

**ADVISORY COMMITTEE ON ANIMAL FEEDINGSTUFFS**

**72nd Meeting of ACAF on 23 February 2017**

**Information Paper**

**EU and other Developments**

**Secretariat  
February 2017**

## EU AND OTHER DEVELOPMENTS

### Update on EU proposal on medicated feed:

1. 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 2016. There is the possibility of a meeting taking place in the next couple of months however that depends on the progress of the Veterinary Medicines proposal.

### Standing Committee on Plants, Animals, Food and Feed (SCoPAFF): Animal Nutrition and Veterinary Medicines (ANVM) Section (October 2016 to January 2017)

2. No meeting was scheduled for January 2017; with meetings generally moving to alternate months and extending to a three-day duration as from April 2017. In January 2017, the Head of Unit, Stefano Soro was replaced in a direct exchange with Christian Siebert, Head of Unit of Biotechnology and Food Supply Chain (Unit D3, DG GROW).

### Feed additive authorisations

3. Standing Committee meetings were held in October, November and December 2016 where thirteen feed additive authorisations (and six other legislative tools) were voted in favour, as summarised in the Annex. Of particular note, are:

#### Formaldehyde

4. Little discussion was held on formaldehyde in the last quarter of 2016. At the October meeting, an indication was sought by Commission to consider a denial of authorisation (i.e. prohibition of use). A variety of views were expressed by Member States, with a shortfall in achieving a qualified majority vote (QMV) as per the current situation in progressing an authorisation. At the December meeting, Commission announced that a regulation for the denial of authorisation would be drafted with no future opportunity to pursue an authorisation. The UK reiterated the minor use of formaldehyde as a feed additive and emphasized the stringent safety requirements proposed for workers in the feed. We will continue to keep the Committee updated on developments.

#### Ethoxyquin

5. At meetings since September, Commission has presented revised versions of the regulation for the partial suspension of ethoxyquin with amendments largely to satisfy legal requirements. This draft document

maintains the 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). At the October meeting, revisions focused on transitional periods; whilst in November, revisions expanded the rationale for the remaining continued use of ethoxyquin. At the December meeting, Commission outlined indicative timelines. Whilst the Regulation is anticipated to be finalised at the meeting in February 2017; there is a requirement to notify the World Trade Organisation, followed by a 60 day consultation through the sanitary and phytosanitary (SPS) notification process, due to potential impacts on global trade. We will update the Committee on the outcomes of future discussions.

#### Trace elements

6. Commission is now undertaking a review of maximum permitted limits (MPLs) for copper (Cu) compounds in feed. This follows publication of the EFSA Opinion (2016)<sup>1</sup> which recommended a reduction from 170 mg to 25 mg 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. Of increasing importance, EFSA also expressed concern relating to antimicrobial resistance, describing that copper is reported to lead to antibiotic co-resistance (i.e. to erythromycin) at 125-250mg/kg Cu, although a direct link to (pig) farm soils has not been demonstrated to date. Commission contextualised the EFSA conclusions as being weighted towards nutritional requirements and environmental impacts, rather than cumulative beneficial effects from copper relating to animal health and growth performance. At the December meeting, Member States expressed diverse views from maintaining current limits (e.g. UK) through to adoption of EFSA recommended reductions. Commission also highlighted that strong opinions had been received from industry regarding opposition to such significant reductions in copper MPLs for piglets. We will keep the Committee updated on developments regarding this important issue.
7. Since the amendment on reducing MPLs for zinc as a feed additive in July 2016, a further development to significantly impact the pig sector is the proposed withdrawal of zinc oxide within veterinary medicine products (VMPs). This preliminary decision was agreed by the European Medicines Agency’s (EMA) Committee for Medicinal Products for Veterinary Use (CVMP). The conclusion reached was that the benefit:risk balance of VMPs containing zinc was outweighed by negative environmental impacts; including the potential for antimicrobial

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<sup>1</sup> 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>)

co-selection; albeit an unquantifiable risk. Additional information may be obtained from the Veterinary Medicines Directorate (VMD) website.<sup>2</sup>

8. Trace element sources containing manganese or iron are also awaiting reauthorisation, although no detailed discussions have taken place to date.

#### Other feed additives

9. Numerous feed additive applications have been progressed throughout recent meetings as routine. Of particular note was during the October meeting, discussions were held on dry grape extract; the first of some 300 botanicals awaiting re-authorization. Discussions focused on developing a suitable nomenclature based upon the Council of Europe Identification system. The authorisation for dry grape extract was then voted in favour at the November meeting. Discussions and voting procedures also continue for the clusters of feed flavouring compounds (as per Annex).
10. Commission continues to progress the market withdrawal of some two hundred feed additives listed within Annex II of Regulation (EC) 1831/2003. This list includes the withdrawal of sodium selenate; an important trace element for the UK (regarding human population deficiencies) and where the UK has requested consideration for its reauthorisation. At the September meeting, Commission stated that those additives which are now deemed as being feed materials will be uncoupled from this withdrawal process and progressed separately due to legal complexities. In addition, feed additives with a temporary expired authorisation would not have transition periods applied; whilst for other feed additives, short transition periods were proposed for 3 months on the market and three months to exhaust existing stocks. This Regulation is anticipated to be voted on by the April meeting at the latest.

#### Amendments to Regulation 429/2008 on feed additive applications

11. Little progress has been made on Annex revisions to Regulation (EU) No.429/2008 on the preparation of feed additive applications. In November, a separate EFSA/industry technical meeting was held, although no outputs have been circulated to date. At the November Standing Committee, the Commission proposed amendments to species/subspecies classification; whilst at the December meeting, Member States were requested to feedback on proposed amendments to trial requirements relating to feed additive efficacy.

#### Amendments to Regulation 767/2009 on marketing feed

12. Since October, discussions on the Annexes of Regulation No.767/2009 have predominantly focused on Annex IV regarding analytical tolerances. These discussions were initiated by a Member State data submission to broaden tolerance margins for fibre, ash, protein and starch. In a

<sup>2</sup> VMD News story: Veterinary medicines containing zinc oxide: European referral outcome.

<https://www.gov.uk/government/news/veterinary-medicines-containing-zinc-oxide-european-referral-outcome>

iterative process; including inputs from Member States and FEDIAF (The European Pet Food Industry Federation) established tolerance levels have been agreed. It is expected that this regulation amendment will be presented for vote by April 2017.

#### Feed additive functional groups

13. At the October meeting, Commission presented a simplified list of new functional groups of feed additives; under Regulation (EC) No.1831/2003, which includes for use via drinking water. New entries include a classification for 'other technological additives' and a new zootechnical category to accommodate additives which favourably affect animal welfare and performance. This latter category remains subject to severe criticism by some Member States, as does the potential for preservatives to be used to maintain the quality of water as debated at the November and December meetings.

#### Unauthorised additives intended for export

14. At the October meeting, the Commission outlined progression as a Regulation in order to maintain tight controls, rather than as a guidance document (as UK preference). Significant discussion was held at the November meeting, where earlier text inferred a requirement for separate production lines be used for unauthorised additives; this was redrafted to convey a responsibility to ensure minimisation of cross-contamination. Parallel discussions were held regarding criteria for transport, storage and labelling requirements of these unauthorised additives during export. At the December meeting, discussions focused on the use of the TRACES system between Member States as an appropriate communication channel for export notification of unauthorised feed additives.

#### PARNUTS

15. Slow progress has been made on the list of intended uses as particular nutritional purposes (PARNUTS) over recent months. No new applications were received in the last quarter of 2016, whilst initial evaluations were received on five applications. Of note, the existing entry for the 'reduction of stress reactions' in equines (No.59) received an unfavourable assessment and recommended removal as a PARNUT, whilst additional information was requested for two other applications.

### **Feed hygiene**

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

16. In relation to Regulation (EC) No.183/2005, at the October meeting Commission outlined a proposal to develop a dedicated database repository for national feed guides. Discussions at the November and December meetings finalised database information criteria and has been submitted for IT development.

17. In addition, under Regulation (EC) No.183/2005, the Commission has made progress on a guidance document concerning the implementation of feed hygiene requirements. At all meetings, general Member State views have been expressed throughout this broad-based document with divergent views as to how useful this document will ultimately prove.

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

18. Over the last quarter of 2016, discussions on Regulation (EC) No. 767/2009 has largely focused on agreement of proposed analytical tolerances within Annex IV. In parallel, minor revisions have been made to finalise Annexes VI and VII on labelling requirements for feed. It is anticipated that a final Regulation amendment will be presented for vote by the April meeting at the latest.

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

19. Final discussions were held on the third amendment to the Catalogue, which was presented for vote at the December meeting, gaining QMV in favour.

Insects as an animal feed

20. At the October meeting, Commission presented an overview of the recently (EC) endorsed concept strategy paper for the use of insects for animal feed; detailing aspects of production, processing, contaminant control and animal feed applications.
21. A number of documents receiving minor discussion included:
- a. the guidelines for the use of former foodstuffs as feed.
  - b. the FEDIAF Code of Good labelling practices for pet food.
  - c. The EU Guide to good practice for the industrial manufacture of safe feed materials for the oleochemical sector.

## **Undesirable substances in feed**

RASFF notifications

22. Between September and December 2016, twenty-one new RASFF notifications were raised. Within this period (in September), the UK raised one non-serious RASFF concerning an exceedance of dioxins in green tea fannings from China (via Germany). Other Member State notifications over this period included dioxins in compound feed raw materials sourced from India (exposed to electrical capacitors); and an Aflatoxin B1 contamination in maize from Brazil, distributed widely across Italian regions.

Directive 2002/32/EC on undesirable substances

23. Over the last quarter of 2016, general discussions were held regarding the amendment/inclusion of entries for the undesirable substances: melamine, dioxins and PCBs, arsenic in peat, arsenic in leonardite (a fossilized organic material), gossypol, mercury, lead in dicopper oxide and removal of the entry for nitrites.
24. At the October meeting, Commission finally presented a skeleton framework for nitrites and nitrate levels in feed; including proposed guidance levels, as a basis to develop a Commission Regulation.

Regulation (EC) No.396/2005 on pesticide residues

25. Over recent months, there has been ambiguity as to how maximum residue limits (MRLs) are applied, with a number of situations where paraquat has been detected in consignments of soya. At the December meeting, Commission provided a summary of three proposed classifications for MRLs in food and feed commodities. Type A commodities are processed exclusively as feedstuffs, and where the exemption of MRLs currently apply in regard of footnote (1) of the Regulation. Type B comprise raw commodities which may be processed into either food or feedstuffs, and where current food MRLs apply. Thirdly, Type C commodities are those processed for feed, but part of the product may subsequently re-enter the foodchain; soy sauce for example is processed in this manner.

Erucic acid

26. At the November meeting, the Commission provided an overview of the recent Opinion on Erucic acid in feed and food (EFSA No. 4593, 2016) indicating concern for certain food sources (especially mustard and rape-seeds and oils) and with slight concern for poultry via feedstuffs.

## **European Food Safety Authority (EFSA)**

27. Between October and December 2016, EFSA's FEEDAP Panel<sup>3</sup> published 15 scientific opinions to assess feed additive applications for authorisation and re-authorisation.  
(<https://www.efsa.europa.eu/en/science/feed-materials>)
28. Of particular note:  
Safety and efficacy of selenium-enriched yeast (*Saccharomyces cerevisiae* NCYC R397) for all animal species.  
(<https://www.efsa.europa.eu/en/efsajournal/pub/4624>)
29. Safety and efficacy of dry grape extract when used as flavouring in water for drinking for all animal species and categories  
(<https://www.efsa.europa.eu/en/efsajournal/pub/4627>)

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<sup>3</sup> FEEDAP - Panel on Additives and Products or Substances used in Animal Feed

30. The CONTAM Panel<sup>4</sup> of EFSA provides scientific advice concerning the presence of contaminants in both feed and food.  
(<http://www.efsa.europa.eu/en/panels/contam>)

31. Of particular note:  
Erucic acid in feed and food.  
(<http://www.efsa.europa.eu/en/efsajournal/pub/4593>)

32. The Panel's advice and summary of the recent 81<sup>st</sup> Plenary meeting, Parma (22 November 2016) can be viewed on:  
(<http://www.efsa.europa.eu/en/panels/contam>)

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

#### **34. Scheduled SCoPAFF meetings for 2017**

- 9-10 February
- 24-26 April
- 23-24 May
- 17-19 July
- 11-13 September
- 8-10 November
- 18-20 December

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<sup>4</sup> The Panel on Contaminants in the Food Chain



## ANNEX – SCoPAFF FEED ADDITIVE AUTHORISATIONS

## Animal Nutrition votes:

## October 2016

Additive	Authorisation type	Proposal number
<b>Technological Additive:</b> Preparations of sodium benzoate, potassium sorbate, formic acid and sodium formate	*New/ Re- authorisation	SANTE_11175_2015
<b>Technological Additive:</b> Preparation of dolomite-magnesite and a preparation of montmorillonite-illite	New authorisation	SANTE_10212_2016
<b>Sensory Additive:</b> [Flavourings group 11-16] 1,8-cineole, 3,4-dihydrocoumarin and 2-(2-methyl prop-1-enyl)-4-methyl-tetra-hydropyran	Re-authorisation	SANTE_10184_2016
<b>Sensory Additive:</b> [Flavourings group 15] 1,1-dimethoxy-2-phenylethane, phenethyl formate, phenethyl octanoate, phenethyl iso-butyrate, phenethyl 2-methyl-butyrate and phenethyl benzoate	Re-authorisation	SANTE_10667_2016
<b>Other legislation:</b> Commission Regulation correcting the Latvian language version of Regulation (EC) No 152/2009 for methods of sampling and analysis for the official control of feed.	Correcting Act	DGT - 1543230
<b>Other legislation:</b> The determination of the levels of dioxins and polychlorinated biphenyls.	Amending Regulation	SANTE_11249_2016

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

## November 2016

Additive	Authorisation type	Proposal number
<b>Other legislation:</b> Change of name holder of authorisation of <i>Pediococcus acidilactici</i> and <i>Saccharomyces cerevisiae</i>	Modification of authorisation	SANTE_11109_2016
<b>Other legislation:</b> Amendment to Regulation (EC) No 882/2004 for the determination of levels of dioxins and polychlorinated biphenyls	Amending Regulation	SANTE_11249_2016
<b>Sensory Additive:</b> isoeugenol	Re-authorisation	SANTE_10669_2016

<b>Sensory Additive:</b> Dry grape extract of <i>Vitis vinifera</i> spp. <i>vinifera</i>	Re-authorisation	SANTE_10860_2016
<b>Technological Additive:</b> Preparations of <i>Lactobacillus plantarum</i> (DSM 29025) and of <i>Lactobacillus plantaran</i> (NCIMB 42150)	New authorisation	SANTE_10888_2016
<b>Nutritional Additive:</b> copper(I) oxide	New authorisation	SANTE_11247_2016

## December 2016

Additive	Authorisation type	Proposal number
<b>Other legislation:</b> Change of name holder of authorisation of <i>Bacillus amyloliquefaciens</i> CECT 5940 and <i>Enterococcus faecium</i> CECT 4515	Administrative Regulation	SANTE_11532_2016
<b>Zootechnical Additive:</b> Preparation of <i>Bacillus subtilis</i> (DSM 29343)		SANTE_11130_2016
<b>Technological Additive:</b> Preparation of <i>Lactobacillus diolivorans</i> (DSM 32074)	New authorisation	SANTE_11481_2016
<b>Zootechnical Additive:</b> Preparation of endo-1,4-beta-xylanase and endo-1,3(4)-beta-glucanase produced by <i>Talaromyces versatilis</i> sp. nov. (IMI CC 378536) and <i>Talaromyces versatilis</i> sp. Nov (DSM 26702)	New authorisation	SANTE_11106_2016
<b>Zootechnical Additive:</b> Preparation of endo-1,4-beta xylanase (EC 3.2.1.8) produced by <i>Bacillus subtilis</i> (LMG-S 15136)	New authorisation	SANTE_11483_2016
<b>Zootechnical Additive:</b> Preparation of <i>Bacillus subtilis</i> (DSM 27273)	Re-authorisation	SANTE_10890_2016
<b>Other legislation:</b> Amending Regulation (EC) 68/2013 on the Catalogue of feed materials.	New authorisation	SANTE_11983_2015

## No meeting held in January

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