

ADVISORY COMMITTEE ON ANIMAL FEEDINGSTUFFS

71st Meeting of ACAF on 27 October 2016

Information Paper

EU and other Developments

**Secretariat
October 2016**

EU AND OTHER DEVELOPMENTS

Standing Committee on Plants, Animals, Food and Feed (SCoPAFF): Animal Nutrition and Veterinary Medicines (ANVM) Section (May to September 2016)

In July 2016, the European Commission launched its open consultation process (http://ec.europa.eu/yourvoice/consultations/index_en.htm) to allow public access and feedback comments on draft Regulations. At the September 2016, meeting delegates were informed that this consultation process would not generally apply to SCoPAFF-ANVM agenda items.

Feed additive authorisations

1. Standing Committee meetings were held in May, June and September 2016 where twenty one feed additive authorisations were voted for in favour, as summarised in the Annex. The July meeting was cancelled.

Formaldehyde

2. Discussions continued at each meeting for formaldehyde under urgent authorisation for a duration of three years. The UK has reiterated that the use of formaldehyde as a feed additive only constitutes on average 0.2-0.3% total use across all business sectors at Member State level. However, whilst only a small shortfall to achieve a qualified majority vote remains, an impasse has been reached. At the September meeting, the Commission sought indications for a denial of authorisation, which was met with little objection by most Member States. Review by the Appeals Committee is a last resort option for the Commission. We will continue to keep the Committee updated on developments.

Ethoxyquin

3. At the September meeting, ethoxyquin was discussed for the first time since April 2016. A draft Regulation was presented for the partial suspension on the use of ethoxyquin, outlining the proposed feedstuffs where this feed additive may continue to be used, along with proposed transitional periods. This draft document defined permitted uses of ethoxyquin; for feed additives (Vitamins A, D, E 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). A request was made to consider additional marine feed materials (i.e. algal and seaweed meals). EFSA¹ recently returned a favourable opinion on the completed genotoxic studies, whilst numerous discreet research packages remain to be completed over coming years as defined in the consortium research roadmap. Concerns were raised by UK over the

¹ European Food Safety Authority

withdrawal of authorisation of the antioxidant; TBHQ², and the delay on EFSA assessments of potential substitute compounds. We will update the Committee on the outcomes of future discussions.

Trace elements

4. At the May meeting, the draft Regulation for zinc compounds as trace element sources achieved a qualified majority vote, incorporating the previously discussed reductions in maximum permitted levels (MPLs), although not to the EFSA proposed recommended levels.
5. Other trace element sources have been introduced into the agendas over recent months: including manganese, iron and copper, although no detailed discussions have taken place to date. Of particular note, the recent EFSA Opinion (No. 4563, Aug 2016) on the 'Revision of the currently authorised maximum copper content in complete feed', recommended a reduction of copper in piglets up to 12 weeks; from 170 to 25mg/kg feed based upon nutritional requirements. EFSA also recommended a lesser reduction in copper intake for bovines from 35 to 30 mg/kg feed. The Commission conveyed that strong negative views had been received from industry concerning these recommendations. Discussion on copper MPLs is anticipated at the October 2016 meeting, and we will continue to keep the Committee updated on progress.

Other feed additives

6. A number of feed additive applications have been discussed throughout recent meetings for natural soils/clays as binders or anticaking agents. Such additives have proved challenging for the Committee to assess, due to their naturally high iron content; albeit deemed as being non-bioavailable. Bioavailability is becoming an increased focus across feed additive authorisations more generally (e.g. ferric oxide); with little clarity to date how best to proceed, especially as the total trace element content cannot be differentiated by their analytical composition.
7. At the June meeting, an application for dry grape extract as a feed additive was introduced for discussion, being the first of some three hundred botanicals scheduled for re-authorisation. At the September meeting, the Commission proposed a common approach to the classification of these botanicals, by adopting a system based on the Council of Europe identification system.
8. At the May meeting, the Commission outlined that some two hundred feed additives fall within Annex II of Regulation (EC) 1831/2003 being subject to formal market withdrawal. In subsequent meetings, a number of corrections have been submitted by Member States and industry which are being incorporated into a revised Annex. A general consensus

² tertiary butylhydroquinone

by the Committee established short transition periods of between 3 and 6 months.

Amendments to Regulation 429/2008

9. At the September meeting, Commission presented Annex revisions to Regulation (EU) 429/2008 on the preparation of feed additive applications, since it was last discussed as a Working Group within the February meeting. Member States have been requested to provide comments on this draft, which Commission requested not to be circulated at this early stage. Commission indicated a further Working Group may be arranged to progress these revisions.

Amendments to Regulation 767/2009

10. Discussions have been held at all recent meetings regarding Annexes IV, VI & VII of Regulation No.767/2009 concerning labelling criteria for feedstuffs. At the May and June meetings, discussions were held on defining units to be declared for different additive sources (e.g. by weight or cfu for micro-organisms) and for shelf-life declarations. Over the last three meetings, discussions on Annex IV regarding analytical tolerances included proposed amendments to tolerance levels based on a Member State submission of evidence. Comments on this analytical evidence were requested at the September meeting.

List of intended uses as particular nutritional purposes (PARNUTS)

11. Little progress has been made on the list of intended uses as particular nutritional purposes (PARNUTS). At the June meeting, the Commission provided a summary of a single new application submitted for evaluation, concerning brain function (concerning epilepsy) in dogs.

Unauthorised additives intended for export

12. Since initial discussions at the March meeting on non-authorised additives intended for export, the Commission presented its first draft Regulation in September, for Member States to feedback comments. The objective of this Regulation is to harmonise national controls in notification and monitoring procedures for unauthorised feed additives or feeds intended for third countries, when passing through EU territories.

Functional groups

13. At the June meeting, the Commission introduced a revised list of new functional groups of feed additives which include for use via drinking water. Commission made the distinction between protecting water quality (here as a feed additive) and the preservative function as a disinfectant under the Biocides Regulation (EC) No.528/2012. At the September meeting, Commission conveyed that industry had indicated that certain proposed functional groups are unlikely to be relevant (i.e. gelling agents or stabilisers in water) so will not be progressed in future revisions.

Feed hygiene

14. At the June meeting, Commission presented a discussion document outlining proposed registration requirements within Regulation (EC) 1831/2003 laying down requirements for feed hygiene, where Member States provided comments. At the September meeting, this draft guidance document was presented incorporating this feedback, with further Member State comments sought before the October 2016 meeting.
15. Following discussions at the June meeting, the Commission presented a working document at the September meeting, on guidelines for the use of former foodstuffs as feed. This document outlined the current legal framework of food-feed waste in context of the Waste Framework Directive, by-products in waste, animal by-products and catering waste regulations. The guidance also provides examples of barriers to trade and recommendations to both industry and competent authorities. Member States were requested to provide additional comments of this early draft.
16. A number of documents continue to be progressed, these include:
 - a. minor amendments to the third amendment of the EU catalogue of animal feed,
 - b. the FEDIAF Code of Good labelling practices for pet food which has been deferred for discussion since May, when comments were last requested.

Undesirable substances in feed

17. At the May meeting, Commission highlighted that five RASFF³ notifications had been raised since the last meeting. The list identified two UK RASFF notifications; 1) high iron content in catfood, and 2) aflatoxin B1 in peanuts from Brazil. At the June meeting, a further sixteen notifications were raised, and fourteen new notifications raised at the September meeting. The Commission did highlight the frequency of notifications concerning ragweed (*Ambrosia* spp.). None of the notifications in June or September were raised by the UK.
18. At the May meeting, the UK requested an indicative timeline for the draft Regulation on nitrites and nitrates in feed; following significant time slippage, this may be presented prior to the end of the year.
19. At the May meeting, the Commission referred to an EFSA Opinion (No. 4425, 2016) which identified modified forms of zearalenone which may be sixty times more potent than zearalenone itself. Consequently, these

³ Rapid Alert System for Food and Feed

modified forms may pose a greater risk to food/feed chains and public health. At the September meeting, Commission informed the Committee of an EFSA survey on these modified forms in food and feed which is scheduled for completion by mid-2018, along with the development for analytical methodologies.

20. At the June meeting, the Commission announced upcoming publications for July in the OJEU⁴ for nickel in feed and a mycotoxin guideline in petfood.

European Food Safety Authority (EFSA)

21. Between 1 May and 12 September 2016, EFSA's FEEDAP Panel⁵ published 33 scientific opinions to assess feed additive applications for authorisation and re-authorisation.

(<http://www.efsa.europa.eu/en/feedap/feedapscdocs>)

22. Of particular note:

- Revision of the currently authorised maximum copper content in complete feed. EFSA Journal 2016;14(8):4563.

(<http://www.efsa.europa.eu/en/efsajournal/pub/4563>)

- Safety and efficacy of iron compounds (E1) as feed additives for all species (including ferric oxide). EFSA Journal 2016;14(6):4508.

(<http://www.efsa.europa.eu/en/efsajournal/pub/4508>)

- Safety and efficacy of manganese hydroxychloride as feed additive for all animal species. EFSA Journal 2016;14(5):4474.

(<http://www.efsa.europa.eu/en/efsajournal/pub/4474>)

- EFSA Info session on Applications – Feed Additives – Technical meeting with Stakeholders, Brussels (14-15 July 2016): EFSA met with stakeholders to exchange views on scientific issues related to the preparation and the risk assessment of applications for market authorisation of feed additives, as per Regulation (EU) 429/2008.

(<http://www.efsa.europa.eu/en/events/event/160714>)

23. The CONTAM Panel⁶ of EFSA provides scientific advice concerning the presence of contaminants in both feed and food. The Panel's advice and summary of the recent 79th Plenary meeting, Parma (12 July 2016) can be viewed on:

⁴ Official Journal of the European Union

⁵ FEEDAP - Panel on Additives and Products or Substances used in Animal Feed

⁶ The Panel on Contaminants in the Food Chain

<http://www.efsa.europa.eu/en/panels/contam>)

24. Forthcoming agendas of FEEDAP and CONTAM Panels (amongst others) may be viewed on:

<http://www.efsa.europa.eu/en/events/advanced-search>)

Future SCoPAFF meetings

- 13-14 October 2016
- 3-4 November 2016 (tentatively cancelled)
- 15-16 December 2016

Update on EU proposal on medicated feed

25. Unfortunately 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. The proposal has been put on ice whilst negotiations on the Veterinary Medicines proposal catch up (estimated to be another 6 to 12 months).

26. However, in late June, the Veterinary Medicines Directorate did hold a second series of stakeholder workshops to give an update on how the proposals were progressing; copies of the presentations given and summaries of the ensuing discussions are available on request by emailing Lorna Shelley at l.shelley@vmd.defra.gsi.gov.uk.

**ACAF Secretariat
October 2016**

ANNEX – SCoPAFF FEED ADDITIVE AUTHORISATIONS

Feed additive votes:

May 2016

Additive	Authorisation type	Proposal number
Zootechnical Additive: Preparation of endo-1,4- beta-xylanase & endo-1,3(4)-beta-glucanase produced by <i>Trichoderma reesei</i>	New	SANTE_10211_2016
Zootechnical Additive: Ammonium chloride	New	SANTE_10208_2016
Nutritional Additive: [Zinc compounds]: Zinc acetate dihydrate, Zinc chloride anhydrous, Zinc oxide, Zinc sulphate heptahydrate, Zinc sulphate monohydrate, Zinc chelate of amino acids hydrate, Zinc chelate of protein hydrolysates, Zinc chelate of glycine hydrate (solid) and Zinc chelate of glycine hydrate (liquid)	Re-authorisation /new*	SANTE_12194_2015
Nutritional Additive: Zinc bislysinate	New	SANTE_12192_2015
Nutritional Additive: L-Arginine produced by <i>Corynebacterium glutamicum</i>	New	SANTE_12190_2015
Sensory Additive: [Chemically defined flavourings Gp1] butan-1-ol, hexan-1-ol, octan-1-ol, nonan-1-ol, dodecan-1-ol, heptan-1-ol, decan-1-ol, pentan-1-ol, ethanol, acetaldehyde, propanal, butanal, pentanal, hexanal, octanal, decanal, dodecanal, nonanal, heptanal, undecanal, 1,1-diethoxyethane, formic acid, acetic acid, propionic acid, valeric acid, hexanoic acid, octanoic acid, decanoic acid, dodecanoic acid, oleic acid, hexadecanoic acid, tetradecanoic acid, heptanoic acid, nonanoic acid, ethyl acetate, propyl acetate, butyl acetate, hexyl acetate, octyl acetate, nonyl acetate, decyl acetate, dodecyl acetate, heptyl acetate, methyl acetate, methyl butyrate, butyl butyrate, pentyl butyrate, hexyl butyrate, octyl butyrate, ethyl decanoate, ethyl hexanoate, propyl hexanoate, pentyl hexanoate, hexyl hexanoate, methyl hexanoate, ethyl formate, ethyl dodecanoate, ethyl tetradecanoate, ethyl nonanoate, ethyl octanoate, ethyl propionate, methyl propionate, ethyl valerate, butyl valerate, ethyl hex-3-enoate, ethyl hexadecanoate, ethyl trans-2-butenoate, ethyl undecanoate, butyl isovalerate, hexyl isobutyrate, methyl 2-methylbutyrate, hexyl 2-methylbutyrate, triethyl citrate, hexyl isovalerate and methyl 2-methylvalerate	Re-authorisation	SANTE_12049_2015

<p>Sensory Additive: [Chemically defined flavourings Group 2] 2-methylpropan-1-ol, isopentanol, 3,7-dimethyloctan-1-ol, 2-ethylhexan-1-ol, 2-methylpropanal, 3-methylbutanal, 2-methylbutyraldehyde, 3-methylbutyric acid, 2-methylvaleric acid, 2-ethylbutyric acid, 2-methylbutyric acid, 2-methylheptanoic acid, 4-methylnonanoic acid, 4-methyloctanoic acid, isobutyl acetate, isobutyl butyrate, 3-methylbutyl hexanoate, 3-methylbutyl dodecanoate, 3-methylbutyl octanoate, 3-methylbutyl propionate, 3-methylbutyl formate, glyceryl tributyrate, isobutyl isobutyrate, isopentyl isobutyrate, isobutyl isovalerate, isopentyl 2-methylbutyrate, 2-methylbutyl isovalerate and 2-methylbutyl butyrate</p>	Re-authorisation	SANTE_10017_2016
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* Re-authorisation of existing application (1831/2003 Article 10(2)) with co-application for additional scope (Article 10(7))

June 2016

Additive	Authorisation type	Proposal number
<p>Nutritional Additive: L-threonine produced by <i>E.coli</i></p>	Re-authorisation	SANTE_12000_2014
<p>Sensory Additive: [Chemical defined flavourings Group 5] octan-2-ol, isopropanol, pentan-2-ol, octan-3-ol, heptan-2-one, pentan-2-one, 6-methyl- hepta- 3,5-dien- 2- one, nonan- 3- one, decan- 2 -one, isopropyl tetradecanoate</p>	Re-authorisation	SANTE_10376_2016
<p>Sensory Additive: [Chemical defined flavourings Group 6] alpha-terpineol, nerolidol, 2-(4-methylphenyl)propan-2-ol, terpineol, and linalyl acetate</p>	Re-authorisation	SANTE_10018_2016
<p>Sensory Additive: [Chemical defined flavourings Group 30] glycyrrhizic acid, ammoniated</p>	Re-authorisation	SANTE_10377_2016
<p>Sensory Additive: [Chemical defined flavourings Group 31] 1-isopropyl- 4- methylbenzene, pin-2(10)-ene, pin-2(3)-ene, beta-caryophyllene, camphene, 1-isopropenyl-4- methylbenzene, delta-3- carene, d-limonene</p>	Re-authorisation	SANTE_10378_2016

July 2016 - meeting cancelled

September 2016

Additive	Authorisation type	Proposal number
Zootechnical Additive: 6-phytase produced by <i>Aspergillus oryzae</i> (DSM 22594)	Modification to authorisation	SANTE_10420_2016
Zootechnical Additive: A preparation of kidney bean (<i>Phaseolus vulgaris</i>) lectins	New authorisation	SANTE_10874_2016
Nutritional Additive: Guanidinoacetic acid	Modification to authorisation	SANTE_12191_2015
Sensory Additive: [Chemical defined flavourings Group 9] lactic acid, 4-oxovaleric acid, succinic acid, fumaric acid, ethyl acetoacetate, ethyl lactate, butyl lactate, ethyl 4-oxovalerate, diethyl succinate, diethyl malonate, butyl-O-butyrylacetate, hex-3-enyl lactate, hexyl lactate, butyrolactone, decano-1,5-lactone, undecano-1,5-lactone, pentano-1,4-lactone, nonano-1,5-lactone, octano-1,5-lactone, heptano-1,4-lactone and hexano-1,4-lactone	Re-authorisation	SANTE_10183_2016
Sensory Additive: [Chemical defined flavourings Group 18] 4-allyl-2,6-dimethoxyphenol and eugenyl acetate	Re-authorisation	SANTE_10672_2016
Sensory Additive: [Chemical defined flavourings Group 20] 3-(methylthio) propionaldehyde, methyl 3-(methylthio) propionate, allylthiol, dimethyl sulphide, dibutyl sulphide, diallyl disulphide, diallyl trisulfide, dimethyl trisulfide, dipropyl disulphide, allyl isothiocyanate, dimethyl disulphide, 2-methylbenzene-1-thiol, S-methyl butanethioate, allyl methyl disulphide, 3-(methylthio) propan-1-ol, 3-(methylthio) hexan-1-ol, 1-propane-1-thiol, diallyl sulphide, 2,4-dithiapentane, 2-methyl-2-(methylthio) propanal, 2-methylpropane-1-thiol, methylsulfanyl methane, propane-2-thiol, 3,5-dimethyl-1,2,4-trithiolane and 2-methyl-4-propyl-1,3-oxathiane.	Re-authorisation	SANTE_10185_2016
Sensory Additive: [Chemical defined flavourings Group 23] benzyl alcohol, 4-isopropylbenzyl alcohol, benzaldehyde, 4-isopropylbenzaldehyde, salicylaldehyde, p-tolualdehyde, 2-methoxybenzaldehyde, benzoic acid, benzyl acetate, benzyl butyrate, benzyl formate, benzyl propionate, benzyl hexanoate, benzyl isobutyrate, benzyl isovalerate, hexyl salicylate, benzyl phenylacetate, methyl benzoate, ethyl benzoate, isopentyl benzoate, pentyl salicylate and isobutyl benzoate as feed additives for all animal species and of	Re-authorisation	SANTE_10186_2016

veratraldehyde and gallic acid.		
Sensory Additive: Tannic acid	Re-authorisation	SANTE_10386_2016
Sensory Additive: Glycyrrhizic acid ammoniated	Re-authorisation	SANTE_10376_2016

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