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

170th Plenary Meeting

14-16 November 2023
09:00-18:00 / 09:00-18:00 / 09:00-16:00
Open session 15 and 16 November 2023
MINUTES – agreed on 4 December 2023

Location: European Food Safety Authority (Parma)

Participants:

- **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, Alena Pechová, Mariana Petkova, Fernando Ramos, Roberto Edoardo Villa and Ruud Woutersen.

- **Hearing Experts:**

  Not applicable.

- **European Commission:**

  Not applicable.

- **EFSA:**

  FEEDCO Unit: Angelica Amaduzzi, Montserrat Anguita, Nicole Bozzi Cionci, Rosella Brozzi, Anna Dioni, Yvette Dirven, Stefani Fruk, Jaume Galobart, Yolanda García Cazorla, Mary Bridget Gilsenan, Davide Guerra, Orsolya Holczknecht, Matteo Lorenzo Innocenti, Marianna Kujawa, Paola Manini, Alberto Navarro Villa, Jordi Ortuño, Daniel Pagés Plaza, Elisa Pettenati, Fabiola Pizzo, Anita Radovnikovic, Joana Revez, Barbara Rossi, Jordi Tarrés-Call, Piera Valeri and Maria Vittoria Vettori.

  FDP Unit: Irene Baratto, Sara De Berardis, Oscar Gonzalez, Patricia Romero.

  FIP Unit: Gloria López-Gálvez.

  LA Unit: Federica Bruno, Nicole Falessi, Gunda Kriz.

- **Observers (in application of the guidelines for Observers)[1,2]:**

  Hanna Abbas (DSM-Firmenich), Chiara Achilli (Università di Parma), Yvonne Agersø (Chr, Hansen A/S), Aikaterini Alexopoulou (FEFANA asbl.), Caroline Andersson (Cefic - European Chemical Industry Council), Ludovic Arnaud (Lallemand), Zoltán Balázs (Leveret GmbH), Gerard Bertin (ERAWAN CONSULTING), Levashni Bijou (Nestle Purina), Caroline Boudergue (Anses), Ruud Bremmers (Regal BV), Benjamin Buckle (Salus Animal Health Ltd), Giuseppe Luca Capodieci (FEFANA), Gemma Choi (CJ Europe GmbH), Lisa Conboy-Schmidt (Nestlé Purina), Benjamin Costerousse (Dr. Benjamin Costerousse - CoGreen consulting), Fabiola Cuevas (Corteva Agriscience BV), Chloé Damour (METEX NOOVISTAGO), Teresa Debesa (Nutreco), Julian Debiais (All4feed), Ruud Detert (Food Basics), Sabina Díaz (Novus Spain SA), Juliane Dohms (Phytobiotics Futterzusatzstoffe GmbH), Daisy Rocio Duchen Bocangel (Pen & Tec Consulting), Esraa Elewa (Nutreco), Tanja Erbs (Novozymes), Mari Eskola (Medfiles Ltd), Melani Garcia (Volac Feeds Ltd.), Katrin Grothaus (Biochem Zusatzstoffe Handels- und Produktionsges. mbH), Nicholas Guthier (Evonik Operations GmbH), Marie-Julie Hannoun (Metex Noovistago), Yujie He (Nutreco), Michaela Herzog (Feed and Additives GmbH), Clémentine Hincelin (ADISSEO), Vera Houriet (ADM), Ruud Huibers (Elanco Deutschland GmbH), Philip Jones (Volac International Ltd), Alicia Juárez Pallarés (FEFANA), Niovi Kordali (Nutreco Nederland BV), Serol Korkmaz (Veterinary Control Institute, Istanbul), Paulina Kosakowska (Józef Gręda "JFARM"), Daria Królikowska (Proteon Pharmaceuticals S.A), Sonja Krone-Wolf (Feed and Additives GmbH), Anni Laffitte (Royal Canin), Anouk Lanckriet

[1] this file was republished because of an editorial
[2] https://www.efsa.europa.eu/sites/default/files/observersguidelines.pdf; attending on the 15th and 16th of November

(Huvepharma NV), Alexandra Lensch (Evonik Operations GmbH), Agata Litwinowicz (Proteon Pharmaceuticals), Monica Longares (Lucta, S.A.), Carmen McConochie (European Chemical Industry Council), Typhaine Morisset (MIXSCIENCE), Daniel Munoz (Zinpro Animal Nutrition (Europe), Inc.), Katherine Niederberger (Leveret West Ltd), Sheehan Noel (AB Agri Ltd, trading as AB Vista), Alicia Pardo (Lucta, S.A.), Fabrizio Pasanisi (Federico II University of Naples), Marta Perez de Nanclares (KEMIN), Tifenn Perrot (ALL4FEED), Susanne Pippig (LANXESS Deutschland GmbH), Miroslava Piskorikova (Pen & Tec Consulting SLU), Valerie Ravidat (ERAWAN CONSULTING), Emilie Raynaud (Royal Canin), Johana Reinhardt (Anses), Oriol Ribo (dsm-firmenich), Agustina Rodriguez (Elanco Animal Health), Raquel Rodriguez (Kemin Europa n.v.), Diego Rodriguez Manzano (Corteva Agriscience), Ron Roet (RM Associates Ltd), Carmen Rosas (ADISSEO NUTRICION ANIMAL SLU), Susan Schoenmann (taro services GmbH), Karin Schöndorfer (dsm-firmenich), Regine Schreiner (Feed and Additives GmbH), Ariela Setzer (Elanco), Ahmad Taghipour (Dr. Benjamin Costerousse - CoGreen consulting), Ilse Tuinman (IFF), Liza Van den Eede (Eastman), Elisa Varona Sanchez (Kemin Europa), Bettina Wagner (German Federal Institute for Risk Assessment), Sian Wall (AB Agri (Greencoat Ltd)), Brandon Walters (Intertek Health Sciences Inc.), Fabienne Zeugin (perpende GmbH), Ivana Nikodinoska (Alltech).

- **Others:**

  Not applicable.

1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Baltasar Mayo. The Chair welcomed Anna Dioni, Marianna Kujawa and Piera Valeri as trainees in the FEEDCO Unit.

2. Adoption of agenda

The agenda was adopted after the inclusion of the item "Biomin® C3 (Preparation of *Enterococcus faecium* DSM 21913, *Bifidobacterium animalis* DSM 16284 and *Ligilactobacillus salivarius* DSM 16351) for all growing poultry (EFSA-Q-2022-00374)".

3. Declarations of Interest of Panel members

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

4. Report on written procedures since the 169th FEEDAP Plenary meeting

The minutes of the 169th FEEDAP Plenary meeting were agreed by written procedure on 4 October 2023.[5]

The Panel adopted the following opinion by written procedure:

[3] Policy on Independence
[4] Competing Interest Management
[5] https://www.efsa.europa.eu/sites/default/files/2023-10/feedap_230926-28_m_1.pdf

- aXiphen (phenylcapsaicin) for chickens for fattening (EFSA-Q-2022-00355) adopted on 31 October 2023

5. Scientific topics for discussion

5.1. Natrolite-phonolite for all animal species (EFSA-Q-2014-00888)

This question refers to the re-evaluation under Article 10 of Regulation (EC) No 1831/2003 of natrolite-phonolite 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.

5.2. Natrolite-phonolite for all animal species (EFSA-Q-2014-00890)

This question refers to the re-evaluation under Article 10 of Regulation (EC) No 1831/2003 of natrolite-phonolite 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.

5.3. Sepiolite and diatomaceous earth for all terrestrial species (EFSA-Q-2019-00301)

This question refers to the authorisation under Article 4 of Regulation (EC) No 1831/2003 of sepiolite and diatomaceous earth 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.

5.4. Kieselgur (diatomaceous earth, purified) for all animal species (EFSA-Q-2019-00662)

Not discussed due to lack of time.

5.5. Zinc chloride hydroxide monohydrate for all animal species (EFSA-Q-2021-00548)

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

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

5.6. Kalama® Animal Feed Grade (benzoic acid) for pigs for fattening and piglets (weaned) (EFSA-Q-2021-00740)

This question refers to the authorisation under Article 4 of Regulation (EC) No 1831/2003 of Kalama® Animal Feed Grade (benzoic acid) as a zootechnical additive for pigs for fattening and piglets (weaned).

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

5.7. PB6 *Bacillus velezensis* ATCC PTA-6737 for all pigs (EFSA-Q-2022-00320)

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 PB6 *Bacillus velezensis* ATCC PTA-6737 as a zootechnical additive for all pigs.

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

5.8. *Pediococcus acidilactici* CNCM I-4622 for all insect species and categories (EFSA-Q-2022-00340)

This question refers to the authorisation under Article 4 of Regulation (EC) No 1831/2003 of *Pediococcus acidilactici* CNCM I-4622 as a zootechnical additive for all insect species and categories.

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

5.9. Biomin® C3 (Preparation of *Enterococcus faecium* DSM 21913, *Bifidobacterium animalis* DSM 16284 and *Ligilactobacillus salivarius* DSM 16351) for all growing poultry (EFSA-Q-2022-00374)

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 Biomin® C3 (preparation of *Enterococcus faecium* DSM 21913, *Bifidobacterium animalis* DSM 16284 and *Ligilactobacillus salivarius* DSM 16351) as a zootechnical additive for all growing poultry.

The draft opinion was adopted in the 169th Plenary meeting of the FEEDAP Panel. However after adoption, it was identified that an aspect on the efficacy assessment was not included in the opinion. Therefore, the Panel agreed to withdraw the adoption of the opinion. An updated draft opinion considering all the information was discussed; the discussion focused on the efficacy of the additive. The Panel unanimously adopted the opinion.

5.10. Lactiferm® (*Enterococcus faecium* NCIMB 11181) for piglets (weaned), calves for fattening and calves for rearing (EFSA-Q-2022-00553)

This question refers to the renewal of the authorisation under Article 14 of Regulation (EC) No 1831/2003 of Lactiferm® (*Enterococcus faecium* NCIMB 11181) as a zootechnical additive for piglets (weaned), calves for fattening and calves for rearing.

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

5.11. Folic acid for all animal species (3a316) (EFSA-Q-2022-00555)

This question refers to the renewal of the authorisation under Article 14 of Regulation (EC) No 1831/2003 of folic acid (3a316) as a nutritional additive for all animal species.

The draft opinion, which was partially presented in the previous plenary meeting, was discussed focusing on the characterisation and safety of the additive. The Panel unanimously adopted the opinion.

5.12. *Duddingtonia flagrans* (Dudd) Cooke NCIMB 30336 (EFSA-Q-2022-00742)

EFSA was requested to deliver an opinion on the safety of *Duddingtonia flagrans* (Dudd) Cooke NCIMB 30336 as a zootechnical additive for all grazing animals.

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

5.13. PB6 *Bacillus velezensis* ATCC PTA-6737 for all growing birds (EFSA-Q-2022-00746)

This question refers to the authorisation under Article 4, 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 PB6 *Bacillus velezensis* ATCC PTA-6737 as a zootechnical additive for all growing 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.

5.14. Zinc-L-selenomethionine (3b818) for all animal species (EFSA-Q-2022-00857)

This question refers to the modification of the conditions of the authorisation under Article 13 of Regulation (EC) No 1831/2003 of zinc-L-selenomethionine (3b818) as a nutritional additive for all animal species.

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

5.15. *Levilactobacillus brevis* DSM 23231 for all animal species (EFSA-Q-2023-00276)

This question refers to the renewal of the authorisation under Article 14 of Regulation (EC) No 1831/2003 of *Levilactobacillus brevis* DSM 23231 as a technological additive for all animal species.

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

5.16. Copper (II)-betaine complex for all animal species (EFSA-Q-2023-00401)

EFSA was requested to deliver an opinion on the safety and efficacy of copper (II)-betaine complex as a nutritional additive for all animal species.

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

5.17. Availa-Cr (chromium chelate of DL-methionine) for dairy cows (EFSA-Q-2023-00089)

EFSA was requested to deliver an opinion on the efficacy of Availa-Cr (chromium chelate of DL-methionine) as a zootechnical additive for dairy cows.

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

5.18. Aviax® 5% (semduramicin sodium) for chickens for fattening (EFSA-Q-2023-00353)

EFSA was requested to deliver an opinion on the safety of Aviax® 5% (semduramicin sodium) as a coccidiostat for chickens for fattening.

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

OPEN SESSION

15 November 2023, 14:30-18:00

16 November 2023, 09:00-16:00

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 FEEDCO Unit presented the guidelines for observers for open plenary meetings.

9. New mandates

9.1. New applications under Regulation (EC) 1831/2003 since the previous meeting

The Commission 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-2023-00551	TechnoCare® 50 (*Bacillus licheniformis* DSM 33806 and *Weizmannia faecalis* DSM 32016) for piglets (suckling and weaned), pigs for fattening, sows and physiologically related minor growing and reproductive porcine species
EFSA-Q-2023-00674	Clinoptilolite of volcanic origin (E567) for all terrestrial animal species
EFSA-Q-2023-00688	4-Hydroxy-2,5-dimethylfuran-3(2H)-one (2b13010) for cats and dogs
EFSA-Q-2023-00704	Perlite (E599) as an anticaking agent for all terrestrial animal species
EFSA-Q-2023-00705	Inositol (3a900) for fish and crustaceans
EFSA-Q-2023-00712	L-lysine sulphate produced by *Corynebacterium glutamicum* for all animal species
EFSA-Q-2023-00715	*Saccharomyces cerevisiae* (NBRC 0203) and *Lacticaseibacillus rhamnosus* (NBRC 3425) for all animal species

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

Applications considered valid for the start of the assessment:

EFSA-Q number	Subject	Valid on
EFSA-Q-2022-00873	L-threonine produced by fermentation with *Corynebacterium glutamicum* KCCM80367 for all animal species	02/10/2023
EFSA-Q-2022-00882	L-tryptophan produced by fermentation with *Corynebacterium glutamicum* KCCM80346 for all animal species	02/10/2023
EFSA-Q-2023-00207	L-isoleucine for all animal species	11/10/2023
EFSA-Q-2023-00254	Quantum® Blue (preparation of 6-phytase (EC 3.1.3.26) produced by a genetically modified strain of *Trichoderma reesei* (CBS 126897)) for poultry, weaned piglets, pigs for fattening and sows	29/09/2023
EFSA-Q-2023-00298	Lactosil (*Lactiplantibacillus plantarum* 14D/CSL - CECT 4528) for all animal species	26/09/2023
EFSA-Q-2023-00355	*Levilactobacillus brevis* 16680 for all animal species	28/09/2023
EFSA-Q-2023-00362	*Loigolactobacillus coryniformis* DSM34345 for all animal species	09/10/2023
EFSA-Q-2023-00409	Vitamin B12 or cyanocobalamin produced by *Ensifer adhaerens* CGMCC 21299 for all animal species	16/10/2023
EFSA-Q-2023-00440	Lanthan One (lanthanum carbonate octahydrate) for dogs	02/10/2023
EFSA-Q-2023-00454	Bovacillus® (*Bacillus paralicheniformis* DSM33902 + *Bacillus subtilis* DSM33903) for dairy cows for milk production and other dairy ruminants (sheep, goat, buffalo etc.)	28/09/2023
EFSA-Q-2023-00483	Lutein-rich extract of *Tagetes erecta* for turkeys for fattening	09/10/2023
EFSA-Q-2023-00518	Pantothenic acid as calcium D-pantothenate and D-panthenol for all animal species	19/10/2023
EFSA-Q-2023-00539	Fumaric acid for all animal species	16/10/2023
EFSA-Q-2023-00544	*Lacticaseibacillus paracasei* NCIMB 30151 for all animal species	19/10/2023

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

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

EFSA-Q number	Subject
EFSA-Q-2023-00354	Cashew nut shell liquid for all animal species
EFSA-Q-2023-00519	Nilablend™ 200G (lasalocid A sodium and nicarbazin) for chickens for fattening
EFSA-Q-2023-00520	Beta-Xylanase/Beta-Glucanase/*Talaromyces versatilis* IMI 378536/DSM 26702 (Rovabio® Advance)
EFSA-Q-2023-00545	Natupulse® TS/Natupulse® TS L (endo-1,4-beta-D-mannanase, EC 3.2.178) for all growing poultry species (chickens for

EFSA-Q number	Subject
	fattening, turkeys for fattening and minor growing poultry species and other poultry for fattening (e.g. ducks, geese, pheasants, quail, guinea fowl, ostrich) and ornamental birds
EFSA-Q-2023-00638	Sepiolite (E562) as feed additive for all animal species
EFSA-Q-2023-00668	Plexomin® L-Fe (Ferrous lysinate sulfate) for all animal species
EFSA-Q-2023-00694	BioCell® (*Saccharomyces cerevisiae* DBVPG 48 SF) for horses, pigs and ruminants

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

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

10.1. Scientific Committee/Scientific Panels

The Chair of the Panel informed on the publication of the "Guidance on protocol development for EFSA generic scientific assessments".[6]

10.2. EFSA

The Panel experts were informed on the upcoming Expert's feedback survey, intended to provide insights into how satisfied the Experts are feeling with respect to their collaboration with EFSA.

10.3. European Commission/EURL

Not discussed.

11. Workplan of the FEEDAP Panel

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 also to the development and update of guidance documents. At present, work is ongoing on the update of the guidance document on efficacy and on the characterisation of microorganisms.
The Chair allowed questions from observers, which are reported below.

Q: In your presentation it is shown that 200 dossiers were not conclusive; wouldn't it be better to ask questions during the assessment phase, knowing that these inconclusive opinions mean more work for the Commission, EFSA and the applicants? (Ruud Huibers, Elanco Deutschland GmbH)
A: Most of the 200 inconclusive opinions regard flavouring compounds. In most of the cases, EFSA came back to the applicants to request supplementary information regarding the safety of the additive in order to allow completing the assessment.
Q: Part of the inconclusive opinions are due to the fact that we do not get questions, I wonder whether you have the chance to go back to the applicants as you were doing in the past, requesting the missing data that are required by the working groups or the FEEDAP Panel to conclude. (Ludovic Arnaud, Lallemand)

A: It is the applicant's responsibility to provide data in compliance with the Guidance documents at the time of submission of the application. Then, it is up to EFSA and/or the

[6] https://www.efsa.europa.eu/en/efsajournal/pub/8312

working groups to check the data and come back to the applicant in case additional information or clarifications are necessary. EFSA cannot disclose conclusions to the applicants during the assessment phase.

Q: Is it possible to know the technological additives that are still under re-evaluation? (Ludovic Arnaud, Lallemand)

A: The table below reports the dossiers for all feed additives categories that are ongoing for Article 10 applications.

EFSA-Q number	Subject
EFSA-Q-2010-01282	Botanically defined flavourings from Botanical Group 07 - Geraniales, Myrtales, Poales for all animal species and categories
EFSA-Q-2010-01286	Botanically defined flavourings from Botanical Group 02 - Apiales and Austrobaileyales for all animal species and categories
EFSA-Q-2010-01516	Botanically defined flavourings from Botanical Group 18 - Gymnosperms (Coniferales, Ginkgoales) for all animal species and categories
EFSA-Q-2011-00180	Botanically defined flavourings from Botanical Group 14 - Malvales for all animal species and categories
EFSA-Q-2011-00183	Botanically defined flavourings from Botanical Group 19 - Equisetales, Fucales for all animal species and categories
EFSA-Q-2011-00185	Botanically defined flavourings from Botanical Group 13 - Malpighiales for all animal species and categories
EFSA-Q-2011-00188	Botanically defined flavourings from Botanical Group 16 - Rosales for all animal species and categories
EFSA-Q-2013-00070	Polyethyleneglycol of fatty acids from soya oil (E487) for calves
EFSA-Q-2014-00886	Synthetic calcium silicate (E552) for all animal species
EFSA-Q-2014-00887	E 551a silicic acid, precipitated and dried and E 551b colloidal silica for all animal species
EFSA-Q-2015-00518	Silicic acid, precipitated and dried (E 551 a) for all animal species
EFSA-Q-2015-00767	Citranaxanthin (Lucantin CX® forte) for laying hens
EFSA-Q-2016-00780	Chemically defined flavourings from Chemical Group 22 - Aryl-substituted primary alcohol/aldehyde/acid/ester/acetal derivatives, including unsaturated ones: 5-methyl-2-phenylhex-2-enal [05.099] for all animal species and categories
EFSA-Q-2019-00527	Kaolinitics clays, free of asbestos (E 559) for all animal species
EFSA-Q-2019-00662	Kieselgur (diatomaceous earth, purified) for all animal species
EFSA-Q-2019-00768	Nicarb® (nicarbazin) for chickens for fattening
EFSA-Q-2020-00584	Sodium nitrite (E 250) for pigs, poultry, bovines, ovines, goats, rabbits and horses
EFSA-Q-2020-00585	Sodium nitrite (E 250) (Safesil) for pigs, poultry, bovines, ovines, goats, rabbits and horses

12. Update on the Guidance on studies concerning the safety of feed additives for users (EFSA-Q-2022-00226)

This question refers to the self-task of the Panel on the update of the guidance for the assessment of the safety of feed additives for users.
The draft guidance was endorsed by the FEEDAP Panel for public consultation on 4 July 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 Chair allowed questions from observers, which are reported below.

Q: With regards to the dusting potential, when you mention that an additive is dust-free, what does this mean in terms of dusting potential data? Do you have in mind a threshold from which you will consider the additive as dust-free? (Ludovic Arnaud, Lallemand)

A: In principle, dust-free means zero dust or near zero dust emission. However, EFSA is not setting a threshold.

Q: From the presentation of the new Guidance on the safety for the user, I understand that the sensitization potential has not to be tested for microorganisms because the OECD methods were not developed for microbial-based product, but I am wondering whether we can ascertain the methods for eye irritation for those kind of additives. (Ludovic Arnaud, Lallemand)

A: At present, no validated methods are available for testing dermal sensitisation for microbial-based products. However, there are *in-vitro* tests available for the assessment of eye irritation potential for these additives.

Q: For what concerns the implementation date, if an application will be submitted before the implementation date, the old Guidance will be used for that but as the risk assessment will take longer, will EFSA consider the new Guidance for the risk assessment of these applications? (Michaela Herzog, Feed and Additives GmbH)

A: The guidance will be implemented three months after its adoption (i.e., 15 February 2024). The implementation date means that those applications submitted after that date should follow the provisions of the guidance. However, applicants may already follow the adopted guidance when submitting new applications or supplementary information.

Q: We often read in EFSA opinions, when it comes to user safety, that in the absence of data, it is not possible to conclude on user safety. Do you have signals from the EU Commission that you should be stringent on these data? With regards to inconclusive/absence efficacy data, the Commission is asking the applicant the missing data. Will the situation be the same for the user safety? (Ludovic Arnaud, Lallemand)
A: The present guidance significantly reduced the amount of data/studies needed. However, it is responsibility of the applicants to submit the data to allow EFSA to perform a complete assessment. In case of safety issues, EFSA usually requests additional information, if this is not provided in the dossier.

13. Update of the Guidance on the assessment of the 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 discussed. The Panel endorsed the draft guidance for public consultation.

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

Q: Would there be a list of possible stressors published? (Sabina Díaz, Novus Spain SA)

A: At present a list of the stressors is not available, and it is up to the applicant to choose the stressor applied and justify it. Once more experience is gained, some examples of stressors might be included.

Q: Can you please clarify what is meant by 'claimed effect of the additive' in relation to the study design? (Lisa Conboy-Schmidt, Nestlé Purina)

A: The applicant should provide a rationale on how the additive is supposed to affect the animal and how it is expected to ameliorate the physiological conditions of the animal following exposure to the stressor.

Q: What if three studies show significant effects and three studies do not show significant effects? Will efficacy be accepted? (Regine Schreiner, Feed and Additives GmbH)

A: In principle, if three studies showing positive significant effects are provided, these would be enough to conclude on the efficacy of the additive.

Q: In relation to *in-vivo* study independence, is there a percentage of variation established for "difference in diet formulation"? (Daisy Rocio Duchen Bocangel, Pen & Tec Consulting)

A: The scope of having independent studies is to cover different conditions being representative of the EU conditions. Considering different diets, it is not just a matter of having 5% vs 10% of a specific cereal, as an example, in the same diet, but having diets that are formulated with different feed materials.

Q: If renewal dossiers need to follow the approach for this guidance, does it mean that I have to do new studies on a product (e.g., a silage additive) that has been on the market for 10 years or even more, and has proven its efficacy? This has a big impact on company, especially on the small-medium ones. (Ruud Bremmers, Regal BV)

A: In renewal dossiers, if the conditions of use and characterisation of the additive have not changed, no further demonstration of efficacy is considered necessary, as indicated in the FEEDAP Panel guidance on the renewals.

Q: When is it foreseen for the new Guidance to come into effect, as this has a huge impact on applications which are planned to be submitted next year? Will there be a transition period allowing both 'systems'? (Anouk Lanckriet, Huvepharma NV)

A: The guidance is foreseen for adoption by June 2024. There will be an implementation period (likely six months) after which all dossiers should follow the provisions of the guidance. However, the applicants will have the possibility to provide in their dossiers' data in accordance with the requirements of the new guidance before the implementation date.

Q: The product we wish to present requires more than six months of preparation for submission, and we are already doing the studies for the application that we wish to submit in two years. So, my question is what do we do with the studies we are already doing? (Ruud Huibers, Elanco Deutschland GmbH)

A: No major changes in the study requirements are proposed in the endorsed guidance. In any case, the applicant can always provide justifications for any deviations.

Q: Regarding the welfare certification, there might be some problems in the future with the anticoccidial sensitivity testing (AST) studies that can only be done in cages which are, on a practical point of view, no more allowed in Europe. So, until now it was fine, but what should we do if we cannot obtain the certification? (Ruud Huibers, Elanco Deutschland GmbH)
A: For the certification of compliance with the welfare, AST should be considered an experimental procedure with animals, and it would fall under Directive 2010/63/EU.

Q: Can you give some examples of what you mean by independency of studies? (Mari Eskola, Medfiles Ltd)

A: For example, studies conducted in two locations in Europe that are far away from each other.

Q: How do you balance the following two scenarios, on one side the intensive farming and on the other the green deal and not high production farming and animal species? (Ludovic Arnaud, Lallemand)

A: Efficacy demonstrated in high producing animals would, in principle, cover also animals with lower performances, but not the other way around.

14. Risk assessment of microorganisms intentionally added to the food chain

The status of the work on the update of the guidance on the risk assessment of microorganims intentionally added to the food chain was presented.

EFSA staff gave an overview of the Microorganisms Pipelines Service (MoPS), a tool developed by EFSA to support the risk assessment of microorganisms. The scope of the tool and its functionalities were presented.

The Panel also discussed a proposal establishing criteria for the quantification of active agents composing a feed additive. The Panel agreed on the criteria, which are available in ***Annex 1***.

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

Q: With these new criteria for quantification, is EFSA asking applicants to check that only the wanted strain/strains is/are multiplied and not contaminants? Five batches for this kind of analysis might be too much for proving this. Also, microbial strains used to produce multi strain products are usually produced in separate reactors to avoid cross-contamination (Ludovic Arnaud, Lallemand)

A: According to Commission Regulation (EC) No 429/2008, the qualitative and quantitative batch to batch variation of the agent(s) should be determined. Regarding multi strain products, the ratio between the strains composing the additive, according to the specifications set by the applicant, must be confirmed in the final product.

Q: Which molecular method should be used for the identification of the active agent? (Philip Jones, Volac International Ltd)

A: Applicants may choose the most suitable molecular method to identify the strain(s) under assessment.

Q: Will this new requirement on the identification of microorganisms be included on the updated guidance on the characterisation of microorganisms used as feed additives or production organisms next year, or will they be published separately sooner? From when will they be applicable? (Daisy Rocio Duchen Bocangel, Pen & Tec Consulting)

A: The new requirements will be published in the Plenary minutes and included in a future update of the guidance on the identity and characterisation of feed additives.

Q: Regarding the update on the guidance on the characterisation of microorganisms used as feed additives or production organisms: the guidance on enzymes for food have similar but different language for absence of viable cells and DNA. Does EFSA foresee a cross-cutting guidance and removal of language in older guidance to ensure a consistent approach? (Brandon Walters, Intertek Health Sciences Inc.)

A: A cross cutting guidance is foreseen in order to provide a consistent approach for different sectors.

Q: Regarding the MOPS, does it mean that EFSA will only need raw data to perform the Risk Assessment? (Ludovic Arnaud, Lallemand)

A: EFSA will eventually analyse the raw data in case of doubts during the assessment. Applicants will still need to perform their own analyses in any case.

Q: It is our understanding that if the dossier is in good shape there is no need to run the MOPS tool. What happens if applicants do not send the raw data, given that usually they are considered confidential data? (Ludovic Arnaud, Lallemand)

A: Applicants may deviate from the requirements set in the guidance and give a justification for not providing the raw data. However, EFSA may ask the applicant to submit the data, if needed.

15. Update on pre-submission activities and completeness check of feed additives applications

EFSA staff from the Front-Desk and Workforce planning unit (FDP) 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 applications. The activities available to the applicants prior to the submission of an application may help in the preparation of the 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. The information that is available to the applicants for a better understanding of the overall process was also presented.
The questions received during the registration phase were answered and the Chair allowed for further questions, which are reported below.

Q: In the last update of August 2023 of the Questions and Answers on EFSA's Practical Arrangements, it is mentioned that analyses to assess the identity/composition of a product and physico-chemical properties don't need any more to be notified on EFSA portal. Please could you confirm when this statement is applicable? Do you plan to update the practical arrangements? (Tifenn Perrot, ALL4FEED)

A: As of 28 August 2023, analyses to assess the identity/composition of a product and its physico-chemical properties do not need to be notified, in line with the updated Questions and Answers on Practical Arrangements. This is applicable to new applications and to applications for which the validity check was still ongoing on the date of the re-publication. There are currently no plans to update the Practical Arrangements.

Q: Proposal to provide the extensive, specific, and official list of studies that do not need to be notified anymore. It would be very useful for applicants as it takes a lot of time and coordination for notifications activities. (Miroslava Piskorikova, Pen & Tec Consulting SLU)

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A: EFSA will consider this proposal. For any question on notification of studies (NOS) please contact EFSA via the Ask a Question service.

Q: Do small particle analysis fall under these studies not needing a NOS? (Mari Eskola, Medfiles Ltd)

A: These studies do not require notification anymore.

Q: What is in the scope of pre-application advice for new products/uses? What can be discussed? (Miroslava Piskorikova, Pen & Tec Consulting SLU)

A: The objective of this service is to explain to applicants the rules related to the application procedure, answer questions and doubts on the content of their future application.

Q: In case we notified a study which doesn't need to be submitted now (for example the analysis of the active substance), do we have to complete the notification references of this study in ESFC when submitting the dossier? Or can

we consider not completing this part for studies which are not any more mandatory to notify? (Tifenn Perrot, ALL4FEED)

A: The notified information of an analysis which does not require notification is not checked anymore during the completeness check. Any information not relevant for the NOS will not be considered, and it will not be published on the NOS table. If applicants are not sure whether the NOS information is relevant or not for their application, it is suggested to include the information.

Q: Will the request for metadata in the ESFC system be adapted regarding the necessity for notification? (Ruud Bremmers, Regal BV)

A: There are no changes foreseen for ESFC platform linked to the change of the Q&A on EFSA Practical Arrangements, since a modification of the system is not considered necessary. ESFC tool already allows applicants to categorise a document (e.g. study report, certificate of analysis etc.) and to specify whether the content of a document has been subject to study notification or not.

Q: What is the procedure for invalid dossiers which are kept on hold for six months, do applicants need to contact EC or perform other actions? (Ruud Huibers, Elanco Deutschland GmbH)

A: Applications deemed as invalid can be re-submitted at any time after the non-validity. The completeness check of the re-submitted application will start only six months after the re-submission. Applications will need to be submitted as normal to EC, while making reference in the ESFC tool to the previously declared non-valid dossier. The EC will forward re-submitted applications to EFSA.

Q: Can we consider stability studies as studies related to the chemico-physical properties of additives? (Ludovic Arnaud, Lallemand)

A: It is clearly indicated in the Q&A on Practical Arrangements that for stability studies a notification pursuant to Article 32b of the GFL is still required.

Q: Do stability studies need to be notified? (Brandon Walters, Intertek Health Sciences Inc.)

A: Yes, stability studies must be notified to comply with the notification obligations.

Q: Regarding NOS, what are acceptable justifications for delays and what is the relation with confidentiality? (Ludovic Arnaud, Lallemand)

A: EFSA cannot provide a list of valid justifications. Applicants should provide all elements in their possession to support their justifications. In general, every justification provided is assessed on a case-by-case basis, in the light of the information and supporting evidence provided by the applicant. Information related to the notified information and the justifications for any deviation from the notification obligations are published on the OpenEFSA portal once the application is declared valid.

16. Update on the confidentiality assessment of feed additive applications

EFSA staff gave an overview of the underlying principles of confidentiality assessment post Transparency Regulation, listed the legal grounds contained in the closed positive list for which confidentiality can be requested for feed additive dossiers, highlighted the substantive requirements contained in Article 10 of EFSA's Practical Arrangements concerning Transparency and Confidentiality which must be satisfied by applicants and provided information on the sanitisation of documents in line with the confidentiality decision. The presentation also included lessons learnt and examples of best practice in relation to the submission of documents and confidentiality requests, provided some updates on the submission portals and indicated the responsibilities and role of applicants in the confidentiality decision-making process and the duration of the overall process.

Finally, there were some practical examples to better guide applicants on how to claim confidentiality in relation to some specific types of documents.

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

Q: SMEs do not have a team of people having experience, only one person dedicated to the job, is he/she allowed to have two-week holidays? How to deal in such case? For a small company this is really a problem. (Ruud Detert, Food Basics)

A: EFSA acknowledges the problem but there are legal deadlines to respect. Due to the novelty of the Transparency Regulation, EFSA took steps aimed to address certain issues with the scope to meet applicants' needs where possible. However, there is no room for flexibility concerning the two-week mandatory consultation period on the EFSA draft decision which is foreseen by the Transparency Regulation and cannot be derogated. Please also consider that the exchange between EFSA and the applicant could, in some cases, also happen before the draft decision level when EFSA may send an optional request for clarification, so please consider the importance of this step in clarifying the justifications behind your requests.

Q: What exactly is now the task of the Portalino with regards to feed additive applications since 27/07/2023? (Regine Schreiner, Feed and Additives GmbH)

A: The process has been simplified, and since 27 July 2023 follow up applications for inconclusive opinions (under Article 29 of Regulation (EC) No 178/2002) should be submitted through the EFSC platform, instead of through Portalino. Consequently, Portalino will no longer be relevant as a submission portal for feed additive applications and this will have the benefit of allowing applicants to use the same tool for all the submissions.

Q: How does it work in practice if a fully blackened document is rejected by EFSA? Does the applicant get a second chance to redact the document, will EFSA do so, or is the entire document disclosed? (Tanja Erbs, Novozymes)

A: Applicants shall avoid submitting completely blackened documents in relation to documents that cannot be claimed fully confidential. These unjustified claims are usually rejected at draft decision stage and applicants are given the opportunity to comment and clarify their claims and when necessary to submit a new version of the document related to the element clarified in the comments submitted.

Q: How can the Applicant communicate the issues encountered - who can we reach out to in EFSA? (Juliane Dohms, Phytobiotics Futterzusatzstoffe GmbH)

A: You can contact EFSA's Team Confidentiality Food Chain at the functional mailbox for any issue related to the confidentiality assessment process: confidentialityrequestassessment@efsa.europa.eu. If the issue is of a technical nature, you should contact our IT support at the following functional mailbox: servicedesk@efsa.europa.eu. If the issue concerns ESFC platform: SANTE-E-SUBMISSION-FOOD-CHAIN@ec.europa.eu.

Q: It would help a great deal to allow complete Annexes to be confidential. E.G: Judge whether more than 50% is confidential and in this case the whole Annex should be treated as Confidential. (Regine Schreiner, Feed and Additives GmbH)

A: Transparency is the rule, confidentiality is the exception, so this is not possible.

Q: Regulation (EC) No 178/2002 Article 39(2)(a) states: the manufacturing or production process, including the method and innovative aspects thereof, as well as other technical and industrial specifications inherent to that process or method, except for information which is relevant to the assessment of safety. As in-house analytical methods and their validation data are often integrated parts of the quality control of the manufacturing process and hence developed for such reasons, can analytical methods and their validation data be asked to be treated as confidential under the above article? (Mari Eskola, Medfiles Ltd)

Q: Is the method of analysis for the feed additive confidential or not? (Ludovic Arnaud, Lallemand)

A: to the above two questions: Methods of analysis can be claimed as confidential under Art. 39(2)(a) as far as it relates to information that regards company's know-how. Confidentiality may be granted to all in-house methods except for the type of method (UV-VIS spectrophotometry, HPLC, etc). For internationally recognized methods, the reference/protocol number (e.g. EN/ISO number) should be disclosed.

Q: With regards to the accurate blackening, it can happen that in the reports of trials done by the study locations, it is possible to see the location in the header or in the footer of every page, therefore if we do not blacken the whole page, it is not possible to blacken the location. Blacken every single page is really time demanding. (Michaela Herzog, Feed and Additives GmbH)

A: Blackening of a whole page is only acceptable when that page does not contain any information considered non-confidential and this is properly justified by the applicant in their claim.

Q: When do you start with the confidentiality assessment, after validation or at the moment of submission? Because if it is included in the six months assessment time, I guess you have to do the assessment in parallel. Moreover, how do you expect us to react in two weeks' time to a dossier of more than 200 documents? (Ruud Huibers, Elanco Deutschland GmbH)

A: EFSA starts the assessment of the confidentiality after the validation of the dossier. EFSA's draft decisions tend to be very precise and accurate, so applicants do not need to screen the entire dossier but are only required to check the considerations of EFSA's draft decision and its outcome and submit comments on this. The applicant is given two weeks deadline during which he/she can submit comments to EFSA should he/she not agree with EFSA's assessment included in the draft decision.

Q: You recommended us to not copy-paste justifications. The legal ground per se is the legal justification, if we do not do copy-paste the justification, it takes too much time. (Michaela Herzog, Feed and Additives GmbH)

A: EFSA acknowledges that providing specific justifications takes time. However, it is not acceptable to copy-paste the same justification for requests of different nature and based of different legal grounds (e.g. personal data vs manufacturing process).

17. Chemicals Strategy for Sustainability and One Substance One Assessment – Impact to EFSA

EFSA staff gave an overview of the Chemicals strategy for sustainability (CSS) focusing on the One Substance One Assessment (1S1A) and the activities that EFSA is performing to implement the strategy. The CSS[7] was published in October 2020; the strategy aims to an EU toxic-free environment by 2050. EFSA is contributing to the relevant strategy's objectives, among which the 'One substance one assessment' (1S1A). Whilst the legislative proposals which will implement 1S1A are still on the making, an outline of the main activities being conducted in EFSA to implement the CSS-1S1A and a summary of the items which will impact EFSA's work was provided; among the latter, the early identification of cross-cutting substances, the data sharing and the study on mapping data requirements and risk assessment methodologies were presented. A note on the EU Common data platform on chemicals was also given.

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

7 https://environment.ec.europa.eu/strategy/chemicals-strategy_en

Q: What happens if ECHA disagrees with EFSA? (Regine Schreiner, Feed and Additives GmbH)

A: Article 30 of Regulation (EC) No 178/2002 deals with the possibility of diverging opinions. Should diverging opinions be produced by other bodies carrying out similar tasks (including Agencies and Member States) it is foreseen that a joint document shall be prepared clarifying the contentious scientific issues and identifying the relevant uncertainties in the data. This document shall be made public.

Q: What happens if companies do not want to share their data? (Regine Schreiner, Feed and Additives GmbH)

A: The applicable legal provisions will respect all legitimate interests of data owners and applicants.

Q: What is the timeframe of this new strategy and its implementation? Do some existing guidelines already apply this approach? (Mari Eskola, Medfiles Ltd)

A: The legal proposals supporting the 1S1A should be adopted relatively soon. Once the legal framework is in place, the requirements of the 1S1A will be implemented with an appropriate transitional period. Some features such as the EU Common data platform on chemicals will be developed in various steps.

Q: Is IUCLID going to be used also for the submission of feed additives dossiers? (Ludovic Arnaud, Lallemand)

A: One of the main objectives of the 1S1A is to enhance chemical data interoperability. This will be facilitated with the use of harmonised templates for data submission. IUCLID is the platform/software of preference according to the CSS document. IUCLID is currently used to build dossiers under various Regulatory frameworks in ECHA and also for plant protection products in EFSA; it is also being piloted in some food applications. It should be therefore expected that IUCLID would be also extended to all the other relevant regulatory frameworks in EFSA, including feed additives.

18. Other scientific topics for information and/or discussion

18.1. New Assessment Methodologies (NAMs)

Several projects on new approach methodologies (NAMS) are currently ongoing at EFSA. Case studies are being developed to explore the possibility to integrate NAMs in the risk assessment. The case study on essential oils as feed additives (OC/EFSA/SCER/2021/14) was presented. The project is aimed at fill data gaps identified in the assessment of essential oils containing compounds belonging to the class of *p*-allylalkoxybenzenes (e.g. estragole, methyleugenol, safrole, elemicin and myristicin). These compounds are genotoxic and carcinogenic and are naturally present in herbs, spices, and food. These data gaps concern: the qualitative and quantitative differences and similarities in metabolic competences across different species (food-producing animals and cats); the potential transfer of residues from feed to food; the relative potency of the different *p*-allylalkoxybenzenes; and the potential matrix modulation in the bioactivation of these compounds. In the context of the project, *in vitro* metabolism data are generated for these compounds in metabolic systems from different animal species and the results extrapolated (*in vitro* to *in vivo*) using physiologically based kinetic (PBK) models. The project is currently ongoing, and the final report is expected by the end of November 2023. In the context of NAMs, EFSA developed an online platform for modelling and predicting the toxicity of chemicals (TKPlate). The platform was launched on November 14th.

Q: Are you able to say at what stage the TKPlate is? Could we skip the metabolic study for the feed studies and use the TKPlate? (Mari Eskola, Medfiles Ltd)

A: The TKPlate went live only this week. Further testing is needed before including the use of the TKPlate in the requirements of FEEDAP guidance documents. For example, the comparability of the results predicted with those obtained in metabolic and residue studies should be assessed. In the meantime, the requirements of the current guidance should be followed.

Q: Do you know when the data obtained via the TKPlate platform can be used for the consumer safety section of the files? (Julian Debiais, All4feed)

A: It is really difficult to predict when the data obtained via the TKPlate could be used to assess the safety for the consumer. Within the case study on NAMs, EFSA is now exploring the possibility to use the modelling to assess the safety for the consumer. However, it is limited to cases where the sensitivity of the analytical method is not sufficient to generate reliable residue data.

Q: Why not directly addressing potential zootechnical effects of botanicals in opinions? (Benjamin Costerousse, Dr. Benjamin Costerousse - CoGreen consulting)

A: The majority of applications for botanicals were submitted as flavouring compounds. Some botanicals are ingredients of zootechnical additives. For an application as a zootechnical additive, an appropriate dossier should be prepared and submitted, including demonstration of efficacy.

19. Answers to questions from Observers

Questions from observers not addressed in the specific sections above.

Q: When we fill the excel file for the list for annexes provided in a dossier, can we have it non-protected, in order to have it more usable and user friendly for applicants? We applicants appreciated the past situation when we described studies. (Ludovic Arnaud, Lallemand)

A: Appendix B to the EFSA Administrative guidance on feed additives has been republished as a non-protected file shortly.[8]

Q: Regarding the use of different languages between guidance documents, which direction is the cross-cutting guidance on microorganisms going to take? (Mari Eskola, Medfiles Ltd)

A: EFSA is aware on the differences between sectoral guidance documents and a cross cutting guidance is foreseen.

Q: I am facing some issue accessing OpenEFSA and Portalino and I reported some technical issue (error or not available message). Are these resolved? (Mari Eskola, Medfiles Ltd)

A: For technical issues, applicants are invited to contact our IT service writing to servicedesk@efsa.europa.eu.

Q: Upon an inconclusive opinion due to efficacy data, it would be very welcome to receive a clock-stop asking for needed efficacy data as the one included in the dossier is rejected, rather than re-initiate the procedure to submit a follow-up dossier and a second opinion. (Sabina Díaz, Novus Spain SA)

A: Comment noted.

Q: We would like to have the EC present to open plenary sessions (Ruud Huibers, Elanco Deutschland GmbH)

A: Comment noted. The EC is always invited to attend the FEEDAP Plenary meetings.

[8] https://efsa.onlinelibrary.wiley.com/action/downloadSupplement?doi=10.2903%2Fsp.efsa.2021.EN-6508&file=efs36508e-sup-0002-Appendix-B.xlsx

Q: You mentioned a new form of involvement of Member States in the assessment of dossiers. Can you explain better? Would we risk a loss of consistency between EFSA and MS opinions? What happens after the four years of this collaboration expire? Will we know who works on our dossiers? (Ludovic Arnaud, Lallemand)

A: It is a four-years framework partnership agreement awarded to member state organisations which may start before the end of the year. This partnership aims at increasing the capacity of the Panel to perform risk assessments, which will be adopted by the FEEDAP Panel. The assessments of the technical dossiers may be outsourced in full or in parts and consistency in the approaches will be ensured as per current practice.

Q: Will there be an implementation of automatic notifications to inform applicants about the start of Public Consultations on their dossiers? (Michaela Herzog, Feed and Additives GmbH)

A: Comment noted for future developments in the tool.

Q: As mineral oil is sometimes added to FA in small amount (1-2%), it was usually not imposing a safety concern for FA, as per recent EFSA opinion. Considering the last statement from EFSA on mineral oils, and that usually for a fermentation-produced FA, the liquid intermediate is tested (90-day study and/or tolerance study). How will this impact the FA applications? Will it be necessary to test the final product? For target species safety? And consumer safety? Especially in cases where a 90-day study in rats can be used to cover target species and consumer safety. (Esraa Elewa, Nutreco)

A: In principle all the components of a feed additive should be safe. The applicant should provide evidence to support the safety of each component of the additive, following the relevant guidance documents.

20. Any other business

The Chair closed the session by thanking all the participants.

Annex 1

CRITERIA FOR THE QUANTIFICATION OF THE ACTIVE AGENT(S) COMPOSING A FEED ADDITIVE

According to Commission Regulation (EC) No 429/2008, a feed additive must be fully identified and characterised, and "*the qualitative and quantitative batch to batch variation of the active substance(s)/agent(s) shall be determined*". Specifications of the additive in terms of concentration of the active substance(s)/agent(s) should be set by the applicant and compliance with such specifications confirmed, following the requirements of Commission Regulation (EC) No 429/2008 and the Guidance on the identity, characterisation and conditions of use of feed additives (EFSA FEEDAP Panel, 2017).

Evidence should be provided by the analysis of at least five independent production batches that those specifications are satisfied in practice (EFSA FEEDAP Panel, 2017). The number of viable cells or spores of the active agent expressed as Colony Forming Unit (CFU) per gram should be determined. This should be done using laboratory-based studies by means of appropriate criteria as reflected in recognised acceptable methods. These methods should ensure the specificity against contaminating microbiota possibly occurring in the sample.

In general, counts of the active agent should be established based on a cultivation method coupled with identification of isolates with molecular methods, which represent the most accurate source of information for the unambiguous identification of a strain. The following criteria should be followed when designing the method:

- The culture-based method used to grow the active agent should be the optimal one to detect the microorganism under assessment.
- For each batch, the enumeration of the microorganism should be performed in triplicate. The dilution resulting in 30 to 300 colonies on the plate should be considered and at least five colonies should be randomly selected and subjected to molecular identification at strain level.
- The active agent under assessment should be included as a positive control.

In case of additives containing more than one active agent, the following is required: "*If the additive is a mixture of active substances or agents, each of which is clearly definable (qualitatively and quantitatively), the active substances/agents must be described and the proportions in the mixture given*" (EFSA FEEDAP Panel, 2017). Therefore, each active agent composing the additive should be unambiguously quantified to i) reach a full characterisation of the product in terms of ratio among the active agents, and ii) confirm compliance with the specifications set for the individual counts. In order to choose the proper methodology, the applicant should refer to the requirements described above and provide evidence that the method is capable to discriminate between the active agents present in the additive.

Reference

EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed), Rychen G, Aquilina G, Azimonti G, Bampidis V, Bastos ML, Bories G, Chesson A, Cocconcelli PS, Flachowsky G, Gropp J, Kolar B, Kouba M, López-Alonso M, López Puente S, Mantovani A, Mayo B, Ramos F, Saarela M, Villa RE, Wallace RJ, Wester P, Anguita M, Galobart J and Innocenti ML, 2017. Guidance on the identity, characterisation and conditions of use of feed additives. EFSA Journal 2017;15(10):5023, 12 pp. https://doi.org/10.2903/j.efsa.2017.5023