EUROPEAN COMMISSION

HEALTH AND FOOD SAFETY DIRECTORATE-GENERAL

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SUMMARY REPORT OF THE STANDING COMMITTEE ON PLANTS, ANIMALS, FOOD AND FEED HELD IN BRUSSELS ON 19 DECEMBER 2017 - 20 DECEMBER 2017

(Section Animal Nutrition)

CIRCABC Link: *https://circabc.europa.eu/w/browse/565a1226-fe2d-4277-8e8e-fcc44b7fc041*

A.01 Feed Additives - Applications under Regulation (EC) No 1831/2003 Art. 4 or 13

Documents were distributed.

A.02 Feed Additives - Applications under Regulation (EC) No 1831/2003 Art. 9

A.02.1. AviMatrix (benzoic acid, calcium formate and fumaric acid) for chickens for fattening, chickens reared for laying, minor avian species for fattening and minor avian species reared to point of lay - Annex

A discussion was held. A new Annex will be presented in a future meeting.

A.02.2. RONOZYME® WX (endo-1,4-b-xylanase) as a feed additive for laying hens

After the discussion, supplementary information will be requested to the applicant.

A.02.3. Levucell SC (Saccharomyces cerevisiae CNCM I-1077) as a feed additive for dairy cows, cattle for fattening, minor ruminant species and camelids - Annex

After the discussion, supplementary information will be requested to the applicant.

A.02.4. VevoVitall® (benzoic acid) as feed additive for minor porcine

A discussion was held. A new Annex will be presented in a future meeting.

A.02.5. Copper compounds (E4) for all animal species - Copper(II) diacetate monohydrate, Copper(II) carbonate dihydroxy monohydrate, Copper(II) chloride dehydrate, Copper(II) oxide, Copper(II) sulphate pentahydrate, Cupric chelate of amino acids, hydrate, Cupric chelate of glycine, hydrate (solid), Cupric chelate of glycine, hydrate (liquid) - Annex entry

More support for the draft Annex entry was obtained. Member States were informed that the Copper content of Copper(II) carbonate dihydroxy monohydrate and Copper(II) chloride dehydrate might be reduced in order to allow a higher purity with the Copper(II) oxidation state.

A.03 Discussion on amendment of Regulation (EC) No 429/2008.

The discussion was focused on the safety requirements for the submission of the dossiers. The Member States were invited to send comments and to pay special attention to the part on user safety. The discussion will continue in a future meeting.

A.04 Issues related to Regulation (EC) No 183/2005 laying down requirements for feed hygiene.

A.04.1. Commission working document - Guidance document on the implementation of certain provisions of Regulation (EC) No 183/2005 on the hygiene of feedstuffs

The Commission's representative presented for discussion a new version of the document. There seems to be agreement on most of the issues addressed in the document, except regarding “registration of establishments” that still needs further discussion in the line of the Guide for the use of former foodstuffs as feed, and especially in the case of retailers. It was agreed on sending written comments by the end of January 2018.

A.04.2. Guide to good practice for the manufacture of safe pet foods - FEDIAF

Some delegations submitted observations to the document. A final version will be prepared and presented for its endorsement during the next PAFF Committee.

A.04.3. Other issues related

Some delegations have already sent the information about the non-EU countries which are currently exporting feed products to the EU. Some delegations informed that they have not received the harmonised document prepared for that purpose.
The Commission's representative will forward immediately the document to those delegations.
It is intended to have a first draft of the list ready for the discussion during the next PAFF Committee in April.

A.05 Implications for the National Reference Laboratories with the entering into force of the new controls Regulation (EC) No 625/2017.

The Commission's representative informed about the implications of the entering into force of the new controls Regulation (EC) No 625/2017 and the importance of the activities carried out by the European Reference Laboratory on feed additives, in particular the proficiency tests and the two workshops organised yearly: the EURL

Feed Additives Control Workshop and the Workshop of the European Union Reference Laboratory for Feed Additive Authorisation. The activities financed by the European Commission required the participation of all Member States. Therefore, it is important to encourage the participation of laboratories.
Member States will be informed about the next workshops and the laboratories that are involved in those activities.

A.06 Information about the status on the evaluation of 4-phenylbut-3-en-2-one and benzophenone (CDG 021).

The Commission's representative informed that these two substances are under evaluation by other EFSA panels. Once the evaluation is concluded the FEEDAP panel will prepare an opinion and a decision will be taken.

A.07 RASFF.

A.07.1. Update and exchange of views on recent RASFF notifications.

The Commission's representative informed the Committee on the RASFF notifications related to undesirable substances in animal feed, issued since the meeting of the Committee in November 2017.
The notifications related to a too high level/content of:

- aflatoxins in groundnut kernels from Argentina (2), in groundnuts for birds from US and in groundnuts from Sudan (2)
- cadmium in fish meal from Mauritius
- cadmium and mercury in fish meal from Spain
- dioxins in herbal mixture from India
- dioxins and dioxin-like PCBs in herbal mixtures for horses from Germany.

As regards the source of contamination of the dioxins in herbal mixtures from India and dioxins and dioxin-like PCBs in herbal mixtures from horses, following an assessment of the congener patterns made by the EURL on dioxins and PCBs, the source of contamination is related to the drying practice. However, no conclusion could be drawn with certainty as regards the (inappropriate) combustion material used for drying.

A.08 Undesirable substances.

A.08.1 Further exchange of views on nitrates and nitrites in feed

The discussion on this point has been postponed.

A.08.2 Further exchange of views on the different topics for possible future amendment of the annexes of Directive 2002/32/EC (arsenic in peat and leonardite, nitrites, gossypol, definition of trace amounts, dioxins and *p*-phenetidine)

The Commission informed the Committee that a draft Regulation amending the annex to Directive 2002/32/EC on undesirable substances in feed as regards arsenic in peat and leonardite, gossypol in cotton seed and dioxins in binders and anti-caking agents) shall be presented at the next meeting for discussion. The discussion on the other items shall be continued before proposing a possible amendment to Directive 2002/32/EC on these items.

A.08.3 Update on assessment by EFSA on detoxification processes

The Committee was informed of the adoption of assessment by EFSA on the detoxification by physical filtration with activated carbon of fish oil as regards dioxins and dioxin like PCBs. The Committee was informed that the assessment has been published on the EFSA website at the date of the meeting (20 December 2017).
From the 6 applications received before 1 July 2016, EFSA has already adopted three opinions. It is expected that EFSA will be able to finalise early 2018 its assessment of two other applications (exchange of dioxin contaminated fish oil from fish meal to dioxin filtered oil and another application related to physical filtration with activated carbon. The assessment of the application as regards the decontamination of groundnut meal for aflatoxin by ammoniation shall only be finalised later in 2018 as additional data were requested by EFSA to the applicant, which shall only be provided later in 2018**.**

A.08.4. Follow-up to recent EFSA opinions/statements. Undesirable substances of relevance for future monitoring in feed

The discussion on this point has been postponed. A delegation raised the issue of the template to use to submit the data to EFSA.

A.08.5. Discussion on provisions in Directive 2002/32/EC related to the presence of Ambrosia seeds

The delegations were informed of the information provided by FEDIOL and Starch Europe. Extraction of oils during oilseed processing involves processing of meals at temperatures of at least 100°C for a prolonged period of time. In particular the solvent recycling step is relevant for making weed seeds unviable. At the end of the desolventising step, the meal temperature raises to about 100 °C.
A research project HALT Ambrosia provided recommendations on safety of composting or use as biogas fuel of Ambrosia seed contaminated material. Following the experiments performed in this research project, 55°C for 36 hours was enough to kill the seeds but the ability of ragweed seeds to survive heat strongly depends on their condition:

- Dry seeds can have survival rates of 80 % after 72 and 96 hours

- Moist and wet seeds are reliably killed after 36 hours at 50°C or after 24 hours at 55°C. - both the viability and the ability of seeds to survive heat are reduced in older seeds.

Taking into account this information the following aspects in relation to the legal provisions need to be discussed in more detail at the next meeting.
Article 1(2) of Commission Regulation (EU) 2015/786 of 19 May 2015 defining acceptability criteria for detoxification processes applied to products intended for animal feed as provided for in Directive 2002/32/EC of the European Parliament and of the Council provides that the Regulation shall not apply to a detoxification process through which the contamination by an undesirable substance is reduced or eliminated by the usual refining process.
At the next meeting a more in depth discussion on the legal consequences shall have to take place in particular under which situations does the application of the detoxification process fall within or outside the scope of Regulation (EU) 2015/786, the appropriateness of making a distinction in the provisions of Directive 2002/32/EC between viable/non-viable seeds and on the footnote related to the need for cleaning of contaminated seeds intended for milling and crushing.

A.08.6 Arsenic in dimanganese chloride trihydroxide

The maximum level for arsenic in dimanganese chloride trihydroxide is 30 mg/kg, being the general limit of arsenic for trace elements. Data are provided by the company indicating levels of arsenic in dimanganese chloride trihydroxide in the range of 28-30 mg/kg making use of the Inductively coupled plasma mass spectrometry (ICP-MS) and in the range of 50-65 mg/kg making use of Inductively coupled plasma atomic emission spectroscopy (ICP-AES). The company is requesting to establish a higher maximum level for arsenic in dimanganese chloride trihydroxide. It was noted that in the EFSA opinion on dimanganese chloride trihydroxide the specification set in the dossier for Cd (< 30) and As (< 100) is considerably above the legal maximum allowed for compounds of trace elements. While as specification the level of arsenic requested was < 100 mg/kg the data provided in the dossier as regards arsenic contamination did not exceed the current maximum level of 30 mg/kg. The EURL on metals shall be requested to provide an explanation on the divergence of analytical results obtained by ICP-MS versus ACP-AES. Once this information is received, the discussion on a possible change of the maximum level for arsenic shall be continued.

A.08.7 Presence of THC in hemp derived products

Commission Regulation (EU) No 68/2013 of 16 January 2013 on the Catalogue of feed materials (as amended by Commission Regulation (EU) 2017/1017) stipulates that hemp derived feed materials have to be derived from varieties of *Cannabis sativa* L. with a maximum tetrahydrocannabinol (THC) content (0.2 %) according to Regulation (EC) No 1782/2003. For hemp derived products intended for use in animal feed placed on the market (including import) in EU, it would be appropriate to define the THC level above which it can reasonably be assumed that the hemp derived product has not been produced from hemp varieties complying with the requirement that only varieties with a maximum of 0.2 % of THC can be used in feed. The Commission's representative indicated to examine this and committed to propose a level for discussion at the next meeting.

A.08.8 Other issues

Reference was made to Commission Regulation (EU) 2017/2229 of 4 December 2017 amending Annex I to Directive 2002/32/EC of the European Parliament and of the Council as regards maximum levels for lead, mercury, melamine and decoquinate. FEDIAF raised that the maximum level for mercury in fish, other aquatic animals and products derived thereof fed directly to pet animals was before the amendment 0.5 mg/kg and is now after the amendment 0.1 mg/kg (both relative with feed 88 % dry matter). This was an unintentional consequence of the amendment. Before considering addressing this issue by an amendment to the legislation, FEDIAF shall be requested to provide information of the importance of this kind of commercial products (i.e. fish, other aquatic animals and products derived thereof fed directly as feed materials to pet animals).

A.09 Discussion on the content of some antioxidants in complete feed - (UK request).

On request of one Member State, use of Butylated hydroxytoluene (BHT) as a replacement antioxidant for ethoxyquin was discussed.

It was concluded that the

- inclusion rate of BHT in feed shall be in compliance with the respective maximum content established in the authorisation act
- added amount of BHT shall be labelled on the feed material and compound feed
- official control should take into account that antioxidants by their nature degrade and thus their recovery in the feed is significantly reduced over time
- EFSA opinion of BHT in the margins of the re-authorisation should indicate typical degradation curves.

A.10 Feed marketing Regulation (EC) N° 767/2009.

A.10.1. Dietetic feed (Directive 2008/38/EC): state of play of pending evaluations, new applications and draft Regulation for repealing the Directive

A Commission's representative gave an update on the new and pending applications. Member States commented on the draft new Annex. A revised draft will be prepared for the next Committee.

A.10.2. Feed material classification - Polyethylene glycol and Bromelain

- The Committee came back on the status of polyethylene glycol (PEG) substances listed in the Register of feed materials. It was concluded that such products are not considered feed materials and that the authority in the respective Member States shall induce the withdrawal of those entries in the Register.
- Concerning the entry of Bromelain, the Committee concluded that this enzyme product is not considered a feed material and that the authority in the respective Member States shall induce its withdrawal from the Register.

A.10.3. Revision of the FEDIAF Code of Good Labelling Practice

The revised text was examined by the Committee. Member States are invited to send in their comments by 26 January 2018.

A.11 Information of the Committee on the Guidelines for the use of former foodstuffs as feed.

The Commission's representative presented the latest draft of the guidelines. The text has been sent to the Member States for a last round of comments by 12 January cob. The delegations were asked to coordinate nationally with the experts on Animal By-products and TSE.

A.12 Control of processed insect protein in feed for aquaculture species.

The Commission's representative presented the state of play on feed ban official controls following the authorisation of insect Processed Animal Protein (PAP) in feed for aquaculture animals. Concerning controls of aquafeed, the authorisation has no impact on laboratory control methods since other non-ruminant PAP are also authorised, and therefore only ruminant PCR is needed to control the absence of ruminant prohibited materials. Concerning controls of other feeds, light microscopy remains the method in force, however the EU Reference Laboratory for Animal Proteins (EURL-AP) is working on the validation of an adapted light microscopy method, with a double sedimentation, which would be more suitable for the detection of insect particles in order to control that such particles are absent from feed in which insect PAP are not authorised. This validation should take place during the first half of 2018. In parallel, an amendment to Annex VI of Regulation (EC) No 152/2009 is being prepared in order to insert a new category, "particles from invertebrates", in addition to the two existing ones (particles from fish and particles from terrestrial animals).

The Commission's representative also recalled that the authorisation of insect PAP in aquafeed is subject to official control requirements at the level of the compound feed establishment. If the establishment is not dedicated to producing compound feed for aquaculture animals, it must, in order to produce compound feed containing insect PAP, meet a series of requirements laid down in the TSE Regulation (separate production lines, regular laboratory analysis, etc.) which must be checked on-the-spot by the competent authority. The competent authority must maintain a list of compound feed establishments authorised to produce compound feed for aquaculture animals containing insect PAP.

Finally, the Commission's representative informed of the next steps envisaged on revising the TSE Regulation as regards insect PAP. Due to current difficulties in feed ban laboratory control techniques, the authorisation of insect PAP in feed for poultry is linked to the authorisation of pig PAP in feed for poultry. On the latter, EFSA is currently working on a mandate from the Commission concerning an update of the Quantitative Risk Assessment of the BSE risk of PAP, including an assessment of a possible technical zero or action limit approach for the ruminant PCR method, which

should partly address the PCR "false positive" issue. The EFSA opinion is due for June 2018. Depending on the outcome of the EFSA opinion and internal Commission discussions, the Commission could then propose a package of draft texts including an authorisation of pig and insect proteins in poultry feed, and a modification of Annex VI to Regulation (EC) No 152/2009 to include a technical zero or action limit approach.

A few questions were asked by Member States. Portugal asked about methods for checking the species of the insects used for producing the PAP, and for checking the substrate given. The Commission's representative replied that this should be checked during on-the-spot visits of the establishment producing the insect PAP. France asked about the authorisation of poultry PAP in pig feed.
The Commissions' representative replied that in this case the action limit approach would not solve the issue of "false positive" results. United Kingdom asked about the ELISA and mass spectrometry method. The Commission's representative replied that ELISA had become less relevant thanks to the action limit approach, however the EURL-AP was still working on the development and validation of the mass spectrometry approach which should enable determining the exact tissue of origin of a PCR positive result.

B.01 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation concerning the denial of authorisation of formaldehyde as a feed additive belonging to the functional groups of preservatives and hygiene condition enhancers.

The Commission's representative presented the last version of the draft measure, which concerns the denial of authorisation of formaldehyde as an additive belonging both to the group of "preservatives" and to the group of "hygiene condition enhancers".
The draft Implementing Regulation has been published on 21 November 2017 on the Better Regulation Portal for a 4-week public consultation (http://ec.europa.eu/info/law/better-regulation/iniatives/ares-2017-5676888en).
The period of public consultation ended on 19 December 2017.
The Commission's representative reported to the Committee's members the outcome of that public consultation, as regards statistical information and the content of the comments received.
In total, 98 comments were submitted, including from the authorisation's applicant companies or associations. As regards the "type of user" mentioned, 47 comments were received from companies/business organisations or associations, 37 from citizens (including 2 from non-EU citizens), 6 from non-governmental organisations, 4 from academic/research institutions, 2 from consumer organisations, 1 from a trade union and 1 was mentioned as "other".
As regards the "country" mentioned by the contributors, 30 comments were from the United Kingdom, 17 from Poland, 12 from Finland, 8 from Belgium, 7 from Germany, 4 from The Netherlands, 4 from Spain, 3 from Latvia, 2 from Hungary, 1 from Italy, 1 from Ireland, 1 from France, 3 from the United States, 1 from Brazil, 1 from Chili, 1 from Morocco, 1 from Egypt and 1 from the United Arab Emirates.
The comments relate mainly to the following issues:

- the need to ensure that the measure be based on scientific evidence;
- the alleged current lack of efficient alternative to formaldehyde in order to reduce salmonella contamination in feed and the fear of resulting risks for feed and food safety and of jeopardising Union industry's capacity to produce safe feed;
- the reference to the EFSA and ECDC ("European Centre for Disease Prevention and Control") report on trends and sources of zoonoses, zoonotic agents and food-borne outbreaks in 2016 (published in the EFSA Journal 2017;15(12):5077, http://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2017.5077/epdf), as regards statistical data on the evolution of salmonellosis cases and any link with feed contamination;
- the assumption that the measure would not consist in a proper application of the precautionary principle;
- the fact that formaldehyde is still used in other sectors and that occupational exposure limits are being developed for formaldehyde in the framework of the Union legislation on health and safety at work; in the same context, the fact that specific measures are already in place in order to protect workers' safety towards the exposure to formaldehyde;
- the use of formaldehyde in feed as a processing aid and not as an additive;
In response to the comments received, a representative of the Commission explained to the Committee's members how those contributions were considered and taken into account in view of the submitted draft measure.
Member States' representatives were then given the possibility to express their views on the draft measure and on the outcome of the public consultation.

Vote taken: Favourable opinion.

B.02 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation concerning the authorisation of a preparation of endo-1,4-b-xylanase (EC 3.2.1.8) produced by Trichoderma reesei (BCCM/MUCL 49755) as a feed additive for pigs for fattening (holder of authorisation Berg and Schmidt GmbH Co. KG).

The draft Regulation refers to an authorisation as zootechnical additive.

Vote taken: Unanimity.

B.03 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation concerning the authorisation of L-arginine produced by *Corynebacterium glutamicum* KCCM 80099.

The draft Regulation concerns the authorisation of L-arginine as feed additive belonging to the functional group of nutritional feed additives.

Vote taken: Unanimity.

C.01 Exchange of views of the Committee on a draft Commission Regulation amending Regulation (EC) No 1831/2003 of the European Parliament and of the Council amending Annex I to Regulation (EC) No 1831/2003 to create a new functional group.

After discussion, Member States were invited to send comments.

M.01 A.O.B.

Letter from France on the authorisation of L-cysteine and L- cysteine hydrochloride monohydrate.

France asked for a modification of the Regulation in order to prevent that keratin from human hair would be used for the production of these two amino acids. The Commission's representative informed that an amendment will be proposed for taking into account the concern of France.

Question from the UK as regard the authorisations granted to different flavourings where the paragraph establishing the recommended dose was removed from the decision of authorisation

The Commission's representative explained that, even the recommended dose is not established, in fact, the consequences for the operators are, that when such dose is exceeded, the name of the additive, functional group and quantity added should be indicated on the label of the premixtures and on the labelling of feed materials and compound feed. It is expected that operators will not exceed the recommended doses as those doses are reported by the applicants as the normal use levels.

Feed Additives - Applications under Regulation (EC) No 1831/2003 Art. 9

Discussion on following documents:

- safety and efficacy of Natuphos® E (6-phytase) as a feedadditive for avian and porcine species - Annex.
A discussion was held. A draft Regulation will be presented in a future meeting.

- safety and efficacy of Beltherm MP/ML (endo-1,4-beta-xylanase) as a feed additive for chickens for fattening, chickens reared for laying, turkeys for fattening, turkeys reared for breeding, turkeys for breeding purposes and minor poultry species.
The initial discussion was held, but due to the complexity of the dossier the discussion will continue at the next meeting

- safety and efficacy of FRA® Octazyme C Dry (a-galactosidase, a-amylase,endo-1,3(4)-b-glucanase,endo-1,4-b-glucanase,mannan-endo-1,4-b-mannosidase,pectinase,protease,endo-1,4-b-xylanase) for chickens for fattening and weaned piglets.
Due to the complexity of the dossier, the discussion has been postponed.