

ADVISORY COMMITTEE ON ANIMAL FEEDINGSTUFFS

76th Meeting of ACAF on 28 June 2018

Information Paper

EU and other Developments

**Secretariat
June 2018**

EU AND OTHER DEVELOPMENTS

Standing Committee on Plants, Animals, Food and Feed (SCoPAFF): Animal Nutrition Section (February to May 2018)

Feed additive authorisations

1. Standing Committee meetings were held in February (duration 2 days) and April 2018 (3 days), where nine feed additive authorisations and two other legislative tools were voted in favour. No meetings were held in March or May 2018, with the next meeting scheduled for the 27-29 June 2018. Votes are summarised in the Annex and discussion of particular note are:

Vitamin B2

2. In March 2018, competent authorities were notified by the Commission of an authorised vitamin B2 product on the market which was found to contain viable GM cells and genetic material, including for AMR traits. Discussions on this non-compliance were held at the SCoPAFF meeting for Genetically Modified Food and Feed (23 April 2018) and then tabled for vote on the denial of authorisation of this single source of vitamin B2 at the SCoPAFF-AN (24-25 April 2018). In this meeting for Animal Nutrition, the Commission outlined the situation and short transition dates were applied due to the safety concerns of this product on the market; being one month for the feed additive and three months for finished feedstuffs. It was acknowledged that this situation could create market pressures with the production company supplying a significant market-share of vitamin B2. Member States voiced some concern over the short transition periods with requests to extend market withdrawal timelines, although Commission remained firm on this matter. Whilst the vote was deferred at the April meeting in order to finalise legal obligations, the Commission stated that it would be presented for vote at SCoPAFF-AN (27-29 June) at the latest, and could be earlier if presented within an alternative Commission forum. We will keep the Committee updated on this significant matter of concern.

Trace elements

3. Whilst relatively little discussion has been held on copper compounds over this last year, a draft Regulation was presented for vote at the April meeting. The maximum permitted limits previously proposed remained in place and the Regulation was voted in favour, at 150/ 100/ 25mg/kg feed for piglets at 0-4/ 4-8/ +8 weeks post-weaning respectively. This stepwise reduction has largely been viewed as acceptable for the pig sector.

Other feed additives

4. The re-authorisation process remains ongoing for many well-established feed additives; including for the clusters of chemically-defined flavourings and other routine additives. A total of 37 feed additives were discussed at the February and April meetings, this included four applications for coccidiostats. In addition, there were a number of unfavourable opinions discussed; such as for a digestibility enhancer which contains residual rDNA, for bentonite which interferes with the analysis of Aflatoxin B1 and for the antioxidant Butylated hydroxyanisole (BHA) where safety in cats could not be concluded (impacting the pet-food sector).

New Feed Additive Functional Groups

5. At the February and April meetings, discussions continued on the draft Regulation for the proposed feed additive functional groups 'Other technologicals' and 'animal welfare enhancers'. This latter functional group has continued to divide Member States over the scope of use especially concerning veterinary medicine legislation and the use of antibiotic substitutes. One Member State made a recommendation to reduce the scope of functional characteristics and to more appropriately rename the functional group, which was viewed positively by the Commission. We will await the next draft Regulation to establish the acceptability of this proposal, and will keep the Committee updated.

Feed additives for withdrawal and deemed out of scope of Regulation (EC) 1831/2003

6. During the amendment of Annex II of Regulation (EC) 1831/2003, a number of feed additives were identified as no longer being appropriately classified as feed additives (e.g. vegetal carbon or sodium citrate). However, these feed additives were not progressed with the main withdrawal of feed additives under Regulation (EU) 2017/1145, and were to be progressed separately for legal implications. At the April meeting, the Commission presented a list of such feed additives with a view to reclassify, generally as feed materials. The Commission has requested Member States to provide feedback on this list or to propose other potential candidate entries.

Amendments to Regulation (EC) 429/2008 on feed additive applications

7. No further discussions held during this reporting period.

PARNUTS

8. At the February meeting, the Commission reported back on Member State evaluations, confirming the deletion of three PARNUT entries due to unfavourable assessments. Four additional assessments are expected for completion over Summer 2018. At the April meeting, the Commission presented a draft Regulation to update the Annex of Directive 2008/38/EC confirming that this Regulatory amendment will repeal the Directive. The

Commission also accepted the UK request to reinsert text specifying that feed additives used in PARNUTS must align with their authorised functional characteristic.

Feed hygiene

Interim measures for imports from Third Countries

9. In February, interim measures for imports from third countries were discussed, as defined under Article 24 of Regulation (EC) 183/2005 on feed hygiene. This was a complex discussion point where confusion exists over the significant cross-referencing between Regulation (EC) 183/2005 and the repealed Directives 95/69/EC and 98/51/EC on approvals and registration activities undertaken by feed establishments. Under Directive 95/69/EC there was a requirement for feed operators to be registered for activities in the use of specific (higher risk) feed additives, premixtures or compound feed containing such additives. However, Regulation (EC) 183/2005 essentially states that registration is required for any establishment, active in any of the stages of production, processing, storage, transport or distribution of feed. Legal services have now proposed an interpretation of this current text as pertaining to any animal feedstuff whether it is an additive, premixture, PARNUT, feed material or finished feed, no matter what the composition. We await formal publication of the Commission meeting minutes to confirm the current state of play and will keep the Committee updated on this very important issue.

Legal interpretation of processing aids

10. At the April meeting, discussion was held on the legal interpretation of processing aids in context of definitions stated within the legislation for feed additives (Article 2(2)(h) of Regulation (EC) No 1831/2003) and cascaded within Regulation (EC) No.767/2009 on placing feed on the market. The discussion focused on the interpretation of permissible residue levels of processing aids in the finished feed. As part of discussions, the Commission reiterated the requirements for labelling processing aids under part 4 of Annex A within Regulation (EU) No.2017/1017 for the Catalogue of feed materials, where materials with tolerated residues are complemented with relevant information provided by feed business operators in the context of usual commercial transactions. We will keep the Committee updated on further clarification of this topic.

Regulation (EC) 183/2005 on feed hygiene

11. Discussions continued on the Feed Hygiene Guidance document at the February and April meetings, with continued concerns raised over the interplay between animal feed and animal by-products regulations and on operator registration requirements. Following numerous Member State requests, a working group took place on 30 May 2018 to resolve these concerns.

Guidelines for the feed use of food no longer intended for human consumption – formerly, the Guidance on the use of former foods as animal feed.

12. At the February 2018 meeting, the Commission finalised this document with a number of notable amendments. Firstly, the document title was changed (as above) so as to be more meaningful to laypeople. Secondly, emphasis was made on the proposed derogation on feed registration requirements for certain food operators which may be controlled at national level. Finally, within the Annex, clarification was made on the use of food-waste recovery products; where the Commission viewed that unsafe food can be processed into safe feed. The Commission also acknowledged that the Waste Framework Directive (WFD) is currently under revision, and that this Guide will be revised accordingly in light of future WFD outcomes. This [Guideline](#) was published as a Commission Notice on 16 April 2018.

Fediaf Code of Good Labelling Practice for Pet Food

13. With only brief discussion held at the February meeting, a fuller discussion was held in April where the Commission had anticipated to finally endorse. However, a number of concerns remained within this Code; such as for health claims, pet-food composition labelling and GM declarations. Member States were requested to submit final comments in May.

Other Codes of Practice

14. Both the Fediaf Guide to Good Practice for the manufacture of pet-foods and the EU Code on Good Labelling Practice for Compound Feed for Food-Producing Animals (FEFAC/COPA-COGECA) were presented at the February meeting, with Member State feedback requested.

Feed Material Classification

15. At the February and April meetings, the Commission discussed ways in which the Community Register of Feed Materials may be monitored and enforced to maintain valid entries. In April, Member States were requested to provide feedback on existing entries to review their validity.

Undesirable substances in feed

RASFF notifications

16. Between 19 December 2017 and 23 April 2018, forty-five new RASFF notifications were raised. Within this period, the UK raised six serious RASFF notifications, five relating to exceedance of aflatoxin B1 in groundnuts/kernels intended for wild bird feed and one RASFF for a high Enterobacteriaceae count in fish treats for dogs imported from China.

17. Serious notifications raised by other Member States predominantly concerned exceedances of Aflatoxin B1, heavy metals (cadmium, lead), ragweed (*Ambrosia* spp.), *Salmonella*, high Enterobacteriaceae or mould infestation in various feed materials. Further *serious* RASFF notifications included the presence of glass fragments in a feed raw material and another for metal fragments in a pet-food product.
18. Non-serious RASFF notifications of significance over this same period included the presence of a fungicide (propamocarb) in a raw feed material, DON and ZON in a compound feed, ruminant DNA in a pork meal and *Streptococcus dysgalactiae* in a raw pet-food.
19. Over this reporting period; in total, there were two RASFF notifications concerning microbiological contamination of raw pet-foods.

Directive 2002/32/EC on undesirable substances

20. No notable discussion was held at either the February or April meetings.

Recommendation on nitrites and nitrates

21. In January 2018, the UK submitted an updated position paper on nitrites and nitrates, largely based on additional documentation circulated by the Commission in early 2017. The paper highlighted the need for good husbandry practices to mitigate high nitrite levels and to follow science-based evidence on the risk of nitrites as previously presented by EFSA, rather than the need to set threshold limits. This paper was kindly acknowledged by the Commission at the February 2018 meeting. At the April meeting, the Commission outlined the wider EURL work programmes for metals and nitrogenous compounds in feed which includes assay development for nitrites and nitrates.

Detoxification/decontamination processes

22. At the February meeting, the Commission notified the imminent publication on two further assessments for the decontamination of dioxins/PCBs in fishmeal and fish oils (since published as EFSA [No.5173](#) and [No.5174](#)). The sixth and final assessment, for the ammoniation of aflatoxins in groundnut meal is due in the second half of 2018.

Other undesirable substances raised

23. The Commission has compiled a detailed list of substances for potential future monitoring of undesirable substances in feed; these include various mycotoxins, alkaloids and metal elements.
24. At the February meeting, the Commission followed-up discussion on the viability of ambrosia seeds to allow non-compliant consignments to be transported to crushing plants, rather than the current requirement to be incinerated. Whilst there is sufficient evidence that milling/crushing can

ensure non-viability, the issue for the Commission remains as to how enforcers would be able to determine if seeds are viable or not.

25. Also as a follow-up at the February meeting, the Commission stated that low Tetrahydrocannabinol (THC) varieties of Cannabis sativa are permitted for use in animal feed with THC levels of <0.2%. However, the Commission acknowledged that it is difficult to establish which varieties have been used in imported goods and this is further complicated by the multiple feedstuffs (cakes, meals etc) and in determining potential carry-over into foodstuffs. The Commission is to collate further data to review the proposed maximum residue limits for THC.
26. The Commission provided background on the presence of arsenic in dimanganese chloride trihydroxide. Whilst the EURL has a work programme on determining an analytical method for metals in 2018, this is not appropriate for the determination of arsenic in trace elements and therefore a separate ICP-MS method has been recommended.
27. The Commission previously requested Member State feedback in the review of Regulation (EC) No. 152/2009 on analytical methods for official controls in feed. It is now expected that an expert working group will be formed to carry this review forward in 2018.
28. Over the last year or more, there has been numerous discussions on the analysis of urea (carbamide) arising from a situation where fraudulent imports of feedstuffs from Russia contained this feed additive. Discussion now returned on the robustness of the analytical method as laid down in Regulation (EC) No.152/2009 on feed controls. The EURL stated that this colorimetric method remains appropriate for ruminant feeds, although not necessarily for other feed matrices (such as petfood for example). It was acknowledged that the colorimetric method can return higher values due to interference from other compounds, and that the use of enzymatic or LC/MS methods would yield (lower) more accurate results. The Commission acknowledged that the colorimetric method may be outdated and enzymatic or LC/MS methods could be preferred; even for ruminant feed, albeit validation is still required.

European Food Safety Authority (EFSA)

29. Between January and April 2018, the EFSA FEEDAP Panel¹ published 27 scientific opinions to assess feed additive applications for authorisation and re-authorisation.
(<https://www.efsa.europa.eu/en/science/feed-materials>)

30. Of particular note were:

¹ FEEDAP - Panel on Additives and Products or Substances used in Animal Feed

31. Enzymes as silage additives.
(<https://www.efsa.europa.eu/en/efsajournal/pub/5224>)
32. Outcome of the public consultation on the draft guidance on characterisation of microorganisms used as feed additives or as production organisms.
(<https://www.efsa.europa.eu/en/supporting/pub/1389e>)
33. Guidance on the characterisation of microorganisms used as feed additives or as production organisms.
(<https://www.efsa.europa.eu/en/efsajournal/pub/5206>)
34. Safety and efficacy of butylated hydroxyanisole (BHA) as a feed additive for all animal species.
(<https://www.efsa.europa.eu/en/efsajournal/pub/5215>)
35. Safety of vitamin B2 (80%) as riboflavin produced by *Bacillus subtilis* KCCM-10445 for all animal species.
(<https://www.efsa.europa.eu/en/efsajournal/pub/5223>)
36. The CONTAM Panel² of EFSA provides scientific advice concerning the presence of contaminants in both feed and food.
(<http://www.efsa.europa.eu/en/panels/contam>)
37. The CONTAM Panel's advice and summary of the recent 91st Plenary meeting, Parma (14-16 May 2018) can be viewed on:
(<http://www.efsa.europa.eu/en/events/event/180514>)
With discussions on health risks from dioxins and 4,15 – diacetoxyscirpenol in feed (and food).
38. Forthcoming agendas of FEEDAP and CONTAM Panels (amongst others) may be viewed on:
(<http://www.efsa.europa.eu/en/events/advanced-search>)

Scheduled SCoPAFF-AN meetings for 2018

- 27-29 June
- 17-19 September
- 7-9 November
- 17-18 December

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² The Panel on Contaminants in the Food Chain

ANNEX – SCoPAFF VOTES AND FEED ADDITIVE AUTHORISATIONS

Animal Nutrition votes:

February 2018

Additive/ Other legislation	Authorisation type	Proposal number
Zootechnical: Preparation of <i>Saccharomyces cerevisiae</i> CNCM I-1079 as a feed additive for sows and piglets.	Re- authorisation	SANTE/10887/20 17
Zootechnical: (EC 3.2.1.8) produced by <i>Trichoderma citrinoviride</i> Bisset (IMI SD135) as a feed additive for carp.	New authorisation	SANTE/11505/20 17
Technological: Preparation of <i>Lactobacillus buchneri</i> NRRL B-50733 as a feed additive for all animal species.	New authorisation	SANTE/11506/20 17
Zootechnical: Preparation of <i>Bacillus subtilis</i> DSM 29784 as a feed additive for chickens for fattening and chickens reared for laying.	New authorisation	SANTE/11507/20 17
Technological: Preparation of <i>Lactobacillus hilgardii</i> (CNCM I-4785) as a feed additive for all animal species.	New authorisation	SANTE/10702/20 17
Zootechnical: Preparation of 6-phytase.	New authorisation	SANTE/12046/20 17
Other: Correcting Commission Implementing Regulation (EU) No 2017/1145 of 8 June 2017 on the withdrawal from the market of certain feed additives.	Correcting Regulation	SANTE/11345/20 17

No meeting held in March 2018

April 2018

Additive/ Other	Authorisation type	Proposal number
Zootechnical: Preparation of benzoic acid, calcium formate and fumaric acid for chickens for fattening and chickens reared for laying.	New authorisation	SANTE/11975/2017
Zootechnical: Benzoic acid for minor porcine species for fattening and for reproduction.	New authorisation	SANTE/11976/2017
Nutritional: [Copper compounds] Copper(II) diacetate monohydrate, Copper(II) carbonate dihydroxy monohydrate, Copper(II) chloride dihydrate, Copper(II) oxide, Copper(II) sulphate pentahydrate, Copper(II) chelate of amino acids hydrate, Copper(II) chelate of protein hydrolysates, Copper(II) chelate of glycine hydrate (solid) and Copper(II) chelate of glycine hydrate (liquid)	Re-authorisation	SANTE/10898/2016
Other: Correcting the Dutch language version of Regulation (EU) No 68/2013 on the Catalogue of Feed Materials	Correcting Regulation	DGT/2017/5213742

No meeting held in May 2018

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