

4-6 June 2024

09:00-18:00 / 09:00-18:00 / 09:00-13:00

**MINUTES** – Agreed on 26 June 2024

**Location:** EFSA, Parma

**Attendees:**

○ **Panel Members:**

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

○ **Hearing Experts<sup>1</sup>:**

Georges Bories, Jürgen Gropp, Giovanna Martelli and Guido Rychen.

○ **European Commission and/or Member States representatives:**

Not applicable.

○ **EFSA:**

**FEEDCO Unit:** Angelica Amaduzzi, Montserrat Anguita, Nicole Bozzi Cionci, Rosella Brozzi, Anna Dioni, Maria Dulak-Lis, Joana P. Firmino, Jaume Galobart, Yolanda García-Cazorla, Mary Bridget Gilsehan, Davide Guerra, Orsolya Holczknecht, Laura Iancu, Matteo Lorenzo Innocenti, Paola Manini, Alberto Navarro-Villa, Jordi Ortuño, Daniel Pagés Plaza, Elisa Pettenati, Fabiola Pizzo, Joana Revez, Barbara Rossi, Jordi Tarrés-Call, Piera Valeri and Maria Vittoria Vettori.

**FDP Unit:** Irene Baratto, Sara De Berardis, Oscar González, Patricia Romero Fernández.

**LA Unit:** Gunda Kriz, Francesca Volpi.

**MESE Unit:** Irene Cattaneo.

○ **Observers:**

See Annex I.

○ **Others:**

Not applicable.

## 1. Welcome and apologies for absence

The Chair welcomed the participants. No apologies were received. The Chair welcomed Laura Iancu as a new member of the FEED Team.

## 2. Adoption of agenda

The agenda was adopted without changes.

## 3. Declarations of interest of Panel members

In accordance with EFSA's Policy on Independence<sup>2</sup> and the Decision of the Executive Director on Competing Interest Management<sup>3</sup>, EFSA screened the Annual Declarations of

<sup>1</sup> As defined in Article 17 of the Decision of the Executive Director concerning the selection of members of the Scientific Committee, the Scientific Panels, and the selection of external experts to assist EFSA with its scientific work: <http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf>. Hearing experts attended on 6 June 2024

<sup>2</sup> [Policy on Independence](#)

<sup>3</sup> [Competing Interest Management](#)



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. Agreement of the minutes of the 173<sup>rd</sup> FEEDAP Panel plenary meeting held on 17-18 April 2024 via teleconference**

The minutes of the 173<sup>rd</sup> FEEDAP Plenary meeting were agreed by written procedure on 26 April 2024.<sup>4</sup>

#### **5. Report on written procedures**

No written procedures to report.

#### **6. Scientific outputs submitted for discussion/adoption**

##### **6.1 AveMix<sup>®</sup> 02 CS (endo-1,4-beta-xylanase, endo-1,3 (4)-beta-glucanase and polygalacturonase) for piglets (suckling and weaned) ([EFSA-Q-2020-00635](#), [EFSA-Q-2020-00840](#))**

These questions refer to the renewal of the authorisation under Article 14 of Regulation (EC) No 1831/2003 of AveMix<sup>®</sup> 02 CS (endo-1,4-beta-xylanase, endo-1,3 (4)-beta-glucanase and polygalacturonase) as a zootechnical additive for piglets (suckling and weaned).

The Panel discussed the draft scientific opinion, and in particular assessed data regarding product characterisation and safety. The Panel unanimously adopted the opinion.

##### **6.2 AveMix XG 10 (endo-1,4-beta-xylanase and endo-1,3(4)-beta-glucanase) for piglets (suckling and weaned piglets) ([EFSA-Q-2020-00807](#))**

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 AveMix XG 10 (endo-1,4-beta-xylanase and endo-1,3(4)-beta-glucanase) as a zootechnical additive for piglets (suckling and weaned piglets).

The Panel discussed the draft scientific opinion, and in particular assessed data regarding product characterisation, safety and efficacy. The Panel unanimously adopted the opinion.

##### **6.3 MAGNI-PHI<sup>®</sup> (*Quillaja saponaria* and *Yucca schidigera*) for poultry and ornamental birds ([EFSA-Q-2021-00310](#))**

This question refers to the authorisation under Article 4 of Regulation (EC) No 1831/2003 of MAGNI-PHI<sup>®</sup> (*Quillaja saponaria* and *Yucca schidigera*) as a zootechnical additive for poultry and ornamental birds.

The Panel discussed the draft scientific opinion, and in particular assessed data regarding product characterisation, safety and efficacy. The Panel unanimously adopted the opinion.

##### **6.4 AveMix XG 10 (xylanase and beta-glucanase produced by *T. longibrachiatum* (MUCL 49755 & 49754)) for laying hens and minor poultry species ([EFSA-Q-2021-00673](#))**

This question refers to the renewal of the authorisation under Article 14 of Regulation (EC) No 1831/2003 of AveMix XG 10 (xylanase and beta-glucanase produced by *T.*

<sup>4</sup> [https://www.efsa.europa.eu/sites/default/files/2024-04/feedap240417-18\\_m.pdf](https://www.efsa.europa.eu/sites/default/files/2024-04/feedap240417-18_m.pdf)



*longibrachiatum* (MUCL 49755 & 49754)) as a zootechnical additive for laying hens and minor poultry species.

The Panel discussed the draft scientific opinion, and in particular assessed data regarding product characterisation and safety. The Panel unanimously adopted the opinion.

**6.5 RONOZYME<sup>®</sup>HiStarch (CT) RONOZYME<sup>®</sup>HiStarch (L) (alpha-amylase (E.C. 3.2.1.1) produced by *Bacillus licheniformis* DSM 34315) for all growing poultry species ([EFSA-Q-2023-00043](#))**

This question refers to the authorisation under Article 4 of Regulation (EC) No 1831/2003 of RONOZYME<sup>®</sup>HiStarch (CT)/(L) (alpha-amylase (E.C. 3.2.1.1) produced by *Bacillus licheniformis* DSM 34315) as a zootechnical additive for all growing poultry species.

The Panel discussed the draft scientific opinion, and in particular assessed data regarding product characterisation, safety and efficacy. The Panel unanimously adopted the opinion.

**6.6 L-Tyrosine (3c401) for all animal species ([EFSA-Q-2023-00202](#))**

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

The Panel discussed the draft scientific opinion, and in particular assessed data regarding product characterisation and safety. The Panel unanimously adopted the opinion.

**6.7 *Saccharomyces cerevisiae* CNCM I-1079 for dogs and all Canidae ([EFSA-Q-2023-00486](#))**

This question refers to the authorisation under Article 4 of Regulation (EC) No 1831/2003 of *Saccharomyces cerevisiae* CNCM I-1079 as a zootechnical additive for dogs and all Canidae other than dogs.

The Panel discussed the draft scientific opinion, and in particular assessed data regarding product characterisation, safety and efficacy. The Panel unanimously adopted the opinion.

**6.8 Sepiolite for all animal species ([EFSA-Q-2023-00638](#))**

EFSA was requested to deliver an opinion on the safety of sepiolite as a technological additive for all animal species.

The Panel discussed the draft scientific opinion, and in particular assessed data regarding product characterisation and safety. The Panel unanimously adopted the opinion.

**6.9 Potassium hexacyanoferrat (II) (potassium ferrocyanide) and natriumhexacyanoferrat(II)-ferrocyanatium (sodium ferrocyanide) for all animal species ([EFSA-Q-2024-00053](#))**

EFSA was requested to deliver an opinion on the safety of potassium hexacyanoferrat (II)(potassium ferrocyanide) as a technological additive for all animal species.

The Panel discussed the draft scientific opinion, and in particular assessed data regarding product safety. The Panel unanimously adopted the opinion.

**6.10 Vitamin B<sub>12</sub>/cyanocobalamin produced by fermentation with non-genetically modified *Ensifer adhaerens* CGMCC 19596 for all animal species ([EFSA-Q-2024-00056](#))**

EFSA was requested to deliver an opinion on the characterisation of vitamin B<sub>12</sub>/cyanocobalamin produced by fermentation with non-genetically modified *Ensifer adhaerens* CGMCC 19596 as a nutritional additive for all animal species.

The Panel discussed the draft scientific opinion, and in particular assessed data regarding product characterisation. The Panel unanimously adopted the opinion.



**6.11 Botanically defined flavourings from Botanical Group 01 - Lamiales for all animal species and categories: Clary sage oil ([EFSA-Q-2024-00304](#))**

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

The Panel discussed the draft scientific opinion, and in particular assessed data regarding product characterisation, safety and efficacy. The Panel endorsed the opinion, which will be adopted once the report of the EURL is received.

**6.12 Botanically defined flavourings from Botanical Group 01 - Lamiales for all animal species and categories: Lavender oil ([EFSA-Q-2024-00306](#))**

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

The Panel discussed the draft scientific opinion, and in particular assessed data regarding product characterisation, safety and efficacy. The Panel endorsed the opinion, which will be adopted once the report of the EURL is received.

## **7. Other scientific topics for information/discussion**

Not discussed

## **8. Feedback from EFSA**

### **8.1 Experts' survey**

In December 2023 the experts of the EFSA Scientific Panels and of the Scientific committee were invited to fill a survey. The questions investigate the scientific and organisational support provided by EFSA and the expert's engagement in working with EFSA. The main findings of the survey, as well as the specific results for the FEEDAP Panel were presented and discussed. The results of the survey will be used as input for lesson learnt and follow-up actions for the new Panel 2024-2029.



## OPEN SESSION

5 June 2024, 14:00 – 18:00

6 June 2024, 09:00 – 13:00

### 9. Welcome

The Chair welcomed the participants and the observers.

### 10. Panel members introduction

The Panel Chair invited the Panel members to introduce themselves.

### 11. Presentation of EFSA guidelines for observers

A member of the FEEDCO Unit presented the guidelines for observers for open plenary meetings.<sup>5</sup>

### 12. Update on new mandates since the previous meeting

#### 12.1 New applications under Regulation (EC) 1831/2003

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

EFSA-Q number	Subject
EFSA-Q-2024-00222	<i>Pediococcus pentosaceus</i> NCIMB 12674 for all animal species
EFSA-Q-2024-00223	Potassium iodide (No 3b201) and calcium iodate anhydrous (No 3b202) for all animal species
EFSA-Q-2024-00245	Neohesperidine dihydrochalcone for piglets and pigs for fattening, calves, sheep, fish and dogs
EFSA-Q-2024-00246	Neohesperidine dihydrochalcone for piglets and pigs for fattening, calves, sheep, fish and dogs
EFSA-Q-2024-00259	<i>Lactobacillus acidophilus</i> D2/CSL (CECT4529) for laying hens
EFSA-Q-2024-00260	<i>Saccharomyces cerevisiae</i> NCYC R404 for dairy cows for milk production
EFSA-Q-2024-00262	CAPSOZYME SB PLUS (alpha-galactosidase (EC, 3.2.1.22) and endo-1,4-beta-xylanase (IUB 3.2.1.8)) for weaned piglets
EFSA-Q-2024-00263	Belfeed B MP/ML (Endo-1,4-beta-xylanase EC 3.2.1.8 produced by <i>Bacillus subtilis</i> LMG S-15136) for gestating sows
EFSA-Q-2024-00273	25-hydroxycholecalciferol as nutritional additive for salmonids, other fish species and all other animal species
EFSA-Q-2024-00287	Guanidinoacetic acid as zootechnical additive for chickens and turkeys for fattening and reared for laying and breeding
EFSA-Q-2024-00301	Preparation of endo-1,4-beta-xylanase (EC 3.2.1.8) and endo-1,3-beta-glucanase (EC 3.2.1.6) as zootechnical additives for chickens for fattening and reared for laying, laying hens, turkeys for breeding purposes, for fattening and reared for breeding and minor poultry species

<sup>5</sup> [Guidelines for Observers for open plenary meetings](#)



EFSA-Q number	Subject
EFSA-Q-2024-00302	L-Carnitine (3a910) and L-carnitine L-tartrate (3a911) as nutritional additives for all animal species

## 12.2 Valid applications under Regulation (EC) No 1831/2003

Applications considered valid for the start of the assessment:

EFSA-Q number	Subject	Valid on
EFSA-Q-2023-00451	FlorEquilibre® Chien ( <i>Lactobacillus acidophilus</i> CNCM I-3231, <i>Ligilactobacillus salivarius</i> CNCM I-3233, <i>Lactiplantibacillus plantarum</i> CNCM I-3232, <i>Lacticaseibacillus rhamnosus</i> CNCM I-4427, <i>Bifidobacterium animalis</i> subsp. <i>lactis</i> CNCM I-3993) for dogs and other non-food-producing animals	29/04/2024
EFSA-Q-2023-00857	Bonvital ( <i>Enterococcus lactis</i> DSM 7134) for sows	10/04/2024
EFSA-Q-2023-00867	GalliPro® Fit 10 ( <i>Bacillus subtilis</i> DSM32324, <i>Bacillus subtilis</i> DSM32325 and <i>Bacillus amyloliquefaciens</i> DSM25840) for all poultry species for laying and for breeding	13/05/2024
EFSA-Q-2023-00887	YEA-SACC, YEA-SACC TS ( <i>Saccharomyces cerevisiae</i> CBS 493.94) for dairy cows and minor dairy ruminant species, cattle for fattening and minor ruminant species for fattening	06/05/2024
EFSA-Q-2023-00898	Riboflavin (vitamin B <sub>2</sub> ) and riboflavin (vitamin B <sub>2</sub> ) (80% feed grade) produced by <i>Bacillus subtilis</i> VBB18049 for all animal species	13/05/2024
EFSA-Q-2024-00001	Plexomin L-Cu (copper lysinate sulfate) for all animal species	10/04/2024
EFSA-Q-2024-00005	L-arginine for all animal species	18/04/2024
EFSA-Q-2024-00007	MoNa (molybdenum compound) for pollinator insects	16/05/2024
EFSA-Q-2024-00031	L-histidine and L-histidine monohydrochloride monohydrate from <i>Corynebacterium glutamicum</i> KCCM80389 for all animal species	25/04/2024
EFSA-Q-2024-00032	L-valine (min. 98%) from <i>Corynebacterium glutamicum</i> KCCM80365 for all animal species	22/04/2024

## 12.3 New questions under Regulation (EC) No 178/2002

EFSA-Q number	Subject
EFSA-Q-2024-00212	BLIS K12 ( <i>Streptococcus salivarius</i> K12) for pets and other non food-producing animals.
EFSA-Q-2024-00226	CanBiocin k-9 Heritage Probiotic Blend for dogs
EFSA-Q-2024-00275	Bafasal® (preparation of bacteriophages PCM F/00069, PCM F/00070, PCM F/00071 and PCM F/00097) for all avian species

## 12.4 Generic mandate on environmental risk assessment of additives containing trace elements

A member of the FEEDCO Unit made a general presentation of a mandate which is expected to be received in the near future for the environmental risk assessment of feed additives containing trace elements used as nutritional additives. The need, scope, current status and timelines were presented and discussed.



The Chair allowed for questions from observers, which are reported below.

**Q: In the recent past, has there been specific event or reason (e.g. ecotoxicological problems with trace elements) which triggered this mandate? Or is it just an interesting issue to elaborate on?**

A: What triggered the need of this generic mandate was the coming renewal of applications, the updated guidance document for the environmental risk assessment of feed additives offering different options to perform the assessment, and the fact that for some environmental compartments (e.g., the marine sediment) there are data gaps.

**Q: Although the methodologies are similar, the threshold for stopping the ERA at phase I are much lower in the FEEDAP ERA guidance document in comparison with EMA guidance. Can you elaborate on this?**

A: These threshold values were reviewed when the Guidance on the safety of feed additives for the environment was updated. It was noted that the thresholds used at the time of revision were still acceptable to be used today. From a scientific point of view, these thresholds values should still be used. In addition, they are compliant with the provisions of Regulation (EC) No 429/2008.

**Q: Are these two years the timeline for all trace elements? How far along is the most advanced trace element - can we expect an opinion for a first element soon?**

A: The generic mandate is for a single scientific opinion. All trace elements will be assessed at the same time.

**Q: And this "available data on specific trace element abundance" will be summarised in the scientific opinions, correct? EMEA and EFSA should align and meet in the middle in the sense of "one substance-one assessment".**

A: As explained in the minutes of the FEEDAP Working Group on Environment of 12 December 2022<sup>6</sup>, there is a suitable database with hundreds of samples from pristine areas analysed in different environmental compartments, although from 2005. There are more recent databases (e.g., GEMAS, LUCAS) that will be explored in this two-year period. Natural background concentration of an environment compartment (e.g., soil, water, freshwater sediment) is determined by applying 10% to the 90<sup>th</sup> percentile of the distribution of concentrations of the trace element. Unfortunately, for marine environment, no data are available in this database.

**Q: What about new authorisations of trace elements? What will happen to the dossiers already submitted? Will the scientific opinions be inconclusive in all parts or only in the environmental safety section? Would there be an authorisation just for the terrestrial species?**

A: Once the mandate is in place, the European Commission will manage these situations. The Commission is well aware of the situation, and they may establish special provisions for those dossiers that may be impacted.

**Q: Does the two year period foreseen for this generic mandate include the time to collect data from existing sources? Is public data collection also foreseen?**

A: The 2-years period comprises the whole process. We plan to reach out to relevant institutions and stakeholders and launch a call for data, along with providing precise explanation of what data are needed. There may be the case that new data shall be generated. We may also perform a literature review to seek for relevant information.

**Q: For the marine environment, will further studies be needed? Some stakeholders are ready to generate new data, but they would need a guidance on how to perform the studies so that the data can be used in the assessment.**

---

<sup>6</sup> <https://www.efsa.europa.eu/sites/default/files/2024-01/wg-environment-2018-2024.pdf>



A: EFSA had a dedicated meeting with some stakeholders to explain the mandate. We are in a very initial phase as we just are waiting to receive the mandate from the European Commission. If there is a call for data, this will be advertised on the EFSA website and everyone will be informed, along with necessary explanation. It is in our own benefit that everybody is aware of the next steps, but we are not able to anticipate precisely what and when will be asked.

**Q: Due to missing data, is it the FERA calculation tool still applicable or not?**

A: Yes, it is applicable.<sup>7</sup> It allows to calculate the exposure (what goes to the environment via manure). This is compared with the natural background concentration of the trace element in the particular compartment. Unfortunately, for some trace elements and for some environmental compartments, the comparator (natural background concentration) is missing, and it is for this reason that data are needed. The first step will be the search for measured (background concentration) data and for this, no ecotoxicity tests are required.

## **13. Feedback from Scientific Committee/Scientific Panels/EFSA/European Commission/EURL**

### **13.1 Scientific Committee**

The Chair of the Panel provided an overview of the main items discussed during the last plenary meeting of the Scientific Committee.

### **13.2 Scientific Panel(s) including their Working Groups**

Not discussed.

### **13.3 EFSA**

Not discussed.

### **13.4 European Commission/EURL**

Not discussed.

## **14. Ongoing activities in relation to applications for feed additives**

### **14.1 Update from the Front Desk and Planning Unit**

EFSA staff from the Front-Desk and Workforce planning unit (FDP) presented an overview of recent activities during the pre-submission phase and the intake phase. Information was provided on recent communication to applicants and support initiatives, including an upcoming update of the Administrative guidance document for feed additive applications. Information was provided on the applications trend (FEED applications and submissions of complementary information following EFSA inconclusive opinion) with a comparison of the intake and validity numbers along the years from 2021 and the time needed to validate an application.

The questions received during the registration phase were answered, and the Chair allowed for further questions from observers, which are reported below.

**Q: Currently, for feed additives dossiers deposited online we have successive requests for information (RFI) before the dossiers being valid. It would be easier to manage to have all requests at once.**

---

<sup>7</sup> Feed additives Environment Risk Assessment calculation tool available online at <https://www.efsa.europa.eu/en/applications/feedadditives/tools>





A: During the completeness check of applications/submissions, missing information or unclarities may be identified, in this case, a request for information (RFI) is sent to the applicant at the end of the completeness check deadline. Each request for information contains all the issues identified during the completeness check. After the reply of the applicant, a new completeness check is started to verify the new version of the dossier. In case other issues are identified in the second check, a new request for information is prepared and sent. Therefore, during the intake phase of applications, more than one of RFI can be sent but only in case the new versions of the applications are still not ready for the risk assessment.

**Q: Also, regarding the update of question 4 of the Q&A of the Practical Arrangement: Is it still necessary to notify MIC studies for microbial additives?**

A: MIC studies are part of the characterisation section, therefore they belong to the category of studies that do not need notification.

**Q: The efficacy guidance will be updated, and the new version is expected to be published at the end of the next month. In this new draft updated guidance, it is mentioned that the minimum number of independent studies and target species required for the assessment of efficacy in applications covering multiple species has been changed and softened. For example, with the new efficacy guidance, it will be possible to request an application for all aquatic species by submitting efficacy tests: 1 in salmonids + 1 in another carnivore fish species + 1 in herbivore fish species + 1 in crustacean/mollusc. In the actual guidance, we have to request an authorisation for all fin fish and crustaceans, by submitting efficacy tests: 3 in salmonids + 3 in other species + 3 in shrimp/crustaceans. The softening of these requirements leads us to reconcile our registration strategy. With the actual guidance, 9 efficacy trials were required to submit an application covering all the aquatic species, so only the salmonids were chosen as target species for our application. With this new guidance, only 4 studies are necessary. We have already performed studies on another carnivore fish, herbivore fish and also crustacean, but without notifying them, as they weren't sufficient to submit an application covering all aquatic species, according to the actual guidance. These non-notified studies with this new guidance could allowed us to submit an application for all aquatic species. As this new guidance will be release after the performing of these trials: Will it be possible to justify the non-notification of these efficacy studies by saying that this new guidance has been released after their performing without being clock-stopped for 6 months?**

A: The question regards a specific case and it is not possible to reply without having additional elements. Applicants have the possibility to justify the non-notification of a study if this is in line with the application of a previous guidance which specifies that no notification is requested for that kind of study. Normally efficacy studies need to be notified before their starting date, and there is the possibility to notify them after this date with a justification. However, EFSA cannot indicate a priori if a justification will be automatically accepted or not. It will depend on the elements included in the justification: the more detailed is a justification, the better EFSA can evaluate it. Issues on the notification of studies can also be asked in a RFI during the completeness check.

**Q: Would it be possible to list the exact names of the missing/incorrect references in the missing information requests during the completeness check, since it is difficult to identify the relevant documentation with general questions referring to "references" only, without further indication.**

A: FDP clarified that general requests on references/annexes without listing the exact number and names of the affected ones are included in RFI when the issues is affecting a considerable number of annexes (e.g., dozens, hundreds) for which a complete list is not feasible. FDP took note of the applicant comment for internal discussion.

**Q: With the OSOA, it seems that IUCLID is in the air. Any information on this?**



A: The implementation of IUCLID is under evaluation, but no timelines are currently available. When a decision will be taken, it will be communicated accordingly, but it is not envisaged to happen in the short term.

#### **14.2 Update from the Legal Affairs Services Unit**

EFSA staff gave an overview of the lessons learnt and examples of best practice in relation to the submission of documents and confidentiality requests, provided some clarifications on the confirmatory applications, updates on the notification of studies and on EFSA activities.

The Chair allowed for questions from observers, which are reported below.

**Q: Concerning the confidential earmarking in the documents, does EFSA prefer permanent boxes, temporary boxes that can be removed easily during sanitisation or no boxes at all (confidential parts only earmarked in the redacted documents)?**

A: EFSA prefers earmarked information in the confidential document that can easily be redacted in the non-confidential document and removed during redaction if necessary. EFSA recommends the use of professional software (such as Nuance PDF and KOFAX PDF) which offer these functionalities.

**Q: How will EFSA deal with dossiers which are not following the recommendations clarified during this Open Plenary Session?**

A: In case EFSA needs clarifications on the specific confidentiality requests, the applicant will be contacted through a request for clarification (RfC).

**Q: EFSA mentioned a collaboration with DG SANTE colleagues with the aim to improve the ESFC user. If we want to send suggestions for improvement, to whom we have to send them? Are there any deadlines?**

A: EFSA and DG SANTE have bilateral meetings so applicants can write both to EFSA ([confidentialityrequestassessment@efsa.europa.eu](mailto:confidentialityrequestassessment@efsa.europa.eu)) or to DG SANTE ([SANTE-ANIMAL-NUTRITION@ec.europa.eu](mailto:SANTE-ANIMAL-NUTRITION@ec.europa.eu)). In terms of timelines, it is not easy to provide an exact reply as there are dependencies with the colleagues.

### **15. FEEDAP Panel - upcoming work and working practices**

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 years, work in progress as well as work foreseen for the near future.

The Chair allowed for questions from observers, which are reported below.

**Q: Have you already started to work with experts from the Member States (MS), as announced during the open plenary last November? Could you elaborate a little on the experience so far?**

A: The work with the MS has started and the first deliverables have been submitted, with positive feedback.

**Q: Will the specific contributions of the MS experts be transparent for the applicant and the public?**

A: For now, the specific contributions from MS will not be clearly identified in the opinions, as it is now for the contributions of EFSA staff. In the future there might be changes in the authorship of the opinions.

**Q: The assessment by MS sounds like a serious departure from Regulation (EC) No 1831/2003 philosophy, which sought to centralise the assessment in EFSA.**

A: The Food Law (Regulation (EC) No 178/2002), as modified by the Transparency Regulation, already foresees the need for an involvement of national authorities in the risk assessment carried out by EFSA (see Art 22.7).



**Q: Guidance documents are updated every two years, while some studies to be included in a dossier start five years before dossier submission. The guidelines are applied at the point of submission, meaning that study design is at risk of being obsolete during that step. Would there be a transit period until the guidelines are valid?**

A: Normally the update of guidance documents tends to lower the number of studies and overall requirements, and refine/clarify the requirements. There is always a transition period which is usually of six months. In principle a guidance is updated when a need is identified and scientific evidence can support it. EFSA aims at avoiding ambiguities and providing guidance to concerns that have been identified by the applicant in the previous years.

## 16. Update on the assessment of microorganisms

EFSA staff gave a general presentation on recent updates on the assessment of microorganisms. The presentation included information on the new EFSA guidance on the risk assessment of microorganisms, the BIOHAZ Panel statement on how to interpret the QPS qualification on acquired antimicrobial resistance (AMR) genes and on the status of the Microorganisms pipelines services (MoPS). Regarding the new guidance on microorganisms, EFSA explained that it will be a cross-sectorial guidance repealing existing guidance documents in the area of regulated products. This draft guidance is expected to be endorsed by the Scientific Committee for public consultation within 2024 and finally adopted within 2025. Moreover, the EFSA staff raised awareness on the publication of the BIOHAZ statement that aims at clarifying the means to discriminate between acquired and intrinsic AMR genes which although it was conceived in the context of the QPS assessment, the document is applicable to all microorganisms. EFSA encourages applicants to follow the recommendations of this statement in case the interrogation of the whole genome sequence (WGS) data of their strains for AMR genes identifies hits. Finally, EFSA provided an overview of the MoPS for bacteria, yeasts/fungi and viruses, designed to support and standardise the risk assessment across domains. The MoPS ensures secure data handling, conducts sequence quality checks, and utilises WGS data for taxonomic identification and characterisation, in line with EFSA's guidances' requirements. The Panel was informed about the ad hoc technical meeting with stakeholders held on 29 May, where MoPS was presented. A brainstorming session explored its potential and future developments, including code access and portal availability.

The Chair allowed for questions from observers, which are reported below.

**Q: Regarding the security of the MoPS tool, would the data already submitted be treated as the data submitted in the future?**

A: The MoPS tool allows users to retrieve data from the ESFC platform as well as upload it manually. The same security measures apply; the data are not stored in the platform.

**Q: What does the vast majority of wild type strains mean for the "intrinsic" AMR genes? Is 80% already vast majority for a species where there are hundreds of genes from different strains of the same species available?**

A: It was not possible to propose a threshold that would be universally valid, as it would be gene and species dependent. In absence of a threshold, the assessment will be made on a case-by-case basis.

**Q: Are the analysis tools included in MoPS derived from public tools/available outside the system?**

A: The MoPS tool relies only on publicly available databases. Since no online tool is used, no data are distributed on the web.

**Q: Regarding the horizontal guidance, applicable to all domain sectors, would the coccidiostats be covered in another guidance?**



A: Compatibility of a microbial feed additive with coccidiostats may most likely be out of the scope of the new EFSA guidance. Therefore, the provisions for the assessment of compatibility as well as other elements that are fall out of the scope of the new guidance will be placed in a different document, such as the guidance on characterisation.

**Q: Will the whole genome sequence statement go for public consultation?**

A: No, it will not. The current update is considered to have a minor impact on the document. EFSA will proceed directly with the publication and the applicants will be invited to use it.

**Q: You mentioned that MoPS is not used on a regular basis, so the data are extracted from ESFC, and the analysis is conducted on a case-by-case basis. What may be the doubts?**

A: The use of MoPS to perform checks is based on the discussions within the working group on Microbiology in cases of doubts on the dataset provided. In those cases, the MoPS output is used to refine the questions to be posed to the applicant. Therefore, it mostly depends on the dataset.

## 17. Assessment of feed additives consisting of or containing nanoparticles

EFSA staff gave an overview of the implementation strategy by the FEEDAP Panel of the *Scientific Committee Guidance on risk assessment of nanomaterials to be applied in the food and feed chain: human and animal health (nano-RA)* and the *Scientific Committee Guidance on technical requirements for regulated food and feed product applications to establish the presence of small particles including nanoparticles for the safety assessments of feed additives (particle-TR)*. In the 171<sup>st</sup> Plenary meeting, the FEEDAP Panel agreed to continue the characterisation of feed additives to determine presence of small particles/nanoparticles, but until further guidance is available, the risk assessment of feed additives would continue to follow the currently available sectorial guidance documents. The Panel is also working on the development of criteria to clarify when there is the need to characterise the presence of small particles/nanoparticles in feed additives.

The questions received during the registration phase were answered, and the Chair allowed for further questions from observers, which are reported below.

**Q: I would like to know the status of the FEEDAP plans to start to evaluate nano size particles in feed additives and whether there will be a specific guidance on this matter or whether this will be included in the upcoming revisions of the small/nano particle guidance.**

A: The FEEDAP Panel will work on a specific guidance tailored to feed additive safety assessments.

**Q: Regarding nanoparticles and small particles: How to consider compounds with the physical state declared to be "crystals", "oily liquids" and "viscous liquids"?**

A: The guidance document on particle-TR indicates that the assessment of particles at the nanoscale refers to entities in solid form, including particles in suspension/dispersion. This covers solids in both crystalline or amorphous form. While true liquids (i.e., no particles present) are exempted from the nano risk assessment. The absence of solid particles in liquids should be demonstrated following the guidance document on particle-TR.

**Q: What is the definition of a feed additive consisting of nanoparticles? Is there an existing guidance for applicants on the data/methods requirements for the assessment of feed additives containing nanoparticles?**

A: There is not such a definition. Feed additives should follow the guidance document on particle-TR, which provides decision criteria for all regulated products whether the risk assessment should consider also nano-specific aspects.



**Q: The guidance on technical requirements to establish the presence of small particles including nanoparticles mentions part 1.3, page 10 that this guidance "only addresses the risk for consumers exposed via food". In the case of an application for a feed additive intended for non food-producing animals, is this assessment of the presence of small particles not necessary, considering that the "consumer safety" part for the authorisation dossiers for additives targeting this category of animals is not necessary?**

A: These aspects are included in Appendix B of the Guidance on risk assessment of nanomaterials to be applied in the food and feed chain: human and animal health (EFSA Scientific Committee, 2021a). That guidance outlines the principles on how to evaluate nanoparticle-related aspects for feed additives, including the safety for the consumer, where the focus should be on the residues. The FEEDAP Panel agreed that there is a need for practical guidance tailored to feed additive safety assessments which considers safety for the target species, users, consumers and the environment, to complement the principles described in the above-mentioned guidance documents.

**Q: Would you intend to apply such nano requirements for the authorisation renewal of mineral additives that are on the market forever. Would be nice to take into account the authorisation regime (non-holder) for such additives.**

A: This is one of the aspects that will be considered in the upcoming update of the guidance.

**Q: The dossier on silica (E551) is still under review with specific questions on safety related to nano assessment. Is it possible to have more visibility on the discussions on-going for silica. Obviously silica is widely used for feed additive preparations.**

A: Silicon dioxide is currently under assessment as a food and feed additive. As such, it is considered as a cross-cutting substance, therefore the evaluations are harmonised in terms of timelines. Further information on the status of the work is available in Open.EFSA and in the minutes of the relevant Working Groups and Panels.

**Q: Some of the approved feed materials in the catalogue may contain nano size particles. These feed materials can also be used for carriers of feed additives e.g. enzymes. How will you address this matter of "nano feed materials". Thank you.**

A: Feed materials do not fall in the remit of the Regulation (EC) No 1831/2003. Unless EFSA receives a specific mandate from the EC, we will not address the matter. There is work in progress to provide clarity on the nano-specific considerations for feed additives that are complex mixtures/formulations.

**Q: Following the 50<sup>th</sup> WG of Nanotechnology, in the minutes, it is mention that DLS method is not allowed to characterised the particle size in the nanoscale, even if in the TR nano guidance it is not clearly mentioned that this method is not allowed. Can you please confirm this information?**

A: The scanning electron microscopy (SEM) is the preferred technique. The clarification that dynamic light scattering (DLS) is not suitable for nanoparticle characterisation was indeed provided in the minutes of the Cross-cutting Working Group on Nanotechnologies.

**Q: For clay additives, is it required to go on the second nano guidance on the risk assessment and perform further studies as genotoxicity?**

A: In principle, a nano-specific risk assessment would be required for nanostructured substances such as clays. Nevertheless, for the time being, following the decision of the FEEDAP Panel, these additives need to be properly characterised including the fraction of small/nano particles following the methodology proposed by the Guidance on technical requirements for regulated food and feed product applications to establish the presence of small particles including nanoparticles (EFSA Scientific Committee, 2021b), while the safety assessment will follow sectorial guidance documents. With regards to genotoxicity studies, Ames test is not adequate for substances in particulate form that are practically insoluble like clays.



## 18. Update on renewal applications for coccidiostats and histomonostats

EFSA staff delivered a presentation to echo a decision of the Panel that was adopted in the 172<sup>nd</sup> Plenary meeting of the FEEDAP Panel.<sup>8</sup> During that meeting the FEEDAP Panel decided that, for applications for the renewal of authorisation coccidiostats and histomonostats, tolerance studies should be performed according to the most updated guidance document at the time of submission. These studies should not be older than three years at the time of submission. Applicants should also use these tolerance studies to collect samples of tissues and products for residue determination for an updated assessment of consumer exposure.

The Chair allowed for questions from observers, which are reported below.

**Q: You mentioned before that the studies shouldn't be older than three years. This is a relatively short time for the stakeholders, as in some cases longer time (e.g. five years) are required to complete the preparation of a dossier.**

A: This requirement is applicable since the agreement of the Panel in the March plenary meeting. The Panel needs this evidence in order to conclude on the safety of the products.

## 19. Guidance on the assessment of efficacy of feed additives ([EFSA-Q-2022-00248](#))

This question refers to the self-task of the Panel on the update of the guidance for the assessment of the efficacy of feed additives.

The draft guidance was endorsed by the FEEDAP Panel for public consultation on 16 November 2023. Discussion focused on the modifications introduced in the guidance following the comments received in the public consultation. The guidance was unanimously adopted. The Panel also endorsed the technical report prepared by the FEEDCO Unit regarding the outcome of the public consultation.

The questions received during the registration phase were answered, and the Chair allowed for further questions from observers, which are reported below.

**Q: Efficacy guidance: in the table 6 for dairy cows it is mentioned "<16 weeks and >30 kg/day", this range is surprising. In EU, we have ca. 20 million of cows and the milk range ca. 7,500 kg for 305 days, and vary from 16 kg to 30 kg in function of breed. This constraint excludes breeds and less intensive systems based on forage pasture. Trials <16 weeks correspond to early lactation in which body reserves are used for milk production; at this stage the genetic of the animals will be tested and not the feed additive. The best will be carried out trials on mid-lactation. May I have your comments?**

A: The minimum daily milk production, as reflected in Table 6, refers to the production at the start of the trial, not to the average of the whole experiment (or lactation). This minimum requirement ensures that the trial covers the most productive period of the milk cycle. The Panel considers that demonstrating the efficacy under these intensive conditions would better allow extrapolation to other situations where animals are in less demand. If the additive is not intended to be effective during the whole cycle, the experimental design would need to be justified according to the additive function and its conditions of use.

**Q: The updated Guidance on efficacy of feed additives will include a new table on the 'minimum number of independent studies and target species required for the assessment of efficacy in applications covering multiple species/categories'. That table will include a reduced set of studies required for 'all fin fish' which will consist on 2 studies on salmonids + 1 study on herbivore species + 1 study on carnivore**

<sup>8</sup> <https://www.efsa.europa.eu/en/events/172nd-plenary-meeting-feedap-panel>



**species. Most aquaculture species could be considered omnivore species. Could you please state some examples of acceptable carnivore and herbivore species?**

A: The referred requirement in Table 5 has been modified. The current requirements include two studies on salmonids and two on other fin fish species (one in each).

**Q: How to manage numbers of authorisations for feed flavourings (natural or synthetic origin) for small companies. Would it be possible to simplify efficacy and safety EFSA guidances for these feed additives regarding the facts that most of the are authorised as food additives?**

A: When an additive is already authorised for use in food, and its intended use of the additive in feed is the same, no further demonstration of efficacy is generally necessary, provided that the effect seen when the additive is used in food could reasonably be expected to be seen when it is used in feed at the recommended concentration and that food and feed matrices are comparable.

**Q: Is the term “breeding does” mentioned in the draft guidance the proper one?**

A: It is correct for female breeding rabbits.

**Q: When are these changes going to be implemented in an amended guidance document?**

A: The new guidance document will be published on the EFSA website in the following weeks. After the adoption of the guidance, a transition period of around six months will follow.

**Q: For additives affecting animal welfare, is it required to have physiological and behaviour, or physiological or behaviour endpoints?**

A: For additives affecting stress resilience, the choice of endpoints of additives depends on the stressor applied (if any), the specific claim and the conditions of use of the additive. As indicated in the new Guidance, either physiological, behavioural and/or immunological endpoints can be used to evaluate the link between the stressor (if applied) and the welfare consequence. Each application and the studies provided will be evaluated on a case-by-case basis. Likewise, for additives favourable affecting animal welfare, the selection of the endpoints should be adequately justified.

**Q: Is the notification of the performance of a study by a research facility to the relevant Member State Authority and their approval to conduct such study enough proof of the compliance with the relevant EU Animal Welfare Legislation, correct?**

A: Yes, this is one of the appropriate ways contemplated in the Guidance.

**Q: For additives affecting animal welfare, in the guidance it is mentioned that stressing factors can be applied to assess the welfare and stress resilience. However, is it possible and acceptable to justify the welfare improvement of the animals without adding stressing factors, but only by assessing general factors as behaviour, digestive conditions...?**

A: In the Guidance, two different effects are considered for additives affecting animal welfare: (i) additives favourably affecting welfare and (ii) additives affecting stress resilience. In both cases, it is possible to demonstrate the effect on the welfare without applying any stressing factors. Regarding (ii), the Guidance indicates that there is the option of applying stressing factors to demonstrate the efficacy of the additive, but it is not mandatory.

**Q: Could we receive more information on the models to be used in the efficacy studies for zotechnical additives?**

A: For enzymes intended to be used as zotechnical additives, the new Guidance foresees the possibility of replacing the requirement of three *in vivo* studies in one category of the same species with a combination of *in vitro* studies following validated systems. The Panel does not propose a specific model, but it is acknowledged that there are sufficient methods available in the literature. However, it is noted that the *in vitro* methods used should be validated *in vivo* within the same animal species, taking into account the feed characteristics



and the animal species/category-specific digestive conditions, mimicking the physical, chemical and microbiological characteristics of the *in vivo* gut fluid.

**Q: For the additives that are not enzymes but are intended to be used as digestibility enhancers, is it possible to use short-term study designs or is needed to provide long-term in vivo studies?**

A: As a general rule, for zootechnical additives intended to affect the animal production or the performance of animals, long-term efficacy studies should be provided. Only in the case of enzymes affecting the utilisation of phytate phosphorus or the digestibility of polysaccharides or proteins, short-term studies can substitute long-term studies.

**Q: Is it mandatory that in the health certificates at the beginning of the studies are signed by a veterinarian?**

A: The Panel considers that the animal health and welfare status can only be verified by a veterinarian, who is responsible for ensuring proper monitoring of the animals at the start and during the trial, including the endpoints to be checked.

**Q: Is the health status certificate needed for tolerance studies as well?**

A: For all type of *in vivo* studies, it is recommended to provide health status certificates to ensure that the animals involved in the study are healthy and meet the criteria established in the EU animal protection legislation.

**Q: There are only a handful of laboratories able to perform AST studies for coccidiostats, mainly in the UK. Can these studies be performed in the UK?**

A: The Guidance indicates that inocula used for the artificial infection both in floor pen and anticoccidial sensitivity tests should be sampled from different regions within the EU that are sufficiently distant to guarantee that the *Eimeria* strains are not related. However, there is no geographical limitation preventing the performance of trials in facilities outside the EU, as long as those studies permit conclusions to be drawn on the efficacy of the additive when used in the EU.

**Q: Regarding the ethical committee, can an independent veterinary check the trial protocol?**

A: The position of the Panel is quite clear in this regard, and it is explicitly indicated in the Guidance document: the study protocol needs to be checked and validated by a competent authority or an independent ethical committee to ensure compliance with the rules on animal welfare laid down by the European Union legislation. The approval needs to be documented. The revision by an independent veterinary may not suffice.

**Q: For additives affecting the environmental consequences of animal production none of the comments regarding the direct vs indirect effects of additive were considered in the final version of the guidance.**

A: This comment is considered not related to the risk assessment but to the authorisation process and corresponding legal requirements, which are out of the scope of EFSA. The current guidance document maintains a consistent approach with previous versions. The European Commission agrees with this approach, acknowledging that the effects on the environment may be considered indirectly through changes in the animals' output resulting from the use of certain additives.

**Q: The six months transition period before the implementation of the guidance may have an impact for applicants with dossiers under preparation.**

A: The six-month period following the adoption of the guidance document is intended to allow companies to adapt to the new requirements. When the guidance will be implemented, new submissions should follow the updated requirements; however, ongoing studies may be affected by this timeline. In such cases, any deviation from the guidance should be properly justified. It is essential to note that the changes in the guidance generally reduce requirements and should not create significant obstacles for compliance.





**Q: What should be done for those ongoing studies for which there is not an evaluation by an ethical committee?**

A: As for any other new requirements, the implementation of the Guidance envisages a transition period for the applications to be adapted. In cases involving animal welfare, if an ongoing study did not have the a priori evaluation and approval from an independent ethical committee or a competent national authority, which would be considered good practice, it must comply with the requirements of the current Guidance, clearly indicating compliance with national or institutional guidelines for the care and use of animals, and including a detailed description of the husbandry conditions in which the animals were raised to ensure compliance with the protection rules.

**Q: Different studies may be done in commercial farms or R&D farms where there is no ethical committee. Would it be enough to have a statement from the veterinary?**

A: As already commented, the position of the Panel is quite clear in this regard, and it is explicitly indicated in the Guidance document: the study protocol needs to be checked and validated by a competent authority or an independent ethical committee to ensure compliance with the rules on animal welfare laid down by the European Union legislation. The approval needs to be documented. The revision by an independent veterinary may not suffice. However, it is acknowledged that the revision procedure and the way in which the approval is documented may vary among the different Member States and the type of research facility in which the trial is performed.

## **20. Revised animal dietary exposure assessment model ([EFSA-Q-2023-00406](#))**

This question refers to the self-task of the FEEDAP and CONTAM Panels to update the model currently in use for animal dietary exposure assessment to ensure it is up to date with the current practices (e.g. updated animal diets in line with current recommended diets) and allowing a more flexible approach.

The draft statement was presented. The Statement, already presented to and endorsed by the CONTAM Panel on 4 June 2024, provides updated list of target animals, feed consumption, body weights and diets used for the calculation of dietary animal exposure assessment for contaminants in feed materials. The Panel unanimously adopted the statement.

The Chair allowed for questions from observers, which are reported below.

**Q: In relation to in vivo studies in cattle for fattening, in the exercise presented, there are two main farming systems: feedlots and grassland. Studies performed in feedlot farming systems might not be accepted as they could be considered as not representing farming practices in the EU. Could efficacy studies performed in feedlots be submitted in the dossiers?**

A: In the context of in vivo studies in cattle for fattening, both feedlot and grassland farming systems were considered in the exercise. Considering feed additives, the FEEDAP Panel has accepted studies with diets containing high level of compound feed in comparison with studies mainly based on forage diets. Anyways, the intention was to evaluate the potential exposure to contaminants present in concentrates and the conclusion was that feedlot systems could be representative of feeding practices in EU relative to concentrate to forage ratio in beef cattle diets, therefore these should be accepted. As a result, efficacy studies performed in feedlots are accepted and are preferable to demonstrate efficacy, as they represent a worst-case scenario for compound feed consumption. Therefore, studies performed in feedlots can be submitted in the dossiers for evaluation.



## 21. Safety of feed additives containing selenium for the consumers ([EFSA-Q-2023-00896](#))

EFSA was requested to deliver an opinion on the safety for the consumers of selenium (Se) when used in feed additives, with the aim to determine whether the conditions for authorisation set out in Regulation (EC) No 1831/2003, with regard to the safety for the consumers of relevant animal products, is still met for the existing authorisations of additives containing selenium as active substance, on the basis of available information and data. The draft opinion was discussed, focusing on the assessment of consumer exposure. The Panel unanimously adopted the opinion.

The questions received during the registration phase were answered, and the Chair allowed for further questions from observers, which are reported below.

**Q: Do you expect other mandates similar to the one on selenium (Se) for other trace elements in the future?**

A: The potential for mandates for other trace elements in the future cannot be totally discarded. The decision to mandate a review of a specific trace element will depend on whether a potential hazard is identified, as was the case with the reduction of the tolerable upper level (UL) for selenium in food. As of now, there are no predictions for similar mandates for other trace elements, as the trigger for the selenium mandate was the reduction UL for selenium.

**Q: Selenium intakes from the diet are relatively high using the consumer exposure tool of EFSA for feed additives. Are there any plans to use a more refined tool for intakes or will decisions on the risk posed be based on the existing tool.**

A: The exposure to selenium of consumers of food of animal origin is estimated using the methodology described in the Guidance on the assessment of the safety of feed additives for the consumer, using the data on consumption of edible tissues and products as derived from the EFSA Comprehensive European Food Consumption Database. For the estimate of the exposure, the FACE calculator, which is based on the above methodology, is used.

**Q: Dear Panelists, bees are not at all fed with selenium. Why do you consider residues in honey?**

A: Selenium residues in honey are highlighted as missing data. However, the Panel did not indicate the need to request further studies in honey bees.

**Q: Considering the horizontal nature of this assessment, would it not be appropriate to send it into a public consultation prior to adopt it?**

A: Considering the nature of the mandate by the EC, and the fact that it is based strictly to the data available in the different dossiers, and not in other sources, it was not foreseen to send it to public consultation.

**Q: Dear Panelists, was the risk of consumer under supplementation with Selenium via food considered?**

A: This topic has not been considered, as it is not in the remit of this mandate and of the FEEDAP Panel.

**Q: Were data sets from Se additives which are not yet authorised and currently or recently under assessment by EFSA also considered?**

A: Yes, the EC mandate requested EFSA to consider data available in all dossiers, so also included in the dossiers where the assessment is ongoing.



## 22. Questions from Observers and answers

Questions from observers not addressed in the specific sections above.

**Q: It happened lately that pre-publication notifications were received by applicants at inconvenient times during the week, for example on Friday afternoons, which does not allow applicants to properly check the opinion in 24 hours as requested by the publication procedures. How should I interpret the 24 hours to react to a pre-publication notification of scientific opinions?**

A: As indicated in the EFSA's Catalogue of support initiatives during the life cycle of applications for regulated products, the pre-publication notification of the adopted scientific output aims at informing in a timely manner the applicant, the European Commission and other selected stakeholders of the publication on EFSA's website of the adopted scientific output. The pre-notification is sent to the applicant and selected recipients at least 36 h prior to publication. The applicant can inform EFSA on confidentiality matters (although no new confidentiality requests can be submitted at this stage), manifest typographical errors or other objective inaccuracies until 24 h before publication (no extension of deadline is accepted). EFSA acknowledges that 24 h is a limited period and takes note of the comment.

**Q: In the last stakeholders meeting, it was understood that a new clock stop mechanism was intended to be introduced, in order to avoid so many inconclusive scientific opinions, especially regarding efficacy. Could you further develop on this?**

A: Applicants are responsible for the data submitted to EFSA, and the guidance documents are updated to explain in a clearer way what data is needed for the assessment. Since 2018 the stop-the-clock system for efficacy data does not envisage requests for new studies. EFSA is evaluating the possibility to modify the current approach and the implementation of the new guidance may be a good opportunity.

**Q: Do you think that is logical to perform risk assessments of aromatic substances derived from plants for animal use only but not doing the assessment for use in food?**

A: EFSA is not in a position to answer this question, as the topic is under the remit of European Commission.

## 23. Any other business

### 23.1 Next meeting

The Panel agreed to have an extra meeting on 26-27 June 2024 via teleconference.

### 23.2 Closure

The Chair closed the session by thanking all the participants.



## Annex I List of Observers

### Online:

104 registered (but only 69 observers attended)

Observer	Organization
Alexopoulou, Katerina	FEFANA asbl.
Aly, Doyle	Kerry Ingredients & Flavours Ltd.
Arnaud, Ludovic	lallemand
Auclair, Eric	Société Industrielle Lesaffre
Balázs, Zoltán	Leveret GmbH
Behary, Shannon	FeedInfo
Bento, Helena	Cargill
Bremmers, Ruud	Ruud Bremmers
Capodiecici, Giuseppe Luca	FEFANA
Clasadonte, Laure	Herbonis Animal Health
Colombo, Valentina	Federchimica AISA
Conboy-Schmidt, Lisa	Nestlé Purina
Coudray, Guillaume	Harper Collins
Cuevas, Fabiola	Corteva
Debiais, Julian	All4feed
Dohms, Juliane	Phytobiotics Futterzusatzstoffe GmbH
Elbasyouny, Malak	National Food Safety Authority of Egypt
Eskola, Mari	Medfiles Ltd
Gemma, Choi	CJ Europe GmbH
Giner, Marta	devreg consulta slu
GonzalezSanchez, AntonioLuis	Paleo
Gueganno, tristan	all4feed
Hahn, Ulrike	NHU Europe GmbH
Herve, Maryse	EU Specialty Food Ingredients
Hincelin, Clémentine	ADISSE0
Houriet, Vera	adm
Ishimbaeva, Rimma	AVC - Association of Veterinary Consultants
Jambunathan, Nandini	CJ Europe
Jans, Didier	EMFEMA
Kiehne, Verena	IFF
Kordali, Niovi	Nutreco Nederland BV
Królikowska, Daria	Proeton Pharmaceuticals S. A.
Lanckriet, Anouk	Huvepharma NV
LlamasMoya, Sara	Kerry
Longares, Monica	Lucta, S.A.
Lützwow, Manfred	saqual GmbH
McConochie, Carmen	Cefic (European Chemical Industry Council)
Merino, Ana	Atova Regulatory Consulting S.L.
Millot, Laurence	ADISSE0
Miralles, Pilar	EW Nutrition GmbH
Muñoz, Daniel	Zinpro Animal Nutrition (Europe), Inc.



Observer	Organization
Niederberger, Katherine	Leveret West Ltd
Nikodinoska, Ivana	Alltech
Oliveira, Helena	AB Vista
Pasecinic, Nicoleta	Kerry Taste & Nutrition
Peeters, Nathalie	Orffa Additives B.V.
Perrot, Tifenn	ALL4FEED
Pippig, Susanne	LANXESS Deutschland GmbH
Popiołek, Michał	dsm-firmenich
Pragai, Zoltan	dsm-firmenich
Preynat, Aurélie	ADISSEO
Renaudin, Stéphanie	BIODEVAS LABORATOIRES
Ribo, Oriol	dsm-firmenich
Rodriguez, Raquel	Kemin Europa N.V.
Roet, Ron	RM Associates Ltd
Schmidinger, Stefan	Kemiex AG
Schneider, Julie	AZELIS FRANCE SAS
Schoendorfer, Karin	dsm-firmenich
Schoenmann, Susan	taro services GmbH
Setzer, Ariela	Elanco
Simony, Marie-Louise	Chr. Hansen A/S, part of the Novonesis group
Sørensen, Thomas Seier	Novonesis
Stojecki, Krzysztof	Business Development Manager
Strauß, Pamela	Lactosan GmbH & Co.KG
Truyens, Mathias	Orffa Additives BV
Wall, Sian	Greencoat Ltd
Wielgat, Natalia	Insectarium.pl
Xhufi, Anila	Canadian Food Inspection Agency
Zeugin, Fabienne	perpende GmbH

**Onsite:**

16 registered (but only 11 observers attended)

Observer	Organization
Bertin, Gerard	ERAWAN CONSULTING
Diaz, Sabina	Novus Spain SA
Grothaus, Katrin	Biochem Zusatzstoffe Handels- und Produktionsges. mbH
Guibert, Francois	PHODE
Herzog, Michaela	Feed and Additives GmbH
Huibers, Ruud	Elanco Deutschland GmbH
Juárez Pallarés, Alicia	FEFANA
Lepont, Alexia	Botanical ID
Morisset, Typhaine	MIXSCIENCE
Piskorikova, Mirka	AVC, Argenta
Ravidat, Valerie	ERAWAN CONSULTING