A: During the Completeness Check phase, EFSA needs to receive a confidential version and a non-confidential version of the documents. In the confidential version of the documents, it needs to be clearly marked which are the specific aspects that need to be kept confidential. Annexes submitted as "all confidential" might have been accepted as such in the past but should not be accepted anymore; the parts to be kept confidential need to be clearly earmarked.

Q: EFSA requests that the language of documents is in English, documents in other European languages are not accepted and it is not fully understandable why it is not possible to submit studies to an EU Agency in other EU official languages. (Feed and Additives GmbH)

A: The request for documentation in English is meant to speed-up the following step of risk assessment. EFSA might accept documents in another European language but then these documents will need to be translated during the risk assessment phase, potentially delaying the risk assessment process. EFSA will consider this comment when reflecting whether further discussion is needed on this topic.

Q: A guidance should be published indicating clearly the need to use English in all reports. However, it may be challenging in some cases, as, for example, GLP certificates are requested to be made in the original language of the country where the laboratory is located. A robust summary in English, along with the original document in another European language, would be sufficient to understand the study (Saqual GmbH)

A: The translation of the whole document is requested to speed-up the following step of risk assessment – EFSA will consider this comment when reflecting whether further discussion is needed on this topic.

Q: We have concerns about joint applications; the current system makes difficult to respect the confidentiality between applicants. We cannot grant access to the different applicants to the ESFC as they would have access to the confidential information of the others. There is no guidance for the e-submission platform of EFSA and this should be solved. (Saqual GmbH)

A: FDP Unit acknowledges that, at the moment, joint dossiers are a challenge, and takes note of the concerns shared and will note them to the EC. EFSA can be contacted in writing for any specific case that needs a specific follow-up.

Q: Regarding communications between EFSA and the applicants, sometimes the frequency of the updates (webinars, video presentations, social networks, etc) is too fast to keep up for applicants. It would be appreciated to have slower rate of information but more consolidated. (Feed and Additives GmbH)

A: EFSA takes good note of this proposal and will discuss internally. EFSA encourages the applicants to use the services in place for any clarification they may require.

Q: With regards to the notification of studies, would a study be considered automatically invalid if it is notified after the start date of the study? (Medfiles Ltd)

A: For studies notified after the starting date, during the completeness check a justification needs to be provided in the dedicated section of the metadata of the study report in ESFC. The fact that a study has been notified with delay does not automatically render the application invalid; FDP checks the admissibility of the justification. For that reason, we suggest to submit any documentation or communication that can support the justification. In the case of an invalid application, there is no need to redo the application; however, an applicant cannot re-submit the application until six months from the date an application is deemed invalid.

10.1.2. Update on the confidentiality assessment of feed additives' applications

EFSA staff gave an overview of the procedural steps concerning the confidentiality assessment and sanitisation of the data submitted in post-Transparency dossiers for feed additives. The presentation indicated also the responsibilities and the procedural requirements to which the confidentiality requests are subject. Finally, some practical recommendations were also shared to allow the applicants to get a better understanding of the overall process.

The questions received during the registration phase were answered and the Chair allowed for further questions. All the questions received and the corresponding answers are reproduced here below:

Q: How extensively is data on feed additive applications published under the Transparency Regulation? Are details on the production also published, e.g. solvents used, concentration of the active ingredient in the final product, etc.? (Martin Bauer GmbH & Co. KG)

A: Details on the production process can be claimed confidential, if they are not relevant for safety assessment. The solvent used and the concentration of the active ingredients could fall under the manufacturing process, if not relevant for the safety.

Q: When the toxicological *in vivo* data on an active substance have been registered under REACH and the respective reports are confidential (i.e. owned by the REACH registrant), and are therefore not given an access to because EFSA would publish them under Transparency Regulation, would it be enough to EFSA that the Applicant uses the data on these studies, which are publicly available, on the ECHA website? Naturally, the Applicant would get the right to use them upon payment of the fees to the REACH Registrant. Or would EFSA require new animal toxicological studies to be conducted? (Medfiles Ltd)

A: EFSA carries out its scientific risk assessment on applications for placing on the Union market feed additives in accordance with Regulation (EC) No 1831/2003 (the Feed Additives Regulation). The data requirements are the ones foreseen in this Regulation in Article 7(3) and Commission Regulation (EC) No 429/2008. Applicants are asked to also refer to the Administrative guidance for the preparation of applications on additives for use in animal nutrition.

We understand that the question relates to a scenario in which certain data which are required under the above-described legal framework are actually owned by the company having registered the active substance under the REACH Regulation. It should be noted that the REACH requirements and data sharing mechanisms do not apply in the context of the authorisation procedure under Regulation (EC) No 1831/2003, irrespective of the provisions on proactive Transparency and confidentiality laid down in in the context of the authorisation procedure under Regulation (EC) No 1831/2003, irrespective of the provisions on proactive transparency and confidentiality laid down in Regulation (EC) No 178/2002, as last amended by Regulation (EU) 2019/1381 (the so-called Transparency Regulation). In any event, it should be noted that, pursuant to Article 38(1a) of Regulation (EC) No 178/2002, the proactive disclosure requirements concerning inter alia the applications submitted by applicants under Regulation (EC) No 1831/2003 shall be without prejudice to any provisions set out in Union law protecting the investment made by innovators in gathering the information and data supporting relevant applications for authorisations ("data exclusivity rules").

This being said, Regulation (EC) No 1831/2003 also includes specific provisions concerning regulatory data protection. In particular, Article 20(1) of Regulation (EC) No 1831/2003 states that scientific data and other information in the application dossier may not be used for the benefit of another applicant for a period of 10 years from the date of authorisation, unless the other applicant has agreed with the previous applicant that such data and information may be used. Moreover, concerning data sharing toxicological tests on vertebrates, Article 20(3) of Regulation (EC) No 1831/2003 highlights the importance not to repeat testing on vertebrate animals and states that the applicant and the previous applicant shall take all necessary steps to reach agreement on sharing the use of information. In such case, the use is done by EFSA upon confirmation that a data sharing agreement is in place and that the Authority can use the data for the benefit of another applicant.

In the event that the applicants cannot agree on the data sharing, pursuant to paragraph 3, only the Commission has the power to disclose the information. EFSA plays no role in this context. Consequently, your observations and queries should be better addressed to the Commission.

Q: With regards to the description of the methods, applicants are using laboratories with in-house methods and these laboratories are reluctant to release their methods. Considering that details on the methods should be provided in the technical dossiers, can EFSA advice on how to solve this problem? (Medfiles Ltd)

A: This comment has been duly noted by EFSA. However, this is a bilateral issue that must be negotiated between the applicants and the concerned laboratories, highlighting the safeguards

put in place by the Transparency Regulation to protect commercial business information and intellectual property rights.

Q: We encounter delays in public consultation and we are afraid that the timing of confidentiality assessment can slow down the risk assessment, especially for application of new products. (Elanco Deutschland GmbH)

A: The risk assessment process runs in parallel to the confidentiality assessment process, so there should not be delays due to the confidentiality assessment. Once confidentiality assessment is completed , the public consultation starts. EFSA acknowledges that some issues were encountered in the implementation of the confidentiality assessment which may have delayed the process, but EFSA is aware of the challenge and is doing its utmost to optimise its internal processes and tools to comply with the legal requirements.

Q: If during the validation process amendments to the dossiers have to be done (e.g., adding information), this will have an impact on the confidentiality request. In fact, the page and lines of the part of the document claimed to be confidential should be indicated, and the addition of information will need a revision of these information. In relation to the copy-pasting of text in ESFC, there is a 90 characters restriction. What happens if 100 pages need to be copy-pasted? (Feed and Additives GmbH)

A: This is relevant for small parts of documents partially claimed confidential. If an entire document, or a considerable part thereof is claimed confidential, this should be indicated and reference to the relevant paragraph, page numbers and lines should be made in ESFC. EFSA takes note of this comment for further internal discussion.

Q: If a document is already claimed as confidential because it falls under one legal ground (i.e. manufacturing), why there is the need to use other articles to claim confidential other parts of the document that is already claimed as confidential? (Elanco Deutschland GmbH)

A: It might happen that a confidentiality request is rejected as unfounded, while other parts of the same document, claimed as confidential under a different legal ground, may be accepted. Choosing the most appropriate legal ground for each relevant part of the document claimed confidential increases the chances the confidentiality requests are accepted.

10.2. FEED Team and FEEDAP Panel general planning

EFSA staff gave a general presentation on the FEEDAP Panel and the FEED Team from FEEDCO Unit. The presentation included information on the way of working, work completed in the last five years, work in progress as well as work foreseen for the next year and half. The main work of the Panel relates to the assessment of feed additives but in the next year and half the Panel will devote part of its work to the update of the guidance documents on the safety for the user, efficacy and characterisation of microorganisms.

The questions received during the registration phase were answered and the Chair allowed for further questions. All the questions received and the corresponding answers are reproduced here below:

Q: In what timeframe does EFSA aim to complete the re-evaluation of all botanically defined flavouring feed additives? (Martin Bauer GmbH & Co. KG)

A: In the beginning of the re-evaluation, priority was given to chemically defined flavourings, as many of these individual compounds are also components of botanical feed additives. Botanical preparations are complex mixtures, and adequate methodology was lacking until the scientific committee of EFSA issued a guidance on mixtures in 2019. A plan for submission of data on botanically defined flavourings was agreed both with stakeholders and with the EC. For botanically defined groups, there was the need to adapt the administrative procedures in place (e.g., ungrouping the additives during the assessment). The process in currently ongoing and we expect to be able to complete this exercise in 2026 – 2027.

Q: Due to the new guidance on nanoparticles, when an updated version of identity Guidance and users/workers safety Guidance is planned to be published and implemented? (Erawan Consulting)

Q: If my feed additive contains no particle below 1 µm, what should I do? Make particle size distribution characterisation or look at nanoparticles? (Erawan Consulting)

A: The current guidance document on the identity and characterisation of feed additives considers the need to investigate and characterise the presence of nanoparticles and indicated the threshold mentioned of 1 µm. The implementation of the guidance on nano materials required to update that passage of the guidance. This need was indicated by the FEEDAP Panel in the minutes of the 161st FEEDAP Plenary. At this respect, there is the need to address the presence of nanoparticles in accordance with the Guidance on technical requirements for regulated food and feed product applications to establish the presence of small particles including nanoparticles (EFSA Scientific Committee, 2021a). The guidance on the identity and characterisation is not to be updated in short. The guidance on the safety for the users/workers is currently under update with expected completion in June 2024; the need to address the assessment of nanoparticles will be considered in the development of the document.

Q: Regarding the efficacy guidance, from our point of view there is not a major need to update this guidance, as the update on the Regulatory Framework may establish a new situation that would request a different approach on this topic. The current requirements include the submission of three independent, valid and positive studies. These studies are generally required under a "clinical" environment, which may not reflect the actual conditions in the farm. Therefore, once the additive is authorized, new field trials need to be performed to demonstrate the efficacy in practice, which implies the use of a huge number of animals for that purpose. Is there something which could be done in this regard to reduce the number of studies needed? (i.e. for coccidiostats, three anticoccidial sensitivity tests plus three floor pen studies). (Elanco Deutschland GmbH)

A: Efficacy studies need to be performed under standard European farming conditions, following the applicable legislation. However, EFSA takes note of the comment of the applicant that there might not be the need to update the efficacy guidance; however, there is a clear need to establish and publish guidance to the specific points highlighted in the presentation. For what concerns field studies, most of those that were received in the past showed limitations that precluded reaching conclusions (i.e. missing the control group, very low number of replicates, etc). However, if field studies are performed complying with the guidance, they can be submitted, and the Panel will consider them for the assessment.

Q: Regarding the guidance on safety for user, I suggest to look at alternatives for irritation and inhalation studies, in order to reduce the number of animals used. (Regal B.V.)

A: Currently for the endpoint of skin and eye irritation, EFSA requests *in vitro* studies. In the framework of the update of the guidance on the safety for the user, the Panel will consider new OECD test and possible alternatives, and the possibility to use existing data.

Q: It is important to be able to track the status of the applications. This was easy to be done with the register of questions, but we have lost that with Open EFSA (EMFEMA)

A: EFSA is aware that the discontinuation of the register of question had an impact on the possibility to easily monitor past applications. Discussion is ongoing to retrieve data previously available to the public in the register of questions and make that publicly available.

Q: How is the work done during the risk assessment in relation to the discussion of the dossiers in the different working groups? (EMFEMA)

A: In the past, all the sections of a dossier were discussed in a working group dedicated to specific active substance/agents. With the current approach of using horizontal WGs, the drafts may be discussed in different working groups. The structure of the WGs and the way of working on dossiers was modified in order to have pools of experts that can discuss on specific topics, assuring consistency in the assessment across dossiers.

Q: Does this mean that in the future we will receive different list of questions from different WGs (Elanco Deutschland GmbH)

A: The aim of EFSA is to coordinate the work in order to group all the questions. In some cases, it could happen that not all the necessary WGs could handle the dossier at the same time. In this case, EFSA sends requests at different times.

Q: If a dossier was sent before the guidances' update, the data provided at that time are valid or new data complying with the new guidances need to be re-submitted? Would it be possible to have a soft approach for this? (Danish Veterinary and Food Administration)

A: In principle, if a dossier was submitted before the update of the guidance(s), the info in the dossier are still considered. The impact of the new guidances on the safety aspects may be considered during the assessment. The two main aspects that could be affected by the new guidance documents include: (i) target animal safety studies, in particular fish when the target species are all animal species, and (ii) genotoxicity studies.

Q: Is the new guidance going to include detailed endpoints requested for the functional group Physiological Condition Stabilisers? (Danish Veterinary and Food Administration)

A: Discussion is on-going. It is challenging to establish specific endpoints as it may depend on the claim proposed by the applicant. Up to now, EFSA has received very few applications involving this functional group. For those received, the applicant was requested to clearly define the efficacy claim, and the Panel has reviewed and assessed the endpoints provided in relation to that claim.

Q: Extrapolation to all animal species in the safety for the target species is not always clear. We would like to have some clarifications about how this is done depending on the data provided. (Danish Veterinary and Food Administration)

A: (i) Extrapolation to other species using NOAEL- Maximum Safe Concentration calculation: for some time, the conclusions were limited to the species included in the table provided in the guidance for the safety for the target species. However, this issue was raised by the applicants and the EC, and now it has been corrected. The last adopted opinions including this approach already reflect the extrapolation to all target species considered in the application.

(ii) Extrapolation based on tolerance trials: Extrapolation to all animal species is possible if four tolerance trials are available (salmonids, chickens for fattening, piglets and dairy cows) and show a sufficient margin of safety. When these two conditions are not fulfilled the conclusions may be limited to the extrapolation between physiologically related species as granted by the guidance.

11. Other scientific topics for information and/or discussion

Not discussed due to the lack of time.

12. Answers to questions from Observers

Not applicable.

13. Any other business

The Chair closed the session by thanking all the participants.