ACAF/17/10

ADVISORY COMMITTEE ON ANIMAL FEEDINGSTUFFS

73rd Meeting of ACAF on 14 June 2017

Information Paper

EU and other Developments

Secretariat
May 2017

EU AND OTHER DEVELOPMENTS

Standing Committee on Plants, Animals, Food and Feed (SCoPAFF): Animal Nutrition and Veterinary Medicines Section (February to April 2017)

Feed additive authorisations

1. Standing Committee meetings were held in February and April 2017, where twenty one feed additive authorisations (and two other legislative tools) were voted in favour, as summarised in the Annex. Of particular note, are:

Formaldehyde

2. No formal discussion has been held on formaldehyde over many months now. However, the Commission reiterated in April that a denial of authorisation (i.e. prohibition of use) is currently being drawn up, with no future opportunity to pursue an authorisation. We will continue to keep the Committee updated on developments.

Formic acid

3. Formic acid has been discussed over recent months, falling within the new functional group 'hygiene condition enhancer' created in anticipation of the authorisation of formaldehyde. Formic acid was voted in favour at the April meeting, making it the first entry into this new functional group.

Ethoxyquin

4. At the February 2017 meeting, the Commission informed Member States that a sanitary and phytosanitary (SPS) notification had been submitted (6 February) to the World Trade Organisation due to potential impacts on global trade. Following a 60 day consultation period; the (partial) suspension of ethoxyquin was presented for vote at the April meeting and passed in favour. In summary, the conditions of suspension within the final Regulation maintained previously defined permitted uses of ethoxyquin; for feed additives (Vitamins A, D, E, K and carotenoids) and for specific entries within the Catalogue of feed materials (Ch.10 'Fish, other aquatic animals and products derived thereof' and 7.1.2. for dried algae). Differential long-term transition periods have been applied to these feedstuffs above; whilst products not listed will be suspended, with final products permitted on the market up to nine months from when the Regulation comes into force. The ongoing research roadmap will continue to inform EFSA as to whether a re-authorisation of ethoxyquin may be

progressed. We will provide the Committee with updates as new information is shared.

Cassia gum

5. Cassia gum was presented for discussion for the first time at the April meeting. In a close analogy with ethoxyquin, cassia gum has also been on the market for over forty years (as a gelling agent) and is of global economic importance. During the current re-authorisation process, EFSA identified significant data gaps and safety concerns relating to potential genotoxic effects from the impurity - anthraquinone. Whilst purified food grade cassia gum was deemed safe by EFSA, the same degree of purification would not be economically viable for the feedsector. A mini research roadmap was presented to the Commission to address these concerns over mutagenicity and anthraquinone content, scheduled over coming months. Following discussion, it was agreed to permit the continued use of cassia gum whilst this research is finalised and submitted for further EFSA assessment. We will continue to update the Committee on developments.

Trace elements

6. Substantive discussion is still yet to take place on the re-authorisation of copper compounds, following the EFSA (2016)[1] recommendation for a reduction of maximum permitted limits (MPLs) from 170mg to 25mg Cu/kg feed in piglets up to 12 weeks, as well as a reduction from 35mg to 30mg Cu/kg feed in feed for bovines. Brief discussions have already indicated differential perspectives of copper being used solely as a nutritional additive, rather than supporting other benefits in growth performance and immunological protection. We will keep the Committee updated on developments regarding this important issue.

7. As a follow-up from the February ACAF meeting, the European Medicines Agency (EMA) has confirmed the decision to prohibit veterinary medicine products containing zinc oxide due to concerns of adverse environmental impacts and the potential for antimicrobial co-selection. Following consultation, transition periods of up to ten years are to be considered. Updated information may be obtained from the Veterinary Medicines Directorate (VMD) website.[2]

8. Trace element sources containing manganese or iron are also awaiting re-authorisation and have been briefly discussed. The Commission has conveyed concern for the re-authorisation of ferric oxide due to its

[1] EFSA Opinion No. 4563 (2016). Revision of the currently authorised maximum copper content in complete feed . (https://www.efsa.europa.eu/en/efsajournal/pub/4563)

[2] VMD News story (20 March 2017): Veterinary medicines containing zinc oxide: European referral process. (https://www.gov.uk/government/news/veterinary-medicines-containing-zinc-oxide-european-referral-process)

genotoxic potential. Reductions in MPLs for iron have been proposed; most significantly for pet animals (1,250mg/kg to 600mg/kg feed) and feedback is being sought onto such impacts. The existing MPLs for manganese currently remain unchanged in early discussions.

Other feed additives

9. The market withdrawal of some two hundred feed additives listed within Annex II of Regulation (EC) No.1831/2003 was voted in favour at the April meeting. One Member State requested consideration for a two year transition period in acknowledgement of long production runs for labels within the pet food sector. This request was agreed and expanded for all Annex II entries; which includes the important trace element, sodium selenate which was withdrawn at a late stage in 2015.

10. Discussions continue on the definition of botanicals, with some 300 botanical flavourings awaiting re-authorisation; with a focus to differentiate botanicals as feed additives and those as feed materials. Industry has provided constructive inputs, although further refinement is still required.

Amendments to Regulation (EC) No.429/2008 on feed additive applications

11. In recent months, no discussion has been held on Annex revisions to Regulation (EC) No.429/2008 on the preparation of feed additive applications.

Amendments to Regulation (EC) No.767/2009 on marketing feed

12. In recent months, discussions on Annex amendments have predominantly focused on Annex II to incorporate text facilitating the use of former foods as feedstuffs. At the April meeting, significant time was spent debating this text, with little agreement reached. During meetings held in 2017, no discussion has been held on Annexes VI or VII, regarding labelling requirements for food-producing and non-food producing animals respectively.

13. The development of a guidance document on the use of former foods as animal feed was progressed at both the February and April meetings. Following earlier industry feedback, revisions provided greater clarity on the objective and legal scope of the guide. Meeting discussions have primarily focused on; better defining former foods, transition points from food to feed, legal considerations of animal by-products (ABPs) and the co-transport of food and feedstuffs. As no legal definition exist for former foods, the Commission outlined a proposal that retailed food goods remain

under General Food Law until received by the former foods processor. Prior to the April meeting, significant revisions were introduced expanding on ABPs within former foods. Whilst the direction of these revisions was generally welcomed, it was also recognised that the document had become muddled and it was recommended to separate the guidance into two distinct sections, covering; i) ABPs and former foodstuffs and ii) non-ABPs and former foodstuffs.

Feed additive functional groups

14. Discussions on the development of new feed additive functional groups have been very repetitive over many months with little progress made to date. A key focus of debate surrounds the creation of a new zootechnical function 'animal welfare enhancers' which Commission defends as maintaining animal health; within scope of animal feed legislation. However, views have been expressed that this proposal falls outside of scope and may extend into veterinary medicine legislation. In addition, introduction of new groups specifically for the use of feed additives via drinking water has also been strongly debated, with no resolution to date.

Unauthorised additives intended for export

15. A brief discussion was held on the draft document at the February meeting, where the Commission highlighted requirements for Member State notification via the European TRACES system. Whilst the document had improved, further refinements are still required.

PARNUTS

16. No updates have been provided on existing PARNUTS in 2017; however, at the February meeting, the Commission confirmed receipt of three new PARNUT applications.

Feed hygiene

Regulation (EC) No.183/2005 on feed hygiene

17. At the April meeting, the Commission demonstrated an in-development database repository for national feed guides, which is being integrated into the existing European Commission food database.

18. The draft guidance document on feed hygiene was last discussed at the February meeting, which continues to highlight divergent Member State interpretations of the Regulation. On the specific issue of whether fish-bait falls under animal feed legislation was clarified; where 'fish on a hook'

falls outside regulatory scope, whilst 'ground bait' (scattered across the water) used as an attractant was deemed as falling within scope of animal feed legislation. Further revisions of the guide will still be required.

Regulation (EC) No. 68/2013 on the Catalogue of feed materials

19. Following the vote in favour at the December 2016 meeting, it is anticipated that the amended Regulation will be published in the European Journal and come into force in the coming weeks (May/June).

EFSA opinion of antimicrobial resistance potential in feeding milk to calves

20. At the February meeting, the Commission provided an overview of the recent EFSA Opinion (No.4665)[3] published in January 2017, on the qualitative risk for the development of antimicrobial resistance (AMR) due to feeding calves with milk containing residues of antibiotics. The terms of reference outlined were to:
    a. assess the risk for the development of AMR due to feeding on farm of calves with colostrum potentially containing residues of antibiotics;
    b. assess the risk for the development of AMR due to feeding on farm of calves with milk of cows treated during lactation with an antibiotic and milked during the withdrawal period,
    c. propose options to mitigate risk for development of AMR derived from such practices.

    A key conclusion drawn by EFSA was that milk from cows receiving antimicrobial treatment during lactation would contain substantial residues during the treatment and withdrawal period, leading to faecal shedding of antimicrobial-resistant bacteria by the calves. EFSA detailed three strategic AMR-mitigating recommendations related to; feed management options, destruction of antimicrobial residues and elimination of antimicrobial-resistant bacteria. The Commission indicated that follow-up discussions/actions would take place.

21. At the April meeting a brief discussion was held on the EU Guide to good practice for the industrial manufacture of safe feed materials for the oleochemical sector with the ultimate goal in seeking Commission endorsement.

[3] EFSA Opinion No.4665 (2016). Risk for the development of Antimicrobial Resistance (AMR) due to feeding of calves with milk containing residues of antibiotics. (http://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2017.4665/epdf)

Undesirable substances in feed

RASFF notifications

22. Between 1 January and 31 March 2017, twenty eight new RASFF notifications were raised. Within this period, the UK raised six serious RASFF notifications, all concerning an exceedance of aflatoxin B1 in groundnuts; predominantly from India, intended for wild bird feed.

23. At the February meeting, the Commission also informed Member States on the growing number of aflatoxin B1 non-compliances of groundnuts from the USA over recent years, albeit more commonly observed in food goods. The Commission provided a background into the existing preferential import agreements with the USA, and these criteria are no longer being met. Therefore, this agreement is to be rescinded and imports from the USA may even become subject to enhanced controls.

24. Non-serious RASFF notifications of significance to date in 2017 were dominated by the potential fraudulent supply of fodder yeast from Russia containing urea, with eleven notifications from Latvia and one from Hungary.

25. At the April meeting, a presentation was given by DG SANTE (Unit G5) responsible for food/feed fraud and EU notification systems. To illustrate the activities of the DG Unit, the presentation focused on the potential fraudulent supply of yeast as a case study. Whilst conveying Commission procedures, the presentation detailed the rationale behind this situation, where the addition of urea to feedstuffs will indicate higher protein levels than naturally present and subsequently provide opportunities for significant fraudulent economic gains.

Directive 2002/32/EC on undesirable substances

26. Previous discussions in February and April on the amendment or inclusion of entries for undesirable substances progressed to the presentation of a draft Regulation document. Amendments include maximum residue levels (MRLs) for: melamine, dioxins and PCBs, arsenic in peat, arsenic in leonardite (a fossilized organic material), gossypol, mercury, lead in dicopper oxide and the removal of the entry for nitrites. This draft Regulation was scheduled for vote at the SCoPAFF meeting in May, but this has since been deferred.

Recommendation on nitrites and nitrates

27. With the proposed removal of nitrites from Directive 2002/32/EC, the first draft Commission Recommendation on nitrites and nitrates in feed was presented at the February meeting, based on the previous framework documents to establish guidance levels. The Commission acknowledged challenges in drafting this recommendation due to diverse agri-feed practices across Member States to provide meaningful good practice guidance to farmers and feed-producers to achieve ALARA principles for nitrite levels. Following this initial draft Recommendation, the Commission received strong industry feedback; most notably from the sugar and starch industries where concerns were raised as being linked with (by-)products identified as containing high levels of nitrite under certain circumstances.

Detoxification processes

28. At the April meeting, the Commission provided a progress update on EFSA applications received for permitted detoxification processes. The Commission reiterated that applications received prior to the July 2016 deadline would still be permitted until EFSA had finalised assessments. The Commission indicated that some assessments would be completed by July 2017, and in circumstances where additional information would be required these processes may continue to be used in the interim.

Mycotoxins

29. At the April meeting, the Commission updated Member States on the upcoming EFSA Opinion on the mycotoxin, deoxynivalenol (DON) and its modified forms. The Commission indicated that publication of this +500 page report is now expected late May or early June; anticipating that follow-up work may be required on issues of adverse animal health effects. This follows the 2016 EFSA Opinion[4] on zearalenone (ZEN, formerly referred as ZON), where specific modified forms may be sixty times more potent than ZEN itself.

[4] EFSA Opinion No.4425 (2016). Appropriateness to set a group health-based guidance value for zearalenone and its modified forms. (http://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2016.4425/epdf)

European Food Safety Authority (EFSA)

30. Between January and April 2017, the EFSA FEEDAP Panel[5] published 29 scientific opinions to assess feed additive applications for authorisation and re-authorisation.
(https://www.efsa.europa.eu/en/science/feed-materials)

31. Of particular note:

- Safety of l-tryptophan technically pure, produced by *Escherichia coli* CGMCC 3667, for all animal species.
(http://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2017.4705/epdf)

- Safety and efficacy of iron dextran as a feed additive for piglets.
(http://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2017.4701/epdf)

- Safety of cassia gum as a feed additive for dogs and cats.
(http://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2017.4710/epdf)

- The CONTAM Panel[6] of EFSA provides scientific advice concerning the presence of contaminants in both feed and food.
(http://www.efsa.europa.eu/en/panels/contam)

- The CONTAM Panel's advice and summary of the recent 83rd Plenary meeting, Parma (14 March 2017) can be viewed on:
(http://www.efsa.europa.eu/en/events/event/170314)

32. Forthcoming agendas of FEEDAP and CONTAM Panels (amongst others) may be viewed on:
(http://www.efsa.europa.eu/en/events/advanced-search)

[5] FEEDAP - Panel on Additives and Products or Substances used in Animal Feed
[6] The Panel on Contaminants in the Food Chain

Update on EU proposal on medicated feed

33. We have no further progress to report on the revision of the Medicated Feed legislation as there have not been any additional Council Working Group meetings since we last provided an update in February 2017. There are no meetings scheduled in the near future.

Scheduled SCoPAFF meetings for 2017:

- 23-24 May
- 17-19 July
- 11-13 September
- 8-10 November
- 18-20 December

ACAF Secretariat

May 2017

ANNEX – SCoPAFF VOTES AND FEED ADDITIVE AUTHORISATIONS

Animal Nutrition votes:

February 2017

Additive	**Authorisation type**	**Proposal number**
Nutritional Additive: L-lysine sulphate produced by *Escherichia coli*	New authorisation	SANTE_11862_2015
Technological Additive: Preparation of *Lactobacillus fermentum* NCIMB 41636, *Lactobacillus plantarum* NCIMB 41638 and *Lactobacillus rhamnosus* NCIMB 41640	New authorisation	SANTE_10210_2016
Zootechnical Additive: Preparation of thyme oil, synthetic star anise oil and quillaja powder	New authorisation	SANTE_11131_2016
Zootechnical Additive: Preparation of endo-1,3(4)-beta-glucanase produced by *Aspergillus aculeatinus* (formerly classified as *A. aculeatus)* (CBS 589.94), endo-1,4-beta-glucanase produced by *Trichoderma reesei* (formerly classified as *T. longibrachiatum)* (CBS 592.94), alpha-amylase produced by *Bacillus amyloliquefaciens* (DSM 9553) and endo-1,4-beta-xylanase produced by *Trichoderma viride* (NIBH FERM BP4842)	*New/ Re-authorisation	SANTE_10886_2016
Zootechnical Additive: Preparation of *Bacillus amylo-liquefaciens* PTA-6507, *Bacillus amylo-liquefaciens* NRRL B-50013 and *Bacillus amyloliquefaciens* NRRL B-50104	New authorisation	SANTE_11132_2016

Zootechnical Additive: Preparation of *Bacillus subtilis* DSM 5750 & *Bacillus licheniformis* DSM 5749	*New/ Re-authorisation	SANTE_10484_2016
Other legislation: Change of name of the holder of authorisation of potassium diformate	Amending Regulation	SANTE_11913_2016

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

No meeting held in <u>March 2017.</u>

<u>April 2017</u>

Additive	**Authorisation type**	**Proposal number**
Zootechnical Additive: *Pediococcus acidilactici* CNCM MA 18/5M	*New/ Re-authorisation	SANTE_10889_2016
Zootechnical Additive: 3-phytase produced by *Komagataella pastoris* (CECT 13094)	New authorisation	SANTE_11950_2016
Zootechnical Additive: 6-phytase produced by *Trichoderma reesei* (ATCC SD-6528)	*New/ Re-authorisation	SANTE_11949_2016
Zootechnical Additive: Preparation of fumonisin esterase produced by *Komagataella pastoris* DSM 26643	New authorisation	SANTE_11948_2016
Technological Additive: Preparation of *Lactobacillus plantarum* DSM 29024	New authorisation	SANTE_10061_2017
Zootechnical Additive: Preparation of a micro-organism strain DSM	New authorisation	SANTE_10062_2017

11798 of the *Coriobacteriaceae* family		
Technological Additive: Formic acid	New authorisation	SANTE_10087_2017
Zootechnical Additive: Preparation of endo-1,4-beta-xylanase produced by *Aspergillus niger* (CBS 109.713) and endo-1,4-beta-glucanase produced by *Aspergillus niger* (DSM 18404)	Modification to authorisation	SANTE_11951_2017
Zootechnical Additive: Preparation of endo-1,3(4)-beta-glucanase produced by *Aspergillus aculeatinus* (formerly classified as *Aspergillus aculeatus*) (CBS 589.94), endo-1,4-beta-glucanase produced by *Trichoderma reesei* (formerly classified as *Trichoderma longibrachiatum*) (CBS 592.94), alpha-amylase produced by *Bacillus amyloliquefaciens* (DSM 9553), endo-1,4-beta-xylanase produced by *Trichoderma viride* (NIBH FERM BP4842) and bacillolysin produced by *Bacillus amyloliquefaciens* (DSM 9554)	*New/ Re-authorisation	SANTE_10078_2017
Zootechnical Additive: Preparation of endo- 1,4-beta-xylanase, produced by *Aspergillus oryzae* (DSM 10278)	Modification to authorisation	SANTE_11810_2016
Zootechnical Additive: Preparation of *Enterococcus faecium* CECT 4515	*New/ Re-authorisation	SANTE_11180_2015
Technological Additive: Lecithins	Re-authorisation	SANTE_11482_2016
Zootechnical Additive: Preparation of *Lactococcus lactis* B/00039, *Carnobacterium divergens* KKP 2012p, *Lactobacillus casei* B/00080, *Lactobacillus plantarum* B/00081 and *Saccharomyces cerevisiae* KKP 2059p	New authorisation	SANTE_11780_2016

Other legislation: On the withdrawal from the market of certain feed additives authorised pursuant to Council Directives 70/524/EEC and 82/471/EEC and repealing the obsolete provisions authorising those feed additives	Amending Regulation	SANTE_10894_2016
Technological Additive: Ethoxyquin	Re-authorisation	SANTE_11308_2016
Nutritional Additive: L-tryptophan produced by *Escherichia coli*	Re-authorisation	SANTE_11863_2015

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

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May 2017