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Health and Food Safety Directorate General

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Standing Committee on Plants, Animals, Food and Feed
Section *Animal Nutrition*
02 - 03 May 2022

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SUMMARY REPORT

As mentioned in the invitation to the meeting sent out on 13/04/2022, the meeting was **held via videoconference** due to the situation derived from the COVID-19 pandemic.

The invitation provided relevant information concerning the modalities of the meeting and referred to the use of the written procedure for the delivery of the Committee opinions on the draft implementing acts under Section B of the meeting's agenda.

During the meeting, the following introductory statements were made by a representative of the Commission:

- The confidentiality obligations required by Article 13 of the Standard Rules of Procedure for Committees and referred to in the invitation to the meeting, were recalled.
- The modalities for the delivery of the Committee opinions on the draft acts under Section B of the meeting's agenda by written procedure, were explained.

Section A Information and/or discussion

A.01 Feed Additives - Applications under Regulation (EC) No 1831/2003 Art. 4, 14 or 13

The relevant documents were sent to the Member States.

A.02 Feed Additives - Applications under Regulation (EC) No 1831/2003 Art. 9. Discussion on the following documents:

A.02.01. Safety and efficacy of a feed additive consisting of *Bacillus velezensis* NITE BP-01844 (BA-KING®) for chickens for fattening, chickens reared for laying, turkeys for fattening, turkeys reared for breeding and all avian species for fattening, or rearing to slaughter or point of lay including non-food producing species (Toa Biopharma Co., Ltd.)

A discussion was held. Supplementary information will be requested to the applicant to complete the evaluation.

A.02.02. Safety and efficacy of a feed additive consisting of *Propionibacterium freudenreichii* DSM 33189 and *Lentilactobacillus buchneri* (formerly *Lactobacillus*

***buchneri*) DSM 12856 for all animal species (Lactosan GmbH & Co.KG.) – ANNEX**

A discussion was held. A draft Implementing Regulation will be proposed at a future meeting.

A.02.03. Assessment of the feed additive consisting of potassium diformate for all animal species for the renewal of its authorisation (Addcon GmbH) – ANNEX

A discussion was held. A draft Implementing Regulation will be proposed at a future meeting.

A.02.04. Safety and efficacy of a feed additive consisting of zearalenone hydrolase produced by *Escherichia coli* DSM 32731 for all terrestrial animal species (Biomin GmbH)

A Commission's representative informed the Member States that the applicant has withdrawn the application for the authorisation of zearalenone hydrolase produced by *Escherichia coli* DSM 32731 as a feed additive.

A.02.05. Safety and efficacy of a feed additive consisting of an extract of olibanum from *Boswellia serrata* Roxb. ex Colebr. for use in dogs and horses (FEFANA asbl) – ANNEX

A discussion was held. A draft Implementing Regulation will be proposed at a future meeting.

A.02.06. Safety and efficacy of a feed additive consisting of an essential oil from the leaves of *Agathosma betulina* (P.J. Bergius) Pillans (buchu leaf oil) for use in all animal species (FEFANA asbl) – ANNEX

A discussion was held. A draft Implementing Regulation will be proposed at a future meeting.

A.02.07. Safety and efficacy of a feed additive consisting of an essential oil from the flowers of *Cananga odorata* (Lam.) Hook.f. & Thomson (ylang ylang oil) for use in all animal species (FEFANA asbl) – ANNEX

A discussion was held. A draft Implementing Regulation will be proposed at a future meeting.

A.02.08. Safety and efficacy of the feed additive consisting of *Lactobacillus acidophilus* CECT 4529 (*Lactobacillus acidophilus* D2/CSL) for all poultry species and categories and all ornamental birds (Centro Sperimentale del Latte S.r.l) – ANNEX

A discussion was held. A draft Implementing Regulation will be proposed at a future meeting.

A.02.09. Assessment of the feed additive consisting of *Lactiplantibacillus plantarum* (formerly *Lactobacillus plantarum*) NCIMB 30236 for all animal species for the renewal of its authorisation (BioCC OÜ) – ANNEX

A discussion was held. A draft Implementing Regulation will be proposed at a future meeting.

A.02.10. Assessment of the feed additive consisting of *Lentilactobacillus buchneri* (formerly *Lactobacillus buchneri*) DSM 12856 for all animal species for the renewal of its authorisation (Lactosan GmbH & Co 8 KG) – ANNEX

A discussion was held. A draft Implementing Regulation will be proposed at a future meeting.

A.02.11. Safety and efficacy of a feed additive consisting of disodium 5'-inosinate (IMP) produced by *Corynebacterium stationis* KCCM 80235 for all animal species (CJ Europe GmbH)

A discussion was held. Supplementary information will be requested to the applicant to complete the evaluation.

A.02.12. Safety and efficacy of a feed additive consisting of ferric citrate chelate (CI-FER™) for poultry species for fattening or reared up to the point of lay (Akeso Biomedical, Inc.)

A discussion was held. Supplementary information will be requested to the applicant to complete the evaluation.

A.02.13. Safety and efficacy of a feed additive consisting of astaxanthin-rich *Phaffia rhodozyma* for salmon and trout (Igene Biotechnology, Inc.)

A discussion was held. Supplementary information will be requested to the applicant to complete the evaluation.

A.02.14. Safety and efficacy of a feed additive consisting of sodium alginate for all animal species (ALGAIA)

A discussion was held. Supplementary information will be requested to the applicant to complete the evaluation.

A.02.15. Safety and efficacy of the feed additives consisting of L-glutamic acid and monosodium L-glutamate monohydrate produced by *Corynebacterium glutamicum* NITE BP-01681 for all animal species (METEX NOOVISTAGO) – ANNEX

A discussion was held. A draft Implementing Regulation will be proposed at a future meeting.

A.02.16. Safety and efficacy of a feed additive consisting of ferric citrate chelate (CI-FER™) for poultry species for fattening or reared up to the point of lay (Akeso Biomedical, Inc.)

Discussed under item A.02.12.

A.02.17. Efficacy of a feed additive consisting of endo-1,4-beta-xylanase produced by *Trichoderma citrinoviride* (IMI SD 135) (HOSTAZYM® X) for sows in order to have benefits in piglets (Huvepharma NV)

A discussion was held. Supplementary information will be requested to the applicant to complete the evaluation.

A.02.18. Safety and efficacy of a feed additive consisting of L-valine produced by *Escherichia coli* CCTCC M2020321 for all animal species (Kempex Holland BV) – ANNEX

A discussion was held. A draft Implementing Regulation will be proposed at a future meeting.

A.02.19. Safety and efficacy of a feed additive consisting of manganous lysinate sulfate for all animal species (Phytobiotics Futterzusatzstoffe GmbH) – ANNEX

A discussion was held. A draft Implementing Regulation will be proposed at a future meeting.

A.02.20. Safety and efficacy of a feed additive consisting of lanthanum carbonate octahydrate (Lanthan One) for cats (Porus GmbH) – ANNEX

A discussion was held. A draft Implementing Regulation will be proposed at a future meeting.

A.02.21. Efficacy of a feed additive consisting of nicarbazin (Coxar®) for use in turkeys for fattening (Huvepharma N.V.) – ANNEX

A discussion was held. Supplementary information will be requested to all applicants requesting an authorisation of nicarbazin, to clarify some aspects concerning residues of the substance.

A.02.22. Safety and efficacy of a feed additive consisting of L-methionine produced by the combined activities of *Corynebacterium glutamicum* KCCM 80245 and *Escherichia coli* KCCM 80246 for all animal species (CJ Europe GmbH) – ANNEX

A discussion was held. A draft Implementing Regulation will be proposed at a future meeting.

A.02.23. Safety and efficacy of a feed additive consisting of L-lysine sulphate produced by *Escherichia coli* CGMCC 7.398 for all animal species (Kempex Holland B.V.) – ANNEX

A discussion was held. A draft Implementing Regulation will be proposed at a future meeting.

A.02.24. Safety and efficacy of a feed additive consisting of 6-phytase (produced by *Komagataella phaffii* DSM 23036) (OptiPhos®) for poultry for fattening, chickens reared for laying, laying hens, turkeys reared for breeding, weaned piglets, pigs for fattening and sows for the renewal of their authorisation and for the new use in breeding hens and turkeys, ornamental birds, suckling piglets and minor pig species for fattening and breeding (Huvepharma EOOD) – ANNEX

A discussion was held. A draft Implementing Regulation will be proposed at a future meeting.

A.02.25. Safety and efficacy of a feed additive consisting of endo-1,4-beta-xylanase and endo-1,3(4)-beta-glucanase produced with *Talaromyces versatilis* IMI 378536 and DSM 26702 (Rovabio® Advance) for weaned piglets and pigs for fattening (Adisseo France S.A.S.)

A discussion was held. Supplementary information will be requested to the applicant to complete the evaluation.

A.02.26. Safety and efficacy of a feed additive consisting of guanidinoacetic acid for all animal species (AlzChem Trostberg GmbH)

A discussion was held. Supplementary information will be requested to the applicant to complete the evaluation.

A.02.27. Safety and efficacy of the feed additive consisting of ammonium chloride (Ammonium ChlorideAF) for all ruminants, dogs and cats for the renewal of its authorisation (BASF SE) – ANNEX

A discussion was held. A draft Implementing Regulation will be proposed at a future meeting.

A.02.28. L-Lysine monohydrochloride and L-lysine sulphate for all animal species – ANNEX

A discussion was held. A draft Implementing Regulation will be proposed at a future meeting.

A.02.29. Safety and efficacy of Ethoxyquin as a feed additive for all animal species

Further to the adoption of the new EFSA opinion of 27 January 2022, a discussion took place on the measure to be adopted – by 31 December 2022 at the latest – in order to review the suspension measure concerning Ethoxyquin, as provided for in Implementing Regulation (EU) 2017/962. Taking into account that EFSA could not conclude favourably on several safety issues and after consideration of comments received from a representative of the feed business sector, the Committee agreed to proceed to a denial of the authorisation of the additive, without prejudice to the possibility to submit a new application for authorisation in accordance with the rules and procedures set out in Regulation (EC) No 1831/2003.

A.02.30. Safety and efficacy of 8 chemical flavourings belonging to groups 10, 13, 18, 22 and 28 as feed additives – ANNEX

A discussion was held. A draft Implementing Regulation will be proposed at a future meeting.

A.03 Letter from FEFANA concerning the practical implementation of Implementing Regulation (EU) 2022/320 (“other provisions”)

A discussion was held. The Committee took into consideration the comments from FEFANA as regards the practical implementation of Regulation (EU) 2022/320 in view of future authorisations.

A.04 Status of certain products with regard to the scope of Regulation (EC) No 1831/2003 and feed additives to be withdrawn from the market – Update/new lists

The Committee continued the discussion held at the previous meeting with regard to the status of certain products.

A further case-by-case examination of the characteristics of the products concerned, which are currently included in the Catalogue of feed materials, should be carried out before deciding on their respective status as feed additives, taking account of the criteria laid down in Recommendation 2011/25/EU. Member States’ delegations were invited to send as soon as possible to the Commission any contribution and position with regard to the status of the specific products discussed.

With regard to the product Chabasite (‘Aluminosilicate of sodium, potassium, calcium and magnesium’), which had already been discussed within the Committee on the occasion of previous meetings, a representative of the Commission confirmed the status of that product as a feed additive, which is currently not authorised and is different from the feed additive E 554 (“sodium aluminosilicate, synthetic”).

A.05 Exchange of views and possible endorsement of IPIFF Guide on Good Hygiene Practices for producers of insects as food & feed

A discussion was held. A Commission's representative informed that IPIFF is preparing a new version of the document that will be proposed at a future meeting for possible endorsement.

A.06 Discussion on issues concerning feed in relation to the situation in Ukraine

Certain Member States representatives reported, as a general remark, some shortage in sunflower oil or cereals, but it appears that Member States are not involved at the same level as regards shortage in feed materials for pet food. Therefore, the measures taken vary according to the Member States. Common key principles of safety and transparency of the labelling have been followed for a temporary flexibility on the labelling within Member States, where the measure are reported. Due to the variability of the impact on the Member States, at present, only a temporary flexibility based on the general principle of safety and transparency has been adopted. Since the situation is monitored by Member States, future discussion might be held later if necessary.

A.07 Update on the evaluation and impact assessment of the Feed Additives Regulation

A representative of the Commission informed the Committee on the state-of-play concerning the evaluation of Regulation (EC) No 1831/2003 and the impact assessment for the revision of that Regulation. In particular, reference was made to the launch of a new short survey concerning specific topics.

A.08 Update on certain topics related to undesirable substances and method of analysis

a) Update and exchange of views on recent RASFF notifications

A representative of the Commission informed the Committee on the RASFF notifications related to undesirable substances in animal feed, issued since the meeting of the Committee in February 2022.

The notifications related to a too high level/content of:

- ambrosia seeds in milo grain from Czech Republic (605 mg/kg)
- arsenic in monocalciumphosphate for feed from Turkey (13 ppm) and in supplementary feed for horses from Germany (39.5 mg/kg)
- aflatoxin B1 in groundnuts for feed (60.6 µg/kg), in groundnuts for birdfeed from India (54 µg/kg and 50 µg/kg)
- hydrocyanic acid in linseeds from France (285 mg/kg)
- rye ergot in rye from Germany (2460 mg/kg)

Too high level of dithiocarbamates (0.28 mg/kg) and fluazifop-P-butyl (0.046 mg/kg) in rapeseed meal, chlorpyrifos in sunflower seeds from Slovakia (0.051 mg/kg) and in wheat from Hungary (0.45 mg/kg) have been notified. Also, the presence of the antibiotic sufadimidine (0.06 mg/kg) in straight feed from Germany and the presence of the prohibited nitrofurantoin antibiotic furazolidone (AOZ) in feed for bees was mentioned.

Finally, the notification on the presence of ethylene oxide (in fact 2-chloro ethanol) at a level of 0.11 ppm in wheat gluten for animal feed from France was highlighted.

b) Ethylene oxide

Request from FEFANA to increase the maximum level for ethylene oxide in the emulsifiers E 484 and E 487:

The Committee was informed of the request from FEFANA mentioning that for the two emulsifiers E 484 and E 487, it is not possible to comply with the maximum level for ethylene oxide of 0.1 mg/kg and that a level of 0.2 mg/kg would be analytically and technically achievable. Reference was thereby made to footnote 5 of the [minutes of the dedicated meeting on ethylene oxide which took place on 04 October 2021](#). This footnote specified that for certain food additives a specification for ethylene oxide at <0.2 mg/kg has been established. The Commission highlighted that recently the section Novel Food and Toxicological Safety of the Committee has expressed a favourable opinion on a draft regulation changing the specification for ethylene oxide for all food additives to the Limit of Quantification (LOQ), *i.e.* 0.1 mg/kg (sum of ethylene oxide and 2-chloroethanol expressed as ethylene oxide). (*Information post Committee: The new specification for ethylene oxide in food additives has been established in Commission Regulation (EU) 2022/1396 of 11 August 2022 amending the Annex to Regulation (EU) No 231/2012 laying down specifications for food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council as regards the presence of ethylene oxide in food additives*)

As no specific data have been provided demonstrating that the level of 0.1 mg/kg is not achievable by applying good practices, the Committee agreed that there was no need to change the maximum level of 0.1 mg/kg for ethylene oxide (sum of ethylene oxide and 2-chloroethanol, expressed as ethylene oxide) in the emulsifiers E484 and E487.

Letter from FEDIAF in relation to the findings of 2-chloroethanol in wheat gluten destined for feed:

The detection of 2-chloroethanol in wheat gluten-based mixes from France is related to the use of monochloramine (also known as chloramine, which is commonly used as a water treatment) as a permitted processing aid in the manufacturing process of gluten from wheat. 2-chloroethanol is a by-product of the degradation of monochloramine during the manufacturing process. Its presence in wheat gluten is not due the presence of ethylene oxide / 2-chloroethanol in the raw materials (wheat) as the consequence of illegal use, or to the illegal addition of ethylene oxide :2-chloroethanol to wheat gluten or due to avoidable cross contamination during transport or storage. FEDIAF asked if a temporarily higher maximum level of 2-chloroethanol in this specific case can be considered as a pragmatic solution.

In the discussion, it was also mentioned that besides the unavoidable presence due to the degradation of monochloramine to 2-chloroethanol used as a processing aid in the process water in the production of wheat gluten, also 2-chloroethanol could be present as an impurity in the monochloramine.

The representative of the Commission informed the Committee to discuss this further internally in the Commission with the relevant services.

c) Humic acid

More information on the exact nature of humic acid has been provided by the company by email on 26 April 2022. It was clarified that the product description for leonardite in the Catalogue of feed materials (entry 13.10.2) is also applicable to humic acid.

d) Nitrites and nitrates

The Commission informed the Committee that relevant stakeholder organisations were requested by email on 18 April 2022 to provide available information on nitrites and nitrates in feed for consideration in the context of the review of the regulatory provisions as follow-up to the [EFSA's risk assessment on nitrite and nitrate in feed](#) or to indicate by when this information would be available. One stakeholder organisation has indicated to be able to provide additional information by August 2022.

Taking into account this information, the discussions on the review of the regulatory measures on nitrite and nitrate in feed will be resumed in the autumn in view of finalisation by the end of the year.

e) Δ 9-Tetrahydrocannabinol

The Commission informed the Committee that the section Novel Food and Toxicological Safety of the Committee has expressed a favourable opinion on a draft regulation setting maximum levels for Δ 9-tetrahydrocannabinol in hemp seeds and hemp seed derived products intended for human consumption. (*Information post Committee: The maximum levels have been established in [Commission Regulation \(EU\) 2022/1393 of 11 August 2022 amending Regulation \(EC\) No 1881/2006 as regards maximum levels of delta-9-tetrahydrocannabinol \(\$\Delta\$ 9-THC\) in hemp seeds and products derived therefrom](#)*)

f) Bromine/bromide - request to EFSA

Initially, a request for scientific opinion on the risks for animal health and transfer from feed to food of animal origin related to the presence of bromine in feed, in particular in algae and seaweed and derived product was requested to EFSA on 26 October 2021 (available at: <https://open.efsa.europa.eu/questions/EFSA-Q-2021-00698>) and this request was accepted by EFSA with a deadline for delivery of the opinion by 31 December 2023.

As there is simultaneously an intention to request to EFSA to assess the health risks related to the presence of the bromide ion as a pesticide residue in food, following discussions internally in the Commission and with EFSA, a comprehensive mandate was sent to EFSA on 28 April 2022 to assess the risks for human health related to the presence of bromide ion in food and risks for animal health and transfer from feed to food of animal origin related to the presence of bromide ion in feed, in particular in algae and seaweed and derived products with a deadline for the draft scientific opinion by 31 December 2023 and the final version by March 2024. (Available at: <https://open.efsa.europa.eu/questions/EFSA-Q-2022-00329>)

The Committee stressed the importance that not only the bromide ion is assessed but also the bromine form given that this form is prevalent in algae and seaweed. The representative of the Commission ensured to take care that this will be the case.

g) Hydroxymethylfurfural in bee feed

The representative of the Commission informed the Committee of the publication of the [EFSA scientific opinion on the risks for animal health related to the presence of hydroxymethylfurfural \(HMF\) in feed for honeybees](#).

The follow up will be discussed in the working group "Undesirable substances in feed". A meeting of the working group meeting will be organised before the summer break.

A request was made by a delegation to have closer examination of the proposed maximum level for dioxins and dioxin-like PCBs in fish oil.

h) Methods of analysis

A working group to discuss the final issues (*e.g.* reference to EN standards for methods of analysis not regulated by Regulation (EC) No 152/2009) will be organised before the summer break.

A.09 EFSA update on targeted consultation on new dossiers

EFSA presented the results of the test of the new system concerning the comments of the Member States on the submitted application dossiers. It has been concluded that the system fits for the purpose.

Section B Drafts presented for discussion prior to an opinion by written procedure

The documents concerning the items under this section were communicated to the Committee members in advance of the meeting for possible comments.

During the meeting, an **exchange of views** took place on each of the draft measures referred to under items B.01 to B.07 in order to reach an agreement on the content of the respective documents.

However, as indicated during the meeting, the Committee's opinion on the draft act referred to under item B.01 of the meeting's agenda will be sought at a later stage, in order to allow further verification.

After the meeting, a final version of the documents resulting from the discussions held during the meeting was sent to the Committee members for possible rectification or editorial comments, with a deadline for reply set on 6 May 2022.

In accordance with Article 3(5) of Regulation (EU) No 182/2011, the **written procedure** for the delivery of the Committee opinion on the six draft Implementing Regulations concerned was launched on 12 May 2022 with a deadline set on 19 May 2022.

Nevertheless, the written procedure was terminated without result on 17 May 2022 for the draft act referred to under item B.02 of the meeting's agenda, due to the submission of a wrong version of the related documents.

Member States representatives were informed on the outcome of the written procedure by a note sent on 20 May 2022. The Committee opinion delivered on each draft measure is mentioned below in relation to items B.03, B.04, B.05, B.06 and B.07.

B.01 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation concerning the authorisation of expressed orange essential oil, distilled orange essential oil and folded orange oil as feed additives for certain animal species

The draft refers to the authorisation of flavouring compounds as feed additives for certain animal species.

Vote Postponed

B.02 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation concerning the authorisation of camphor white essential oil as a feed additive for certain animals species and cinnamon tincture as feed additive for certain animal species

The draft refers to the authorisation of flavouring compounds as feed additives for certain animal species.

Vote Postponed

B.03 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation concerning the authorisation of monosodium glutamate produced by fermentation with *Corynebacterium glutamicum* KCCM 80187 as a feed additive for all animal species

The draft refers to the authorisation of a flavouring compound as a feed additive for all animal species.

Vote taken: Favourable opinion.

B.04 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation concerning the authorisation of Allura Red AC as a feed additive for small non-food producing mammals and ornamental birds

The draft refers to the authorisation of a colourant as a feed additive for certain animal species.

Vote taken: Favourable opinion.

B.05 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation concerning the authorisation of essential oil from *Origanum vulgare* spp. *hirtum* (Link) letsw. as a feed additive for certain animal species

The draft refers to the authorisation of a flavouring compound as a feed additive for certain animal species.

Vote taken: Favourable opinion.

B.06 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation concerning the authorisation of vitamin B₁₂ in the form of cyanocobalamin produced by *Ensifer adhaerens* CNCM I-5541 as a feed additive for all animal species

The draft refers to the authorisation of a vitamin as a feed additive for all animal species.

Vote taken: Favourable opinion.

B.07 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation concerning the authorisation of ethyl acrylate, pentyl isovalerate, butyl 2-methyl butyrate, 2-methylundecanal, (2E)-methylcrotonic acid, ethyl (E,Z)-deca-2,4-dienoate, butan-2-one, cyclohexyl acetate, 3,4-dimethylcyclopentan-1,2-dione, 5-ethyl-3-hydroxy-4-methylfuran-2(5H)-one, phenethyl butyrate, hexyl phenylacetate, 4-methylacetophenone, 4-methoxyacetophenone, 3-methylphenol, 3,4-dimethylphenol, 1-methoxy-4-methylbenzene, trimethyloxazole and 4,5-dihydrothiophen-3(2H)-one as feed additives for all animal species

The draft refers to the authorisation of 19 flavouring compounds as feed additives for all animal species.

Vote taken: Favourable opinion.