

ADVISORY COMMITTEE ON ANIMAL FEEDINGSTUFFS

78th Meeting of ACAF on 27 February 2019

Information Paper

EU and other Developments

**Secretariat
February 2019**

EU AND OTHER DEVELOPMENTS

Standing Committee on Plants, Animals, Food and Feed (SCoPAFF): Animal Nutrition Section (June 2018 to February 2019)

Feed additive authorisations

1. Since the previous ACAF meeting in June 2018, Standing Committee meetings on Animal Nutrition were held in June, September, November and December 2018, and February 2019. Over this period, twenty-five feed additive authorisations and ten other administrative tools were voted in favour. The next SCoPAFF-AN meeting is scheduled for the 8-10 April 2019. Votes between June 2018 and February 2019 are summarised in the Annex. Summaries of particular note are listed below.

Trace elements

2. Routine discussions held on progressing the authorisations for a number of trace elements since June 2018, with only a single authorisation concluded at a vote in November 2018 for selenium-based trace elements (sodium selenite, coated granulated sodium selenite and zinc-L-selenomethionine).

Vitamin B2

3. At the February 2019 meeting, three EFSA Opinions¹ were presented for initial discussion on the characterisation of production strains of bacteria. Please also note a [RASFF](#)² notification was raised on 2 October 2018 for the presence of a non-compliant GM source of vitamin B2 found in feed across numerous Member States, as summarised in Paragraph 23 below.

Other feed additives

4. The re-authorisation process remains ongoing for many well-established feed additives; including discussion on numerous coccidiostats. A range of concerns remain; regarding environmental impacts and monitoring, production strain characterisation, efficacy or data quality. The authorisation for the coccidiostat Sacox had previously expired but has been re-presented for urgent authorisation due to changes in EU animal welfare legislation, where an unforeseen consequence in cage design has resulted in increased rates of coccidiosis in European rabbit-breeding farms. Since June 2018, only one coccidiostat has been authorised, solely for a change in specification (see annex entries).
5. Also, in November 2018, the Commission explained that for the new authorisations of eleven silage additive enzymes, only four were being progressed. Requests have been made for additional characterisation data on the other seven enzymes, including on efficacy and confirmation

¹ EFSA 2015 ([No.4349](#)); EFSA 2018 ([No.5531](#)) & EFSA 2018 ([No.5337](#))

² Rapid Alert System for Food and Feed (EU notification system).

whether they are of GM origin. The first four enzymes were voted in favour at the February 2019 meeting (not yet published in OJEU).

New Feed Additive Functional Groups

6. At the September 2018 meeting, Member States' concerns remained on the potential overlap with veterinary medicines for the proposed '*animal welfare enhancers*' group. At the December meeting, this functional group was re-presented under the new title of '*physiological condition stabilisers*' and defined by a narrower scope of use. This was generally well-received by Member States. A second proposed functional group for '*Other Technologicals*' did not receive any significant negative feedback by Member States. The Regulation on these new functional groups was voted in favour at the February 2019 meeting (not yet published in OJEU).

Evaluation and fitness check of Regulation (EC) 1831/2003

7. At the December 2018 meeting, the Commission announced that the European Commission's [public consultation](#) on the evaluation and fitness check of the feed additives was launched on 12 December 2018, with comments invited by 3 April 2019.

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

8. During the 2017 amendment of Annex II of Regulation (EC) 1831/2003, multiple feed additives were identified as no longer being appropriately classified as feed additives. In addition, many entries of feed additive flavourings previously withdrawn under [Regulation \(EU\) 230/2013](#) will require legal de-classification as feed additives before relevant entries could be re-assigned as feed materials. Following discussions at meetings between September 2018 and February 2019, which incorporated Member States' feedback, a near-final list of feed additives deemed out of scope was generally accepted. The next step is for this to be set out in a draft Regulation for the legal withdrawal of the feed additives.

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

9. At the September, November and December 2018 meetings, the Commission presented significantly revised versions of the Regulation Annex text with ongoing requests for Member States to submit feedback. Key amendments included stricter analytical criteria for GM-derived feed additives and a greater flexibility in data requirements for EFSA risk assessment; including the potential to cascade data evidence to reduce the frequency of animal studies (from literature, to animal model studies or feed trials where needed). Discussion at the February 2019 meeting which included participation by the Joint Research Centre (JRC) and EFSA focused on analytical methods to detect GM impurities in feed additives in context of comparing the existing [EFSA Guidance on GMOs](#) and the requirements within Regulation (EC) 429/2008.

Feed hygiene

PARNUTS

10. At the June 2018 meeting, the Commission reiterated that Directive 2008/38 on the list of PARNUTS will be repealed with the creation of a new Regulation. New dietetic entries will be included in this amendment, as well as the loss of a number of existing entries where their re-evaluation was unfavourable based on the data submitted. At the June meeting, the Commission also indicated that the use of boli (boluses) may only be used where specifically referenced within individual Annex entries. In the following months, after a scoping exercise with significant inputs from UK industry, a list of existing boli used as dietetic feed was finalised for the December 2018 meeting. In parallel, the scope of use of other individual oral delivery applications used for dietetic feed was also discussed in December. At the February 2019 meeting, discussion continued on individual oral delivery applications with a focus on the dietetic use of drenches – negotiations ongoing. It is expected this new Regulation will be subject to the European Commission's public consultation process and finalised within the first half of 2019.

Interim measures for imports from Third Countries

11. In February 2018, a revised interpretation of interim measures for imports from third countries was discussed, as defined under Article 24 of Regulation (EC) 183/2005 on feed hygiene. This new legal interpretation would be applicable to any animal feed; including feed raw materials, as summarised in the Commission's [February 2018 meeting summary](#) (Item A.04.3). This position was reflected in the October publication of the [UK Technical Notice for animal feed](#). Following a UK request at the September 2018 meeting, the Commission indicated that this matter was still under consideration by their Legal Services. At the December 2018 meeting, three Regulations were voted in favour to change UK holder authorisations to meet third country requirements.

Legal interpretation of processing aids

12. At the November and December 2018 meetings, discussions were held (under AOB) on processing aids and the permitted use of sodium hydroxide, such as in relation to rumen protection. By analogy, the Commission indicated that the previous discussion on criteria for processing aids at the April 2018 meeting ([Item A.11](#)) outlined that based on EFSA safety use levels, formaldehyde should not be permitted for use as a rumen protector; given the earlier denial of authorisation as a feed additive in December 2017.

Regulation (EC) 183/2005 on feed hygiene

13. Following a working group in May 2018, the Feed Hygiene Guidance document has since been submitted to the European Commission's Legal Services for finalisation. The Guide is anticipated to be presented back to SCoPAFF in the first half of 2019.

Codes of Practice

14. Member States provided feedback comments on the Fediaf Code of Good Labelling Practice for Pet Food at the June 2018 meeting. Following final comments at the September meeting, the Commission is to endorse the Code once revisions have been incorporated.
15. Following final comments at the September 2018 meeting on the EU Code on Good Labelling Practice for Compound Feed for Food-Producing Animals (FEFAC/COPA-COGECA), the Commission is to endorse the Code once revisions have been incorporated.
16. The Guide to Good Practice for the Processing of Former Foodstuffs for Use as Feed for Food-Producing Animals was presented at the November 2018 meeting for Member States' feedback. The European Former Foods Processors' Association (EFFPA) held a separate workshop in February 2019, attended by industry representatives, Member State delegates and other EU stakeholders. The workshop provided an outline of the vision of the sector within a circular economy, and the challenges that the sector face, concluding with a constructive open session for exchange of views.

Feed Material Classification

17. At each meeting since April 2018, discussions have been held on individual entries listed within the Register of Feed Materials. The Commission received feedback from Member States on guiding principles for Register criteria and lists of non-conforming entries. Ongoing discussions have been held between the Commission and the Register Taskforce to address issues and resolution of non-conforming entries. At the December 2018 meeting, the Commission presented a list of such erroneous entries with descriptions more indicative of feed additives (i.e. extracts, tinctures, amino acids or micro-organisms). A new list of erroneous feed materials was presented at the February 2019 meeting. Member States agreed with these conclusions, and for the Taskforce to action their deletion from the Register.

Live insects and insect products as food and feed

18. At the December 2018 meeting, the Commission provided an overview of the Regulatory landscape of live insects and insect products for feed and food. The Commission stated that principally; insects are farmed animals, reared for feed/food production or for technical applications (e.g. biofuels). Therefore; feed legislation applies, and insect farmers are classified as primary producers and Feed Business Operators (FeBOs). For novel foods, primary production still falls under the scope of animal feed legislation and therefore; the substrate that insects are fed for food production will not be captured by the Novel foods Regulation, but under animal feed legislation. The Commission summarised the major types of insects used in feed; either live insects, insects treated but not processed, or processed such as insect oil or processed animal protein (PAP). PAPs are the most highly regulated form of insect material with a defined list of seven permitted insects which may be used to generate PAP under requirements for animal by-products (ABPs) approvals for both the business establishment and processing methods used. Other treatments

of insects are not restricted to this short-list of insects permitted for PAP, but under the requirement of the Catalogue of feed materials, insects must not be pathogenic to humans or animals. A sector code of practice for insect production by the insect trade association (IPIFF) is scheduled for finalisation in the first half of 2019.

Possible establishment of EU harmonised criteria to verify manufacturing and mixing accuracies

19. At the November 2018 meeting, the Commission outlined that there has been interest in developing EU harmonised criteria to verify manufacturing and mixing accuracies for feed, especially following findings from previous audits undertaken by SANTE F (formerly FVO). Whilst it is recognised that there has been improvement in practices observed in recent years, concerns still remain as no criteria exist for analytical or sampling methods to test equipment for carry-over and homogeneity. A request was made to Member States to submit relevant guidelines to help frame this proposed guidance document by pooling best practices developed over many years at national levels.

Undesirable substances in feed

RASFF notifications

20. Between 20 April 2018 and 1 February 2019, 110 new RASFF notifications were raised (excluding notifications for Salmonella). Within this period, the UK raised 26 RASFF notifications, with 22 notifications (21 assigned as serious) relating to exceedance of aflatoxin B1 in groundnuts/kernels intended for wild bird feed. An additional serious notification was raised over this period by the UK for high vitamin D3 content in a pet food imported from Czechoslovakia. Public summaries of RASFF notifications are searchable on the [RASFF Consumers' Portal](#).
21. Serious notifications raised by other Member States predominantly concerned exceedances of Aflatoxin B1 in various bird feeds or the presence of ragweed (*Ambrosia* spp.) in animal feedstuffs. Other serious notifications included exceedances of lead, dioxins, lolitrem (a fungal toxin) or cyanide in linseed, and the presence of foreign bodies in feed.
22. Non-serious RASFF notifications over this same period included exceedances of heavy metals (cadmium, mercury, lead, zinc), insecticide or pesticide residues, coccidiostat carry-over or the presence of foreign bodies, ruminant DNA, animal protein or bone in various feedstuffs. Continued cases of adulterated yeast with urea have also been reported.

RASFF notification on a Vitamin B2 source

23. Following the initial Commission notification in March 2018 of an authorised vitamin B2 product on the market which was found to contain viable GM cells and genetic material (including for AMR traits), the single strain of *Bacillus subtilis* KCCM-10445 was voted for a denial of authorisation in June 2018. Whilst the single manufacturer of this source

of vitamin B2 comprised some 30% market-share and could create market pressures, this prohibition came into force on the 19 September 2018, under [Regulation \(EU\) 2018/1254](#). This same strain of *Bacillus subtilis* was more recently implicated in a RASFF notification (Ref: 2018.2755) in October 2018 and a wide-scale withdrawal and recall of feedstuffs across numerous Member State countries. An EFSA Statement ([No.5165](#)) was published on 29 January 2019 concerning the public health risk of this GM source of vitamin B2. The key conclusions reached are that GM AMR gene fragments do not pose a risk to humans, whilst full-length AMR genes could lead to risks linked to its transmission to pathogens via the food chain and/or to the environmental spread of AMR bacteria/genes, potentially contributing to the environmental reservoir of AMR determinants.

Directive 2002/32/EC on undesirable substances

24. The latest amendment to the Directive was only briefly discussed in June 2018 and was scheduled for vote at the February 2019 meeting, although this was deferred due to ongoing corrections. However, work has progressed on a number of undesirable substances to be incorporated into a future amendment of this Directive. Of note, this has included:

June 2018

- The Commission made a request for information for monitoring data on endosulfan; a former pesticide, in fish feed with a view to reduce MRLs for feedstuffs. Whilst the particular focus is on amending MRLs in complete feed for salmonids, a reduction of MRLs could also be reviewed for other animal species, based on data submitted.
- The Commission circulated an interim report on analytical methods for nitrites as part of the EURL 2018/19 work programme. The Commission is also to progress a Guidance to identify sources and factors which result in the presence of high levels of nitrates and nitrites in feed. Additionally, an EFSA mandate has been submitted for nitrites in feed (see 1st bullet point under paragraph 26 below).

August 2018

- The Commission held an expert Working Group on the review of Regulation (EC) No. 152/2009 relating to analytical methods for official controls in feed. A number of Member States; including the UK, submitted recommendations on the scope and criteria of individual analytical methods. At the February 2019 meeting, the Commission indicated that a second Working Group is to be arranged for March 2019.

September 2018

- The Commission was to consider an EFSA mandate on the efficacy of detoxification of seeds of *Ambrosia* spp. (ragweed) and on the efficacy of crushing processes as a detoxification step, to be based on data provided by industry. At the November meeting, the Commission outlined that data supplied by one Member State required additional consideration by EFSA, over the effectiveness of sorting processes for differing *Ambrosia* seed varieties.

- The Commission outlined a request to industry for data on Tetrahydrocannabinol (THC) levels in hemp-derived feed materials and feed from low-THC hemp cultivars (at <0.2% THC).

November 2018

- The Commission acknowledged the potential wider food impacts from hydroxy-methylfurfural (HMF) in feed for honeybees and is to consider requesting an EFSA mandate on bee health.
- The Commission stated that the final pending application for the detoxification process for Aflatoxin B1 in groundnuts is currently under a refreshed review; due to the integral use of formaldehyde within the process, following the prohibition of formaldehyde as a feed additive since March 2018.

25. Since June 2018, the Commission has highlighted a number of recently published EFSA Opinions, these include:

- EFSA Opinion No.5398; published 19 December 2018, on Scientific assistance to assess the detoxification process for dioxins and polychlorinated biphenyls (PCBs) in sunflower cake by hexane extraction. According to data provided, the process was effective in producing a sunflower meal that contained concentrations of polychlorobenzodioxins and polychlorodibenzofurans (PCDD/Fs) and (dioxin-like polychlorinated biphenyls (DL-PCBs), and non-dioxin-like polychlorinated biphenyls (NDL-PCBs) (6 indicator PCBs) about 90% lower than found in the sunflower cake.
- EFSA Opinion No.5194; published 13 December 2018, on the Risk to human health related to the presence of perfluorooctane sulfonic acid (PFOS) and perfluorooctanoic acid (PFOA) in food. Whilst PFOS/PFOA may be carried over into products of animal origin, it is currently unclear if animal feed is a contributory factor. The primary human exposure to PFOS/PFOA is understood to be through consumption of fish; and to a lesser extent from game (especially offal) and egg products.
- EFSA Opinion No.5333; published 20 November 2018, on the Risk for animal and human health related to the presence of dioxins and dioxin-like PCBs in feed and food. This Opinion has divided scientific views in context of the Russian study upon which the Opinion was largely based; with tolerable weekly intakes of 14pg/kg body weight/week now reduced seven-fold for food. A review of maximum residue limits (MRLs) for feed would be undertaken only after the World Health Organisation (WHO) review of toxic equivalent factors (TEFs) to be concluded by 2020.

26. The Commission also mandated EFSA to undertake risk assessments on:

- The risk of nitrites and nitrates to animal health (submitted 9 September 2018) and scheduled for publication by December 2019.
- Available data on nickel in feed and on estimates of animal exposure (submitted 9 September 2018) and scheduled for publication by April 2019.

European Food Safety Authority (EFSA)

27. The FEEDAP Panel's 137th Plenary meeting Parma (22-24 January 2019) provides information on EFSA's pre-publication progress on feed additive risk assessments. The agenda and meeting summary can be viewed on: (<https://www.efsa.europa.eu/en/events/event/190122>)

28. Between May 2018 and January 2019, the EFSA FEEDAP Panel³ published fifty scientific opinions to assess feed additive applications for authorisation and re-authorisation. (<https://www.efsa.europa.eu/en/topics/topic/animal-feed>)
(Via *Published* tab - *All calls* button – Select *Animal Feed*)

29. EFSA publications of particular note were:

- Safety of cassia gum as a feed additive for cats and dogs based on a dossier submitted by Glycomer GmbH. (<https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2019.5528>)
- Safety and efficacy of vitamin B2 (riboflavin) produced by *Ashbya gossypii* for all animal species based on a dossier submitted by BASF SE. (<https://www.efsa.europa.eu/en/efsajournal/pub/5337>)
- Safety and efficacy of vitamin B12 (in the form of cyanocobalamin) produced by *Ensifer* spp. as a feed additive for all animal species based on a dossier submitted by VITAC EEIG. (<https://www.efsa.europa.eu/en/efsajournal/pub/5336>)
- Guidance on the assessment of the efficacy of feed additives. (<https://www.efsa.europa.eu/en/efsajournal/pub/5274>)

30. The CONTAM Panel⁴ of EFSA provides scientific advice concerning the presence of contaminants in both feed and food. (<http://www.efsa.europa.eu/en/panels/contam>)

³ FEEDAP - Panel on Additives and Products or Substances used in Animal Feed

⁴ The Panel on Contaminants in the Food Chain

31. The CONTAM Panel's agenda (awaiting publication of summary) of the 96th Plenary meeting (Parma, 29-31 January 2019) can be viewed on: (<http://www.efsa.europa.eu/en/events/event/190129>)
Discussions included health risks related to the presence of chlorinated paraffins, glycoalkaloids and quinolizidine alkaloids in feed and food.

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

European Commission: SCoPAFF - Animal Nutrition Section

33. Published agendas and meeting summaries can be accessed via the EU [link](#) (scroll down page) whilst wider background on European Commission responsibilities for animal feed can be located [here](#).

Scheduled SCoPAFF-AN meetings for 2019

- 8-10 April
- 24-26 June
- 9-11 September
- 12-13 November
- 16-18 December

Negotiations on the Medicated Feed Proposal

34. Negotiations on the revision of this proposal have been ongoing since September 2014 but have finally reached a conclusion and a new revised text has been agreed upon in the European Parliament. This text, along with the Veterinary Medicinal Products revised proposal, concluded the jurist linguists process whereby the text was scrutinised for accuracy in translation – to make sure what is said translates the same across the 27 Member States and the UK. The Regulations were published in the Official Journal of the European Union on 7 January 2019 and can be viewed using the link below:

<https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=OJ:L:2019:004:TOC>

35. However, the Regulations do not come into force until 28 January 2022.

Preparing businesses for the UK leaving the EU

36. If a business deals in animal feed, or food, it is their responsibility to make sure it is safe. This will remain a requirement of law from day one of the UK leaving the EU. The FSA has published information to help businesses prepare for the UK leaving the EU. The FSA will keep this page updated so businesses can find out about any change which means they may have to do some things differently.

<https://www.food.gov.uk/business-guidance/prepare-your-business-for-the-uk-leaving-the-eu>

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ANNEX – SCoPAFF VOTES AND FEED ADDITIVE AUTHORISATIONS

Animal Nutrition votes:

June 2018

Additive/ Other legislation	Authorisation type	Proposal number
Nutritional: Denial of authorisation of riboflavin (80%) produced by <i>Bacillus subtilis</i> KCCM-10445.	Denial of authorisation	SANTE/10011/2018
Technological: Preparation of <i>Pediococcus pentosaceus</i> DSM 32291 for all animal species.	New authorisation	SANTE/10428/2018
Technological: Preparation of sodium and potassium alginate for cats, dogs, other non-food-producing animals and fish.	New/Re-authorisation*	SANTE/10440/2018
Zootechnical: Benzoic acid for weaned piglets and pigs for fattening.	Re-authorisation	SANTE/10137/2018
Zootechnical: Preparation of <i>Bacillus subtilis</i> DSM 29784 for minor poultry species for fattening and reared for laying.	New authorisation	SANTE/10433/2018
Zootechnical: Preparation of <i>Bacillus subtilis</i> C-3102 (DSM 15544) for pigs for fattening.	New authorisation	SANTE/10437/2018
Zootechnical: Preparation of <i>Bacillus subtilis</i> DSM 28343 for weaned piglets.	New authorisation	SANTE/10442/2018
Zootechnical: Preparation of endo-1,4-beta-xylanase and endo-1,3(4)-beta-glucanase produced by <i>Komagataella pastoris</i> (CBS 25376) and <i>Komagataella pastoris</i> (CBS 26469) for chickens for fattening, chickens reared for laying, turkeys for fattening, all avian	New authorisation	SANTE/10446/2018

species reared for laying or for breeding purposes, weaned piglets and all porcine species (weaned).		
Administrative: Amending Annexes II, V, VI and VII to Regulation (EC) No 767/2009 - to correct the German language version.	Correcting Regulation	SANTE/10595/2018
Administrative: Correcting certain language versions of Implementing Regulation (EU) 2017/2330 concerning the authorisation of Iron compounds.	Correcting Regulation	N/A

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

September 2018

Additive/ Other	Authorisation type	Proposal number
Technological: Preparation of dolomite-magnesite for all animal species with the exception of dairy cows and other ruminants for dairy production, weaned piglets and pigs for fattening.	New authorisation	SANTE/10720/2018
Nutritional: Cumin tincture (<i>Cuminum cyminum</i> L.) for all animal species.	New authorisation	SANTE/10550/2018
Nutritional: [Flavourings] 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, glycine, monosodium glutamate and L-glutamic acid for all animal species and L-cysteine hydrochloride monohydrate for all species except cats and dogs.	Correcting authorisation	SANTE/10748/2018
Zootechnical: Preparation of <i>Lactobacillus acidophilus</i> (CECT 4529) for cats and dogs.	New authorisation	SANTE/10276/2018

Technological: Preparation of fumonisin esterase produced by <i>Komagataella phaffii</i> (DSM 32159) for pigs and poultry.	New authorisation	SANTE/10725/2018
Zootechnical: Preparation of endo-1,3(4)-beta-glucanase and endo-1,4-beta-xylanase produced by <i>Aspergillus niger</i> (NRRL 25541) and alpha-amylase produced by <i>Aspergillus niger</i> (ATTC66222) for weaned piglets and minor porcine species (weaned).	Re-authorisation	SANTE/11132/2017
Zootechnical: Preparation of endo-1,4-beta mannanase produced by <i>Paenibacillus lentus</i> (DSM 28088) for chickens for fattening, chickens reared for laying and minor poultry species other than laying birds, turkeys for fattening, turkeys reared for breeding, weaned piglets, pigs for fattening and minor porcine species.	New authorisation	SANTE/10072/2017
Zootechnical: Preparation of endo-1,4-beta-xylanase produced by <i>Trichoderma reesei</i> (CBS 114044) for laying hens, minor poultry species and pigs for fattening.	Amending authorisation	SANTE/10431/2018

November 2018

Additive/ Other legislation	Authorisation type	Proposal number
Nutritional: Betaine anhydrous for all animal species except rabbits.	New authorisation	SANTE/10861/2018
Nutritional: Sodium selenite, coated granulated sodium selenite and zinc-L-seleno-methionine for all animal species.	*New/Re-authorisation	SANTE/10896/2016
Nutritional: L-arginine for all animal species.	Re-authorisation	SANTE/10755/2018

Nutritional: Hydroxy analogue of methionine and its calcium salt for all animal species.	New authorisation	SANTE/10549/2018
Technological: Preparation of a natural mixture of illite, montmorillonite and kaolinite for all animal species.	New authorisation	SANTE/10207/2016
Zootechnical: Preparation of <i>Enterococcus faecium</i> NCIMB 10415 for sows, suckling piglets, weaned piglets, pigs for fattening.	Re-authorisation	SANTE/10439/2018
Zootechnical: Dimethylglycine sodium salt for chickens for fattening.	Modifying authorisation	SANTE/10724/2018
Technological: Preparation of lecithins liquid, lecithins hydrolysed and lecithins de-oiled for all animal species.	Re-authorisation	SANTE/10673/2018
Coccidiostats & Histomonostats: Preparation of narasin and for chickens for fattening.	Modifying authorisation	SANTE/10073/2017

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

December 2018

Additive/ Other	Authorisation type	Proposal number
Zootechnical: Preparation of 3-phytase produced by <i>Komagataella pastoris</i> (CECT 13094) for chickens reared for laying and minor poultry species for fattening or reared for laying or for breeding.	New authorisation	SANTE/10436/2018
Administrative: Amending Commission Regulations (EC) 1356/2004, (EC) 1464/2004, (EC) 786/2007, (EC) 971/2008 and Commission Implementing Regulations (EU) 1118/2010, (EU) 169/2011, (EU) 888/2011	Modifying authorisation	SANTE/11000/2018

and (EU) 667/2013 as regards the name of authorisation holder.		
Administrative: Amending Commission Regulations (EC) 785/2007, (EC) 379/2009, (EC) 1087/2009, (EU) 9/2010, (EU) 337/2011, (EU) 389/2011, (EU) 528/2011, (EU) 840/2012, (EU) 1021/2012, (EU) 2016/899, (EU) 2016/997, (EU) 2017/440 and (EU) 2017/896 as regards representative of authorisation holder.	Modifying authorisation	SANTE/11282/2018
Administrative: Amending Commission Implementing Regulation (EU) 2015/502 of 24 March 2015 as regards representative of the holder of the authorisation.	Modifying authorisation	SANTE/11397/2018
Technological: Hop extract (<i>Humulus lupulus L flos</i>) for weaned piglets, pigs for fattening and minor porcine species.	New authorisation	SANTE/10207/2016

February 2019

Additive/ Other	Authorisation type	Proposal number
Technological: Alpha-amylase from <i>Bacillus amylo-liquefaciens</i> DSM 9553, <i>Bacillus amyloliquefaciens</i> NCIMB 30251, and <i>Aspergillus oryzae</i> ATTC SD-5374, and a preparation of endo-1,4-beta-glucanase from <i>Trichoderma reesei</i> ATCC PTA-10001 for all animal species.	Re-authorisation	SANTE/10723/2018
Legislative: Amending Annex I to Regulation (EC) 1831/2003 for the establishment of new functional groups.	Amending Regulation	SANTE/12088/2015
Administrative: <i>Corrigendum</i> to Commission Regulation (EU) 2018/1565 on the authorisation of a preparation of endo-1,4-beta-mannanase	Correcting Regulation	SANTE/11574/2018

produced by <i>Paenibacillus lentus</i> (DSM 28088) for chickens for fattening, chickens reared for laying and minor poultry species other than laying birds, turkeys for fattening, turkeys reared for breeding, weaned piglets, pigs for fattening and minor porcine species.		
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February 2019