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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*

13 - 14 December 2021

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SUMMARY REPORT

As mentioned in the invitation to the meeting sent out on 30 November 2021, 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 Commission representative:

- 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

A.02.01 Zinc chelate of amino acids hydrate for all animal species (FAD-2019-0078) - Annex

The EFSA opinion was discussed, which concluded that the additive is safe and efficacious, and an Annex entry was presented. A draft authorisation act will be proposed at a future Committee meeting.

A.02.02 Copper (II) chelate of amino acids hydrate for all animal species (FAD-2019-0081) - Annex

The EFSA opinion was discussed, which concluded that the additive is safe and efficacious, and an Annex entry was presented. A draft authorisation act will be proposed at a future Committee meeting.

A.02.03 Manganese chelate of amino acids hydrate for all animal species (FAD-2019-0082) - Annex

The EFSA opinion was discussed, which concluded that the additive is safe and efficacious, and an Annex entry was presented. A draft authorisation act will be proposed at a future Committee meeting.

A.02.04 Iron (II) chelate of amino acids hydrate for all animal species (FAD-2019-0087) - Annex

The EFSA opinion was discussed, which concluded that the additive is safe and efficacious, and an Annex entry was presented. A draft authorisation act will be proposed at a future Committee meeting.

A.02.05 Renewal of Sodium benzoate for weaned piglets and the extension of use to other growing suidae (FAD-2020-0040) - Annex

The EFSA opinion was discussed, which concluded that the additive is safe and efficacious, and an Annex entry was presented. A draft authorisation act will be proposed at a future Committee meeting.

A.02.06 3-nitrooxypropanol for ruminants for milk production and reproduction (FAD-2019-0057) - Annex

The EFSA opinion was discussed, which concluded that the additive is safe and efficacious, and an Annex entry was presented. A draft authorisation act will be proposed at a future Committee meeting.

A.02.07 endo-1,4-beta-xylanase produced by *Bacillus subtilis* LMG S 27588 for laying hens, minor poultry species and all avian species (FAD-2019-0080)

As the EFSA opinion is inconclusive, the Committee agreed to allow the applicant to submit supplementary information to be assessed by EFSA.

A.02.08 Tincture from roots of *Gentiana Lutea* L. as a feed additive belonging to the functional group "flavouring compounds" - State of play

A Commission representative presented the modification of the EFSA opinion in relation to safety aspects which had to be clarified. The Committee agreed that supplementary information will be requested to the applicant in order to allow EFSA to complete the assessment.

A.02.09 *Origanum vulgare* ssp. hirtum (Link) Ietsw (SANTE-0010-2018 - FAD-2010-0245) - complementary information submitted by the applicant

The supplementary information provided by the applicant indicates that at the proposed dose, the additive does not have effects – or has only negligible effects - other than related to the function as flavouring compound. A draft authorisation act will be proposed at a future Committee meeting.

A.02.10 Safety and efficacy of *Ginkgo biloba* L. extract - State of play

A Commission representative explained that in consideration of the EFSA opinion, the authorisation for cats and dogs may not be granted and that it is required to proceed to a denial of the authorisation if there is no withdrawal of the application. However, since

two applications were submitted for the authorisation of this additive, one only for use for cats and dogs and another one for use for all animal species, the Commission has been requested to check the characterisation of the substances that are covered by the two respective applications. Discussions will continue at a future Committee meeting.

A.02.11 Safety and efficacy of 19 chemical flavourings as feed additives – Annex

A discussion was held. A draft authorisation act will be proposed at a future Committee meeting.

A.02.12 Safety of a feed additive consisting of a dried aqueous ethanol extract from the leaves of *Melissa officinalis* L. for all animal species (NOR FEED SUD)

A discussion was held. A draft authorisation act will be proposed at a future Committee meeting.

A.02.13 Safety and efficacy of a feed additive consisting of an aqueous extract of *Citrus limon* (L.) Osbeck (lemon extract) for use in all animal species (NOR-FEED SUD)

A discussion was held. A draft authorisation act will be proposed at a future Committee meeting.

A.02.14 Safety and efficacy of feed additives consisting of expressed sweet orange peel oil and its fractions from *Citrus sinensis* (L.) Osbeck for use in all animal species (FEFANA asbl)

A discussion was held. A draft authorisation act will be proposed at a future Committee meeting.

A.02.15 State of Play on the safety and efficacy of different silage additives (Article 14), and in particular:

- ***Lactobacillus brevis* DSM 12835 for all animal species**
- ***Lactobacillus rhamnosus* NCIMB 30121 for all animal species**
- ***Lactobacillus paracasei* DSM 16245 for all animal species**

A discussion was held. A draft authorisation act will be proposed at a future Committee meeting.

A.02.16 Safety and efficacy of a feed additive consisting of *Lactiplantibacillus plantarum* (formerly *Lactobacillus plantarum*) DSM 26571 for all animal species (Chr. Hansen A/S) – Annex

A discussion was held. A draft authorisation act will be proposed at a future Committee meeting.

A.02.17 Safety and efficacy of Cashew nut shell liquid for all animal species

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 *Bacillus velezensis* DSM 15544 (Calsporin®) for piglets (suckling and weaned), pigs for fattening, sows in order to have benefit in piglets, ornamental fish, dogs and all avian species (Asahi Biocycle Co.)

A discussion was held. A draft authorisation act will be proposed at a future Committee meeting.

A.02.19 Safety and efficacy of a feed additive consisting of *Bacillus subtilis* strains CNCM I-4606, CNCM I-5043 and CNCM I-4607 and Lactococcus lactis CNCM I-4609 for all animal species (Nolivade)

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

A.02.20 State of play of the evaluation of different flavourings as feed additives

This item was not discussed during the meeting.

A.03 Update of evaluation/impact assessment of the Feed Additives Regulation

This item was not discussed during the meeting.

A.04 Information point on import-export issues between the EU and UK (GB)

This item was not discussed during the meeting, considering that no specific question was raised in advance of the meeting.

A.05 Undesirable substances

1) RASFF

Update and exchange of views on recent RASFF notifications

A Commission representative informed the Committee on the RASFF notifications related to undesirable substances in animal feed, issued since the meeting of the Committee in September 2021.

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

- ambrosia seeds in sorghum from France (6) (245 - 702 mg/kg) and in sunflower seeds from Austria (205 mg/kg);
- polycyclic aromatic hydrocarbons (PAH) in dried alfalfa (1700 µg/kg);
- lead in fishmeal from Latvia (49.7 mg/kg);
- mercury in complementary feed for cats from Thailand (0.62 mg/kg);
- aflatoxin B1 in peanut kernels from the United States (258 µg/kg);
- narasin in complete feed for laying hens (1.17 mg/kg), due to unacceptable avoidable cross-contamination;
- phenoxymethylpenicillin (0.17 mg/kg) in life yeast (*Saccharomyces cerevisiae*) from the Republic of North Macedonia, via Italy and from Italy via Germany (0.08 - 0.26 mg/kg). According to the information available, the cause would be contamination with a disinfectant at one of the manufacturer's facilities.

Too high level of pesticide residues were reported in 1 notification: chlorpyrifos in wheat from Slovakia (0.018 - 0.031 mg/kg).

Furthermore, the attention was drawn to the notification on the unauthorised presence of ethylene oxide at a level of 10 ppm in capsicum oleoresin used as feed additive from India.

2) Ethylene oxide in choline chloride.

The Committee was informed of the dedicated meeting on ethylene oxide which took place on 4 October 2021 discussing regulatory and technical aspects (see: Minutes of the meeting of 4 October).

Discussion took place as regards the findings of ethylene oxide (as sum of ethylene oxide and 2-chloroethanol, expressed as ethylene oxide) in choline chloride.
Early November 2021, FEFANA raised the issue of unavoidable presence of 2-chloroethanol in choline chloride as the consequence of the production process whereby trimethylamine, ethylene oxide and hydrochloric acid are used as starting materials. This results in unavoidable presence of 2-chloroethanol formed by reaction of hydrochloric acid with ethylene oxide. (EFSA opinion 2011).
Therefore, the Commission services proposed an approach allowing a maximum of sum of ethylene oxide and 2-chloroethanol, expressed as ethylene oxide, of 30 mg/kg in choline chloride in view of updating the minutes of the dedicated meeting of 4 October 2021. Member States were consulted on this approach by email on 19 November 2021 and no objections were raised. However, the industrial stakeholders could not agree with the approach as being too strict although the proposed solution reflected a proportionate feasible approach ensuring a high level of animal health and public health.

Acknowledging that the current approach, with a maximum level of 0.1 mg/kg for the sum of ethylene oxide and 2-chloroethanol expressed as ethylene oxide, is not feasible for the specific case of choline chloride and would endanger the availability of choline chloride, the Committee agreed with the following statement to be included as footnote in the minutes of the meeting of 4 October 2021:

"The presence of 2-chloroethanol in choline chloride is not the consequence of an illegal use of ethylene oxide (ETO) as disinfectant/biocide, but an unavoidable impurity of the production process following the use of ethylene oxide and hydrochloric acid as starting materials;

Based on the information contained in the EFSA opinion on choline chloride in 2011 indicates that choline chloride (75 % purity) is ethylene oxide free and that 2-chloroethanol can be present in levels from 10 to 55 mg/kg, a maximum level of ETOsum (sum of ethylene oxide and 2-chloroethanol expressed as ethylene oxide) in choline chloride of 40 mg/kg(*), relative to choline chloride with 99 % purity, is to be applied for enforcement in the frame of the management of this incident.

Based on the use levels of choline chloride, the level in the compound/complete feed could exceed the level of 0.02 mg/kg (LOQ). Compound/complete feed exceeding the level of 0.02 mg/kg has not to be withdrawn from the market on the condition that the fraction of ETOsum above 0.02 mg/kg can be attributed to the use of choline chloride with a maximum level of 40 mg/kg (relative to choline chloride with 99 % purity).

(*) 40 mg/kg is 55 mg/kg x 0.55 x 1.32, whereby 0.55 is the factor used to express 2-chloroethanol in ethylene oxide equivalents and 1.32 (99/75) is the factor used to express the maximum level relative to choline chloride with 99 % purity."

The Committee was informed that on 20 January 2022, a dedicated ETO meeting is foreseen as follow-up to the meeting on 4 October 2021. More details on this meeting will be communicated later.

3) Undesirable substances – selected topics

- ergot alkaloids

EFSA has been requested to provide a scientific opinion on the risks for animal health related to the presence of ergot alkaloids in feed.

There is a need for more occurrence data on ergot alkaloids in feed. A discussion is to be held on a dedicated monitoring on ergot alkaloids in feed materials (and compound feed).

- nitrates and nitrites

Relevant EU stakeholder organisations will be requested to provide up to date information on the presence and mitigation of nitrite in wet feed materials (as co-product) as input for the discussions on possible regulatory measures on nitrates and nitrites in feed.

- pyrrolizidine alkaloids:

The opinion of the EURL has been requested to provide advice on the relevant pyrrolizidine alkaloids in feed and the availability of methods of analysis for their analysis in feed.

- quinolizidine alkaloids

Based on the information available, it might be appropriate to establish a maximum level for quinolizidine alkaloids in feed to ensure a high level of animal health protection but further discussion is needed. The EURL on mycotoxins and plant toxins has informed that a method to analyse quinolizidine alkaloids in lupin seeds will become available as EURL method early 2022.

- tropane alkaloids

Taking into account the possible animal health risks for pigs related to the presence of tropane alkaloids in feed as identified in the EFSA opinion, the current maximum level for *Datura sp.* seeds should be lowered from 1g/kg to 0.5 g/kg as a first step.

- Perfluoroalkyl substances (PFAS):

The Committee agreed to elaborate a monitoring recommendation for the monitoring of PFAS in feed separate from food, also later in time, as further work by the EURL on the analysis of PFAS in feed is needed and to allow Member States build up analytical capacity for the monitoring of PFAS in feed with sufficient sensitivity.

In the monitoring recommendation concerning food there will be already reference to feed in consideration of the presence of PFAS in food of animal origin related to feed/soil/drinking water. Therefore, it is important to analyse PFAS in feed/soil/drinking water to be able to establish relationships and there is also a need for further transfer feed/food studies.
The Committee was informed that a meeting of the Working Group Undesirable Substances in feed will be held on Tuesday 11 January 2022.

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 the draft measures referred to under the items B.01 to B.12 of the meeting's agenda, in order to reach an agreement on the content of the respective documents. 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 21 December 2021.
In accordance with Article 3(5) of Regulation (EU) No 182/2011, the written procedure for the delivery of the Committee opinion on the 12 draft acts concerned was launched on 10 January 2022 with a deadline set on 17 January 2022.
Member States representatives were informed on the outcome of the written procedure by a note sent on 20 January 2022. The Committee opinion delivered on each draft measure is mentioned below in relation to items B.01 to B.12.

B.01 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation concerning the authorisation of malic acid, citric acid produced by *Aspergillus niger* DSM 25794 or CGMCC 4513/CGMCC 5751 or CICC 40347/CGMCC 5343, sorbic acid and potassium sorbate, acetic acid, sodium diacetate and calcium acetate, propionic acid, sodium propionate, calcium propionate and ammonium propionate, formic acid, sodium formate, calcium formate and ammonium formate, and lactic acid produced by *Bacillus coagulans* (LMG S-26145 or DSM 23965), or *Bacillus smithii* (LMG S-27890) or *Bacillus subtilis* (LMG S-27889) and calcium lactate as feed additives for all animal species

The draft refers to the re-authorisation of organic acids to be used in feed as preservatives or as acidity regulators.

Vote taken: Favourable opinion.

B.02 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation amending Implementing Regulation (EU) 2016/898 as regards the name of the holder of the authorisation of a preparation of *Bacillus licheniformis* (ATCC 53757) and its protease (EC 3.4.21.19) as a feed additive and Implementing Regulation (EU) 2018/982 as regards the name of the holder of the authorisation of a preparation of benzoic acid, calcium formate and fumaric acid as a feed additive

The draft refers to the change of the holder of the authorisation of two preparations as feed additives.

Vote taken: Favourable opinion.

B.03 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation correcting Implementing Regulation (EU) 2020/1760 concerning the authorisation of the preparation of *Bacillus subtilis* DSM 25841 as a feed additive for all porcine species, including sows, other than lactating sows in order to have a benefit in suckling piglets (holder of authorisation Chr. Hansen A/S)

The draft refers to the correction of an error in Implementing Regulation (EU) 2020/1760 concerning the authorisation of a feed additive.

Vote taken: Favourable opinion.

B.04 Exchange of views and possible opinion of the Committee on a draft Commission Regulation amending Regulation (EU) No 68/2013 on the Catalogue of feed materials

The draft refers to the amendments to the Catalogue of feed materials, as provided for in Article 26 of Regulation (EC) No 767/2009. A Commission representative informed the Committee about the changes in the document compared to the one presented in the last meeting of the Committee. Furthermore, he presented the seven comments received during the Public Feedback period and explained to what extent they have been taken into account.
Based on the discussion of the draft Regulation, several modifications were made on the text of the Annex to the Regulation.

Vote taken: Favourable opinion.

B.05 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation correcting Implementing Regulation (EU) 2021/421 concerning the authorisation of tincture derived from *Artemisia vulgaris* L. (mugwort tincture) as a feed additive for all animal species, Implementing Regulation (EU) 2021/485 concerning the authorisation as feed additives of ginger essential oil from *Zingiber officinale* Roscoe for all animal species, ginger oleoresin from *Zingiber officinale* Roscoe for chickens for fattening, laying hens, turkeys for fattening, piglets, pigs for fattening, sows, dairy cows, veal calves (milk replacers), cattle for fattening, sheep, goats, horses, rabbits, fish and pets and ginger tincture from *Zingiber officinale* Roscoe for horses and dogs and Implementing Regulation (EU) 2021/551 concerning the authorisation of turmeric extract, turmeric oil, turmeric oleoresin from *Curcuma longa* L. rhizome as feed additives for all animal species and turmeric tincture from *Curcuma longa* L. rhizome as a feed additive for horses and dogs

The draft refers to the correction of some errors in the published version of Implementing Regulations (EU) 2021/421, 2021/485 and 2021/551 concerning the authorisation of certain feed additives.

Vote taken: Favourable opinion.

B.06 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation correcting Implementing Regulation (EU) 2021/1410 concerning the authorisation of a preparation of *Bacillus licheniformis* DSM 28710 as a feed additive for laying hens, minor poultry species for laying, poultry species for breeding and ornamental birds (holder of authorisation Huvepharma NV)

The draft refers to the correction of an error in the published version of Implementing Regulation (EU) 2021/1410 concerning the authorisation of a preparation of *Bacillus licheniformis* DSM 28710 as a feed additive.

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 a preparation of *Saccharomyces cerevisiae* MUCL 39885 as a feed additive for all suidae other than weaned piglets and sows, and dogs (holder of authorisation: Prosol S.p.A.)

The draft refers to the authorisation of a preparation of *Saccharomyces cerevisiae* MUCL 39885 as a feed additive for all suidae other than weaned piglets and sows, and dogs.

Vote taken: Favourable opinion.

B.08 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation concerning the authorisation of preparations of *Lacticaseibacillus rhamnosus* IMI 507023, *Pediococcus pentosaceus* IMI 507024, *Pediococcus pentosaceus* IMI 507025, *Lactiplantibacillus plantarum* IMI 507026, *Lactiplantibacillus plantarum* IMI 507027 and *Lactiplantibacillus plantarum* IMI 507028 as silage additives for all animal species

The draft refers to the authorisation of preparations of *Lacticaseibacillus rhamnosus* IMI 507023, *Pediococcus pentosaceus* IMI 507024, *Pediococcus pentosaceus* IMI 507025, *Lactiplantibacillus plantarum* IMI 507026, *Lactiplantibacillus plantarum* IMI 507027 and *Lactiplantibacillus plantarum* IMI 507028 as silage additives for all animal species.

Vote taken: Favourable opinion.

B.09 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation concerning the authorisation of litsea berry essential oil as a feed additive for certain animal species

The draft refers to the authorisation of litsea berry essential oil as a feed additive for chickens for fattening, laying hens, turkeys for fattening, pigs for fattening, piglets, lactating sows, calves, dairy cows, cattle for fattening, sheep and goats, horses, rabbits, salmonids, dogs, cats and ornamental fish.

Vote taken: Favourable opinion.

B.10 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation concerning the authorisation of petitgrain bigarade essential oil as a feed additive for certain animal species

The draft refers to the authorisation of petitgrain bigarade essential oil as a feed additive for chickens for fattening, laying hens, turkeys for fattening, pigs for fattening, piglets,

lactating sows, calves, dairy cows, cattle for fattening, sheep and goats, horses, rabbits, salmonids, dogs, cats and ornamental fish.

Vote taken: Favourable opinion.

B.11 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation concerning the authorisation of expressed mandarin essential oil as a feed additive for poultry, pigs, ruminants, horses, rabbits and salmonids

The draft refers to the authorisation of expressed mandarin essential oil as a feed additive for poultry, pigs, ruminants, horses, rabbits and salmonids.

Vote taken: Favourable opinion.

B.12 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation concerning the authorisation of expressed lemon essential oil, residual fraction of expressed lemon oil distilled, distilled lemon essential oil (volatile fraction) and distilled lime essential oil as feed additives for certain animal species

The draft refers to the authorisation of expressed lemon essential oil, residual fraction of expressed lemon oil distilled, distilled lemon essential oil (volatile fraction) and distilled lime essential oil as feed additives for certain animal species.

Vote taken: Favourable opinion.

M.01 State of play on applications for feed intended for particular nutritional purposes

A Commission representative informed the Committee that an updated list of the pending applications for feed for particular nutritional purposes, including the ones based on Article 2 of Regulation (EU) 2020/354, has been distributed to the Member States.

M.02 Guide on Good Hygiene Practices for producers of insects as food & feed

A Commission representative informed the Committee that the fourth version of the IPIFF Guide on Good Hygiene Practices for producers of insects as food & feed had been distributed to the Member States, inviting them to send their comments by the end of January 2022.