ADVISORY COMMITTEE ON ANIMAL FEEDINGSTUFFS

75th Meeting of ACAF on 15 February 2018

Information Paper

EU and other Developments

Secretariat February 2018

EU AND OTHER DEVELOPMENTS

Standing Committee on Plants, Animals, Food and Feed (SCoPAFF): Animal Nutrition Section (Oct 2017 to January 2018)

Feed additive authorisations

 Standing Committee meetings were held in November (duration 3 days) and December 2017 (2 days), where seventeen feed additive authorisations and two other legislative tools were voted in favour. No meetings were held in October 2017 or January 2018, with the next meeting 5-7 February 2018. Votes are summarised in the Annex and discussion of particular note are:

Formaldehyde

2. At the December meeting, the denial of authorisation of formaldehyde as a feed additive was voted by on and received a qualified majority vote in favour by 26/28 Member States. This denial of authorisation concerns the existing use of formaldehyde as a preservative in skimmed milk for piglets and for the proposed authorisation as a 'hygiene condition enhancer' to decontaminate *Salmonella* in feed. At the time of going to press, the Regulation had not been published in the Open Official Journal of the European Union (OJEU) and therefore, has not yet entered into force. Please refer to Paper ACAF/18/02 for a detailed summary leading up to this vote.

Trace elements

- 3. At the November 2017 meeting, the proposal on the reauthorisation of iron compounds was voted in favour, with changes to reductions in maximum permitted limits (MPLs) for specific categories of animal species. Iron content in feed for bovines and poultry was reduced from 750 to 450mg/kg and for pets reduced from 1,250 to 600mg/kg feed. In addition, a footnote was inserted into the Regulation Annex to exclude inert forms of iron from calculations for total iron content, such as for iron (II) carbonate for young animals. Within this Regulation, the reauthorisation of ferric oxide was denied following a negative EFSA Opinion (2016, <u>No.4508</u>) based on genotoxic potential. <u>Regulation (EU)</u> 2017/2330 on these iron compounds (and denial of ferric oxide) was published 14 December 2017.
- 4. Little discussion has been held on copper compounds over recent months, although at the November meeting a draft Annex was presented proposing MPLs of 150/ 100/ 25mg/kg for piglets at 0-4/ 4-8/ +8 weeks post-weaning respectively. This proposal falls below the FEFAC recommendation of 170/ 110/ 25mg/kg. We will update the Committee with future progress on this important issue.

Other feed additives

5. The authorisation process remains ongoing for many well-established feed additives; including for the clusters of chemically-defined flavourings and other routine additives. A tranche of some 300 botanical feed additives is yet to start.

New Feed Additive Functional Groups

- 6. At the December meeting, the Commission presented a draft Regulation for the proposed feed additive functional groups 'Other technologicals' and 'animal welfare enhancers'. There has been concern that the proposed function of 'animal welfare enhancers' would extend into veterinary medicine legislation. The Commission summarised the scope of this functional group as eliciting effects on emotional, physiological and (physical and thermal) comfort states or reducing stress in healthy animals only; and not extending to reversing ill-health. Examples of potential entries could include the use of amino acids (i.e. L-tryptophan) to reduce stress through increasing serotonin levels or L-arginine rich diets to reduce suffering in pigs. Other natural plant extracts have the potential to reduce ammonia or methane in the environment and to alleviate animal distress associated with high ammonia/methane levels through reducing cortisol levels. The Commission indicated that many such additives are already on the market but their use is borderline under current functional descriptions; therefore, this new functional group would provide greater clarity.
- 7. Functional groups relating to preservatives and feed additives for use via drinking water are to be progressed separately in due course. The Secretariat will keep the Committee updated on progress made on these functional groups.

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

8. At the December 2017 meeting, the Commission dedicated proposed revisions to Regulation (EC) 429/2008 on preparing dossiers for feed additive authorisations. A key factor in the proposed amendments is to maintain alignment with the recently published EFSA guidelines (see EFSA section herein). It is proposed to provide greater flexibility in the provision of trial data with the use of literature-based studies including existing or new laboratory based models to substitute undertaking bespoke and costly feed trials. The proposal will also consider extrapolating data to other animal species; including the use of lower economic value species (e.g. data for sheep extrapolated to dairy cattle).

PARNUTS

9. PARNUTS were briefly discussed at both November and December meetings. The Commission provided an update on the list of PARNUTs, with a small number of existing entries being deleted due to unfavourable evaluations. The Commission also presented a revised draft of the Regulation, with proposals to amend the Annex text (General provisions).

Feed hygiene

Regulation (EC) 183/2005 on feed hygiene

10. At the November and December meetings, there was brief discussion on the guidance for the implementation of the feed hygiene legislation with a continued focus on the requirement for businesses to be registered as feed businesses. The detailed work on this guidance is being taken forward by a working group of Standing Committee members.

Amendments to Regulation 767/2009 on marketing feed

 Following a vote at the July 2017 meeting, delays in publication occurred due to internal Commission errors. <u>Commission Regulation (EU)</u> <u>2017/2279</u> was published on 11 December 2017 and entered into force in January 2018.

Guidance on the use of former foods as animal feed

- 12. At the November meeting, the Commission informed Member States that the guidance on the use of former foods as animal feed would not be presented for vote as a Commission Recommendation, but would be progressed more informally as a Commission Notice. Concern remains on the definition of waste in the context of potential animal feed materials, and on the proposed derogation which may exempt food business operators being registered as feed operators under certain circumstances.
- 13. At the December meeting, the Commission stated that the term 'former foods' had only been retained in the guide where it is explicit that foodstuffs were destined for feed: otherwise, the foodstuff is to be referred to as 'food no longer intended for human consumption' or 'food for processing into feed' (e.g. packaged bread). Similarly, food consisting of, containing or contaminated with products of animal origin (POAO) may not be directly used in the manufacture of feed and therefore cannot be defined as a feedstuff until further processed, according to animal byproduct (ABP) rules. The Commission also emphasized that the derogation to exempt food retailers from registering as feed business operators only applied to products of non-animal origin (PONAO) as businesses handling POAO are required to be registered or approved under ABP Regulations. Member States were requested to submit final comments before concluding on this Commission Notice at the next meeting (5-7 February 2018). The Secretariat will keep the Committee updated on the conclusion of this guidance.

Fediaf Code of Good Labelling Practice for Pet Food

14. At the December meeting, Member States were invited to submit final comments prior to endorsement at a future meeting in 2018.

Fediaf Guide to Good Practice for the manufacture of petfoods

15. Similarly, at the December meeting, Member States were also invited to submit final comments prior to endorsement at a future meeting in 2018.

Feed Material Classification

16. Over recent meetings, the Commission has introduced this topic as a routine agenda item to clarify queries on individual entries within the Register of Feed Materials, to establish whether entries are valid or to approach applicants for their removal. At the November meeting, it was determined that Butaphosphane is a veterinary medicine and not a feed material. At the December meeting, polyoxyethylene glycol (PEG) was identified as a formerly authorised feed additive and the entry for Bromelain (an enzyme mix from pineapples) would also constitute a feed additive.

Insect processed animal protein

17. At the December meeting, Commission provided an update on the use and control of insect processed animal protein (PAP), currently only permitted for use in aquaculture feed. In the context of detection, PCR can be used to ensure compliance of PAP sources in aquaculture feed, such as confirming the absence of ruminant PAP. However, optical microscopy is insufficient to discriminate between insect PAP and the presence of muscle fibres from other species (e.g. poultry or porcine). The EURL has been tasked to refine a (double sedimentary) microscopy method to differentiate insect PAP from other tissues and is scheduled for completion by the end of 2018. In terms of compliance of using insects from the positive list in Regulation (EC) 142/2009; the approach was viewed as any other raw material, being subject to official controls through on-site inspection by competent authorities within the EU or in third countries. Compliance of PAP by species is proposed to be defined by setting action thresholds developed by the EURL (based on DNA copy numbers), where PCR false positive results below this threshold would not trigger further investigation. This methodology is to be assessed by EFSA and if favourable, would pave the way for legislation on feeding poultry PAP to pigs and vice versa. The Secretariat will keep the Committee updated on progress of this innovative feed material.

Undesirable substances in feed

RASFF notifications

- 18. Between 1 September and 17 December 2017, thirty-nine new RASFF notifications were raised. Within this period, the UK raised one serious RASFF notification (and two under consideration), all relating to exceedance of aflatoxin B1 in groundnuts/kernels intended for wild bird feed; imported from Argentina, Tanzania and the USA.
- 19. Regarding alerts on feedstuffs originating from the UK, there were two RASFF notifications raised by other Member States, both concerning Shiga-toxin producing *Escherichia coli* (STEC) contamination in frozen raw petfood.
- 20. Serious notifications raised by other Member States predominantly concerned exceedances of Aflatoxin B1, heavy metals (arsenic, lead) or ragweed (Ambrosia spp.) in various feed materials. Further *serious*

RASFF notifications included the presence of crotalaria (hemp genus) or unauthorised GM seeds and microorganisms in feedstuffs.

- 21. Non-serious RASFF notifications of significance over this same period included the presence of dioxins in various herbal feedstuffs; fraudulent import certificates, and foreign bodies present in feedstuffs.
- 22. Over this reporting period; in total, there were eight RASFF notifications concerning microbiological contamination of raw petfoods.

Directive 2002/32/EC on undesirable substances

23. No significant discussions held at the November or December meetings.

Recommendation on nitrites and nitrates

24. Little progress on the Commission Recommendation for nitrites and nitrates. However, at the December meeting, three key strands were proposed to:

1) request an EFSA mandate to assess nitrites and nitrates in feed;

2) compile a guide to mitigate accumulation of nitrites and nitrates in feedstuffs; and

3) task the EURL to develop analytical methods, especially for wet feed materials.

Detoxification/decontamination processes

25. At the December meeting, an update was provided on timelines for EFSA publications on the six feed decontamination processes, with two having been published previously. The Assessment of decontamination processes for dioxins and dioxin-like PCBs in fish oil by physical filtration with activated carbon was published in December 2017 (EFSA No.5081). Two further EFSA assessments are scheduled for Spring 2018 and the final assessment by Summer 2018.

Other undesirable substances raised

- 26. At the December meeting, the Commission highlighted a request to investigate the viability of ambrosia seeds (even when crushed), and to allow non-compliant consignments to be transported to crushing plants, rather than the current requirement to be incinerated. Information was provided which summarised the extreme production process for oils, concluding that even if all seeds are not crushed they remain non-viable. EFSA is to assess conditions which inactivate ambrosia seeds, prior to the Commission forming a decision on the possibility to divert to crushing plants.
- 27. Tetrahydrocannabinol (THC) in hemp has been frequently raised as an issue over this last year. At the December meeting, it was confirmed that hemp is permitted within the Catalogue of Feed Materials with further entries found in the Register of Feed Materials. However, it is expected that these sources are produced from low THC plant varieties (<2%) with removal of the flowering parts which contain inherently high THC levels. If the level of THC detected is <10mg/kg, then the plant source is likely to be a low THC plant variety.

European Food Safety Authority (EFSA)

28. Between October and December 2017, the EFSA FEEDAP Panel¹ published 15 scientific opinions to assess feed additive applications for authorisation and re-authorisation. (https://www.efsa.europa.eu/en/science/feed-materials)

29. Of particular note were:

- EFSA Guidance on the identity, characterisation and conditions of use of feed additives. (<u>https://www.efsa.europa.eu/en/efsajournal/pub/5023</u>)
- EFSA Guidance on the assessment of the safety of feed additives for the consumer. (https://www.efsa.europa.eu/en/efsajournal/pub/5022)
- EFSA Guidance on the assessment of the safety of feed additives for the target species. (https://www.efsa.europa.eu/en/efsajournal/pub/5021)
 - 30. The CONTAM Panel² of EFSA provides scientific advice concerning the presence of contaminants in both feed and food. (<u>http://www.efsa.europa.eu/en/panels/contam</u>)
 - 31. The CONTAM Panel's advice and summary of the recent 88th Plenary meeting, Parma (23 January 2018) can be viewed on: (<u>http://www.efsa.europa.eu/en/events/event/180123-1</u>) With discussions on mycotoxins, decontamination processes and health risks from dioxins in feed.
 - 32. Forthcoming agendas of FEEDAP and CONTAM Panels (amongst others) may be viewed on: (<u>http://www.efsa.europa.eu/en/events/advanced-search</u>)

Scheduled SCoPAFF-AN meetings for 2018

- 5-7 February
- 23-25 April
- 27-29 June
- 17-19 September
- 7-9 November

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

² The Panel on Contaminants in the Food Chain

• 17-18 December

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ANNEX – SCOPAFF VOTES AND FEED ADDITIVE AUTHORISATIONS

Animal Nutrition votes:

No meeting held in October 2017

November 2017

Additive/ Other legislation	Authorisation type	Proposal number
Sensory: [Flavourings CDG 024] 2,3-Diethyl pyrazine, 2,5 or 6-methoxy-3-methyl-pyrazine, 2- acetyl-3-ethyl-pyrazine, diethyl-5- methylpyrazine, 2- (sec-butyl)-3-methoxy- pyrazine, 2-ethyl-3-methoxypyrazine, 5,6, 7,8- tetra-hydroquinoxaline, 2-ethylpyrazine and 5-methyl-quinoxaline for all animal species.	Re- authorisation	SANTE_11131_2 017
Sensory: [Flavourings CDG 014] Methyl 2-furoate, bis- (2-methyl-3-furyl) disulphide, furfural, furfuryl alcohol, furanmethanethiol, S-furfuryl aceto- thioate, difurfuryl disulphide, methyl furfuryl sulphide,2-methylfuran-3-thiol, methyl furfuryl disulphide, methyl 2-methyl-3-furyl disulphide and furfuryl acetate for all animal species.	Re- authorisation	SANTE_11130_2 017
Sensory: [Flavourings CDG 013] Linalool oxide for all animal species.	Re- authorisation	SANTE_10685_2 017
Sensory: [Flavourings CDG 08] Menthol, d-carvone, menthyl acetate, d,l-isomenthone, methyl-2- cyclopenten-l-one, 3,5,5- trimethylcyclohex- 2-en-l-one, d-fenchone, fenchyl alcohol, carvyl acetate, dihydrocarvyl acetate and fenchyl acetate as feed additives for all animal species.	Re- authorisation	SANTE_10684_2 017
Sensory: [Flavourings CDG 34] Taurine, beta-alanine, L-alanine, L-arginine, L-aspartic acid, L- histidine, D,L-isoleucine, L-leucine, L- phenylalanine, L-proline, D,L-serine, L- tyrosine, L-methionine, L-valine, L-cysteine, L-cysteine hydrochloride monohydrate,	Re- authorisation	SANTE_10196_2 017

glycine, monosodium glutamate and L- glutamic acid for all animal species.		
Sensory: [Flavourings CDG 29] 2,4,5-trimethyl- thiazole, 2- isobutylthiazole, 5-(2- hydroxyethyl)-4-methylthiazole, 2,4,5- trimethylthiazole, 2- acetyl-thiazole, 2-ethyl-4- methylthiazole, 5,6-dihydro-2,4,6,tris(2- methyl-propyl)4H-1,3,5-dithiazine & thiamine hydrochloride for all animal species.	Re- authorisation	SANTE_10636_2 017
<i>Technological:</i> Preparations of lecithins, lecithins hydrolysed and lecithins de-oiled as feed additives for all animal species	Re- authorisation	SANTE_11640_2 017
Zootechnical: Preparation of <i>Bacillus subtilis</i> (DSM 5750) and <i>Bacillus licheniformis</i> DSM 5749 for suckling piglets.	*New/ Re- authorisation	SANTE_10696_2 017
Zootechnical: Preparation of <i>Pediococcus acidilactici</i> CNCM MA 18/5M for pigs for fattening, minor porcine species (weaned) and for fattening, chickens for fattening, minor poultry species for fattening and minor poultry species for laying.	*New/ Re- authorisation	SANTE_10889_2 017
Zootechnical: Bacillus subtilis ATCC PTA-6737 as a feed additive for sows.	New authorisation	SANTE_11118_2 017
Zootechnical: 6-phytase (EC 3.1.3.26) produced by <i>Komagataella pastoris</i> (DSM 23036) as a feed additive for fish	New authorisation	SANTE_10700_2 017
Zootechnical: Preparation of <i>Lactobacillus acidophilus</i> (CECT 4529) as a feed additive for chicken for fattening.	New authorisation	SANTE_10876_2 017
Zootechnical: Preparation of <i>Bacillus subtilis</i> (DSM 15544) for sows, suckling piglets and dogs.	New authorisation	SANTE_10697_2 017
Other: Change in name of the holder of the authorisation of 6-phytase as a feed additive for all avian species and for weaned piglets, pigs for fattening	Administration regulation	SANTE_11670_2 017

<i>Nutritional:</i> [Iron compounds] Iron(II) carbonate, Iron(III) chloride hexahydrate, Iron(II) sulphate monohydrate, Iron(II) sulphate heptahydrate, Iron(II) fumarate, Iron(II) chelate of amino acids hydrate, Iron(II) chelate of protein hydrolysates and Iron(II) chelate of glycine hydrate for all animal species and Iron dextran for piglets.	Reauthorisatio n	SANTE_10899_2 017
Other: Characterisation of selenomethionine produced by Saccharomyces cerevisiae CNCM 1-3399.	Modification to authorisation	SANTE_10165_2 017

* Re-authorisation of existing application (1831/2003 Article 10(2)) with coapplication for additional scope (Article 10(7))

December 2017

Additive/ Other	Authorisation type	Proposal number
<i>Technological:</i> Formaldehyde	Denial of authorisation	SANTE_11998_2 016
Zootechnical: Preparation of endo-I,4-b xylanase (EC 3.2.1.8) produced by <i>Trichoderma reesei</i> (BCCM/MUCL 49755)	New authorisation	SANTE_10275_2 017
<i>Nutritional:</i> L-arginine produced by <i>Corynebacterium</i> <i>glutamicum</i> KCCM 80099	New authorisation	SANTE_11942_2 017

No meeting held in January 2018

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