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 12 SEPTEMBER 2016 - 13 SEPTEMBER 2016

(Section Animal Nutrition)

CIRCABC Link: *https://circabc.europa.eu/w/browse/e360a1b3-c86e-4696-8122-f8c95d0412c5*

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

New applications (copies).

Documents were distributed.

A.01.1. Discussion on Sacox for rabbits - Article 15.

A discussion took place. The Member States agreed on an urgent authorization procedure, supported by an EFSA opinion, provided that the necessity of this coccidiostat is well supported. At present, they didn't receive information on the increase of coccidiosis in rabbits. Therefore, data on coccidiosis in rabbits will be needed before proceeding.

A.01.2. Discussion of the proposal for a new use of an additive for the reduction the mycotoxin contamination as silage additive.

A discussion took place.
Member States supported this new product.

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

Discussion on EFSA Scientific Opinions on the safety and efficacy of :

A.02.1. Bacillus subtilis DSM 28343 as a feed additive for chickens for fattening - Annex

A discussion was taken. A draft Regulation will be presented in a future meeting.

A.02.2. Biostrong® 510 (essential oil of thyme and star anise) for chickens and minor avian species for fattening and rearing to point of lay - Annex

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

A.02.3. Rovabio® Spiky (endo-1,4-betaxylanase and endo-1,3(4)-beta-glucanase) as a feed additive for all major and minor poultry species - Annex

A discussion was taken. An Annex will be presented in a future meeting.

A.02.4. Kemzyme® Plus Dry (endo-1,3(4)-beta-glucanase, endo-1,4-beta- glucanase, alpha-amylase, bacillolysin and endo-1,4-beta-xylanase) for poultry, ornamental birds and piglets (weaned) - Annex

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

A.02.5. Kemzyme® Plus Liquid (endo-1,3(4)-beta-glucanase, endo-1,4-beta-glucanase, alpha-amylase and endo-1,4-beta-xylanase) as a feed additive for poultry species and ornamental birds - Annex

A discussion was taken. The Member States raised the point on the similarity by old and new formulation. A new Annex for both additives will be presented in a future meeting.

A.02.6. concentrated liquid L-lysine (base), concentrated liquid L-lysine monohydrochloride, L-lysine monohydrochloride technically pure and L-lysine sulphate produced using different strains of Corynebacterium glutamicum and Escherichia coli for all animal species - Annex entry

A draft Annex entry was presented and discussed. A draft Regulation will be prepared for L-lysine sulphate produced by Escherichia coli for vote in one of the next meetings.

A.02.7. manganous chloride, tetrahydrate; manganous oxide; manganous sulphate, monohydrate; manganese chelate of amino acids, hydrate; manganese chelate of glycine, hydrate, manganese hydroxychloride as feed additives for all animal species - Annex

Several technical aspects require further reflections. The Committee will come back on the draft in one of the next meetings.

A.02.8. dicopper oxide as feed additive for all animal species - Annex

A draft Annex entry was presented and discussed. A draft Regulation will be prepared for vote in one of the next meetings.

A.02.9. the currently authorised maximum copper content in complete feed (revision)

This point was postponed due to time constraints.

A.02.10. inositol as a nutritional additive for dogs and cats

After the EFSA opinion and examination of additional information, it was decided to contact the applicant in order to discuss the follow-up.

A.02.11. dry grape extract when used as a feed flavouring for all animal species and categories – Annex

After discussion a new annex entry will be prepared for the next Standing Committee.

A.02.12. ethyl ester of ß-apo-8'-carotenoic acid as a feed additive for poultry for fattening and poultry for laying

After discussion and examination of the information submitted by the applicant Member States supported the EFSA opinion on this issue. The applicant will be informed about this position in order to discuss the follow-up.

A.03 Feed marketing Regulation (EC) N° 767/2009

A.03.1. Directive 2008/38/EC establishing the list of intended uses as particular nutritional purposes - state of play of pending evaluations and new applications

The Commission's representative gave an update on the ongoing assessments. Germany and France announced evaluations of their national institutes.

A.03.2. Revision of Annexes IV, VI and VII (labelling provisions)

The new approach for the quantitative labelling of feed additives in Annexes VI and VII was further elaborated. The proposals for the revision of the labelling tolerances in Annex IV from one Member State were discussed in detail. The Committee will come back on the issue.

A.03.3. Third amendment of the EU Catalogue of feed materials (Regulation (EU) No 68/2013)

Some revisions for entries were discussed, including feed materials after microbial fermentation and from insects. A draft Regulation will be prepared for vote in one of the next meetings.

A.03.4. Discussion of the draft revision of the F.E.D.I.A.F. Code of Good labelling practices for pet food.

Several Member States commented on the revised Code. The comments will be forwarded to F.E.D.I.A.F. for consideration. Once this is done, the Committee will come back to the Code with a view of its endorsement.

A.03.5. Guidelines to clarify the legal status of former foodstuffs intended to be used as feed.

A first draft document was distributed to the Committee for comments. The draft will also be shared with the waste Committee in DG Environment in order to create coordinated and consistent guidelines for these borderline issues.

A.04 Update about the dossiers for re-evaluation of vitamin B_2 .

Member States were updated on the situation of the dossiers presented for the re-evaluation of vitamin B_2.

A.05 Discussion on withdrawal from the market of certain feed additives for which no applications for authorisation were submitted before the deadline provided for in Regulation (EC) No 1831/2003.

The document was distributed for comments.
No discussion was taken.

A.06 Discussion on proposal for new functional groups of feed additives.

A draft proposal was discussed and a new draft will be presented for the next Standing Committee.

A.07 Discussion on amendment of Regulation (EC) No 429/2008.

A first presentation of the new revised document was done.

A.08 RASFF.

The Commission representative informed the Committee on the following RASFF notifications related to undesirable substances in animal feed, issued since the meeting of the Committee in June 2016 :

- ragweed seeds (Ambrosia sp.) in soybeans from France (1 notification), in soybeans from Serbia (1 notification), in birdfeed from Hungary (1 notification), in soya feed from Romania (1 notification) and in sunflower seeds from Bulgaria (1 notification);
- aflatoxins in compound feed from the United States;
- adulteration of maize from Ukraine contaminated with stained seeds (treated with a pesticide).

A.09 Undesirable substances.

A.09.1 Exchange of views on a draft Recommendation on nitrites and nitrates in feed

The Committee was informed that the document was not yet available for discussion but the Commission representative committed to have it available for discussion at the next meeting of the Committee.
The opportunity was taken to inform the Committee on the publication of two Commission Recommendations:

- Commission Recommendation (EU) 2016/1319 of 29 July 2016 amending Recommendation 2006/576/EC as regards deoxynivalenol, zearalenone and ochratoxin A in pet food (OJ L208, 2.8.2016, p. 58);

- Commission Recommendation (EU) 2016/1110 of 28 June 2016 on the monitoring of the presence of nickel in feed (OJ L 183, 8.7.2016, p. 68). Analytical results from the monitoring by Member States, with the active involvement of feed business operators, should be submitted to EFSA by 31 October 2017 by the latest.

A.09.2 Commission Regulation (EU) 2015/786 of 19 May 2015 defining acceptability criteria for detoxification processes applied to products intended for animal feed. Applications received and exchange of views on further follow-up

The Committee was informed that 6 applications have been received before 1 July 2016, and that no other applications were received since then. The 6 applications are:

- decontamination of fish oil for dioxins and PCBs;
- decontamination of fish oil for dioxins, PCBs and other unwanted substances;
- decontamination of fish meal for dioxins;
- decontamination of fish oil and fishmeal for dioxins and PCBs;
- decontamination of linseed and linseed cake for hydrocyanic acid;
- decontamination of groundnut meal for aflatoxin B1.

The Commission's representative informed the Committee to provide regularly updates on this file.

A.09.3 Follow-up to the EFSA opinion on zearalenone and modified forms

EFSA adopted recently an opinion on the appropriateness to set a group health-based guidance value for zearalenone and its modified forms. The modified forms of zearalenone (ZEN) identified are phase I and phase II metabolites. Phase I metabolites are mainly formed through reduction. Phase II metabolites are formed by conjugation of ZEN and its phase I metabolites with glucose or sulfate, and in animals glucuronic acid. The few data on the occurrence of modified forms of ZEN indicated that cereal-based foods are the main source, containing amounts varying from a few up to 100% of ZEN. Most of the phase I metabolites have oestrogenic activity and it is assumed that their combined action will be additive. The CONTAM Panel found it appropriate to set a group TDI of 0.25 µg/kg bw per day expressed as ZEN equivalents for ZEN and its modified forms (phase I and phase II metabolites). To account for differences in *in vivo* oestrogenic potency, each phase I metabolite was assigned a potency factor relative to ZEN to be applied to exposure estimates of the respective ZEN metabolites. It was assumed that conjugates (phase II metabolites) of ZEN and its

phase I metabolites, which per se have no oestrogenic activity, will be cleaved releasing ZEN and its phase I metabolites. These conjugates were assigned the same relative potency factors as their aglycones.

Given the high relative potency factor given to certain modified forms (e.g. a potency factor of 60 to α-zearalenol) the presence of certain modified forms in food of animal origin could result that food of animal origin is a more important contributor to the overall human exposure to zearalenone and its modified forms than previously assessed.

Proposed regulatory follow-up:

- EFSA has informed the Commission of their intention to issue a call for a survey on the presence of zearalenone and its modified form in food (including food of animal origin) and feed. The results of this survey are expected to become available by mid-2018.

- The European Union Reference Laboratories (EURLs) -EURL for mycotoxins in feed and food – JRC-Geel and EURL for food of animal origin RIKILT, The Netherlands) are requested to undertake work on the analysis of zearalenone and modified forms in products of plant origin (feed and food) and food of animal origin. The work should consist of several aspects: inventory of available analytical methods (for which matrices, what modified forms are covered, what is the LOD/LOQ for the different modified forms, validation status and any other relevant information), further elaboration/fine tuning of a selected method (s) and organisation of a proficiency test (PT).

- Further regulatory follow-up shall be discussed in the second half of 2018 following the availability of the outcome of the survey (ordered by EFSA) and the experience from the EURLs as regards the analytical feasibility and the sensitivity of the analysis of zearalenone and its modified forms in different matrices (feed and food).

The Committee did not raise comments on the proposed approach forward.

A.09.4 Presence of pyrrolizidine alkaloids in feed

The Committee was informed of the ongoing discussions as regards possible regulatory measures as regards pyrrolizidine alkaloids in honey, tea, herbal infusions and food supplements. The Committee was informed on the data on the presence of pyrrolizidine alkaloids in feed available in the EFSA database. Once the discussions in food have been progressed as regards a number of aspects (such as selection of pyrrolizidine alkaloids, analytical aspects in particular limit of quantification, …) the discussion could be initiated in this committee as regards the appropriateness (and the need) to complete the current provision in Annex to Directive 2002/32/EC on "*weed seeds and unground and uncrushed fruits containing alkaloids, glucosides or other toxic substances separately or in combination including Datura sp.*" by specific provisions on pyrrolizidine alkaloids.

A.09.5 Other issues

- Data on dioxins and dioxin-like PCBs in feed

An overview was provided as regards the available data in the EFSA database on dioxins and dioxin-like PCBs in feed. The data are quite limited and it would be appropriate to have more recent data on the presence of dioxins and dioxin-like PCBs in feed in view of the comprehensive risk assessment on the presence of dioxins and PCBs in feed and food performed by EFSA and expected to be available by mid-2016. Therefore the Commission representative urged the Member States to submit the available data as yet as soon as possible to enable EFSA to perform their risk assessment as accurately as possible.

Several delegations highlighted the significant burden to provide data to EFSA in the EFSA data submission format. Furthermore it was mentioned that in certain cases only limited data were accepted after the application of data acceptance criteria by EFSA despite the efforts invested to submit the data. The Commission's representative committed to prepare a document with the minimum information required by EFSA and the acceptance criteria, so that Member States better can assess in advance the likelihood of acceptance of the data by EFSA and consequently to decide if it is worthwhile to invest in the effort to submit the available data to EFSA. The Commission representative shall also ask EFSA if they can provide assistance to the Member States for the submission of the data.

- Request from the French authorities to provide for an exemption of the application of the maximum level dioxins and PCBs for fresh fish used as fishing bait

The Committee was informed of the request to apply for fresh fish used as fishing bait the same exemption from the application of the maximum levels for dioxins, sum of dioxins and dioxin-like PCBs and non-dioxin like PCBs existing for fresh fish and other aquatic animals directly delivered and used without intermediate processing for the production of feed for fur animals and fresh fish used for the direct feeding of pet animals, zoo and circus animals or used as feed material for the production of pet food.

The Commission's representative indicated to discuss this issue at a next meeting of the Committee.

A.10 Regulation (EC) No 183/2005 laying down requirements for feed hygiene

A.10.1. Discussion of some items

The Commission's representative presented for discussion a new Commission working document : "Guidance document on the implementation of certain provisions of Regulation (EC) No 183/2005 on the hygiene of feedstuffs".
The document reflects the discussions carried out on the criteria for the registration of feed establishments.

Member States welcomed the Guidance document and after discussion agreed on sending written comments.

A.10.2. Exchange of views on measures for non-authorised additives intended for export

The Commission's representative presented for discussion a new proposal for a Commission Regulation in order to set requirements for exporting non-authorised feed additives to third countries.
Member States welcomed the proposal and after discussion agreed on sending written comments.

B.01 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation concerning the provisional authorisation of a preparation of formaldehyde as a feed additive for chickens for fattening, laying hens, piglets (weaned) and pigs for fattening.

The Commission's representative presented to the Committee a slightly revised version of the draft Implementing Regulation taking into account a request made during the last meeting of the Committee, which aims at facilitating controls by the competent authorities of the application of the envisaged measure. A brief exchange of views took place.

Vote postponed

B.02 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation amending Implementing Regulation (EU) No 837/2012 as regards the minimum activity of 6-phytase produced by Aspergillus oryzae (DSM 22594) as feed additive for sows (holder of authorisation DSM Nutritional Products).

The draft Implementing Regulation is related to a modification of the authorisation of this enzyme as zootechnical additive. A discussion took place.

Vote taken: Unanimiy.

B.03 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation concerning a preparation of kidney bean (Phaseolus vulgaris) lectins as a feed additive for suckling piglets (holder of authorisation Biolek, Sp.Zo.o.).

The draft Implementing Regulation is related to an authorisation of this preparation as zootechnical additive. A discussion took place.

Vote taken: Unanimity.

B.04 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation concerning the authorisation of guanidinoacetic acid as a feed additive for chickens for fattening, weaned piglets and pigs for fattening and repealing Commission Regulation (EC) No 904/2009.

The draft Implementing Regulation aims to authorise guanidinoacetic acid for new target species. A discussion took place.

Vote taken: Unanimity.

B.05 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation concerning the authorisation of lactic acid, 4-oxovaleric acid, succinic acid, fumaric acid, ethyl acetoacetate, ethyl lactate, butyl lactate, ethyl 4-oxovalerate, diethyl succinate, diethyl malonate, butyl-O-butyryllactate, hex-3-enyl lactate, hexyl lactate, butyro-1,4-lactone, 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 as feed additives for all animal species (CDG 09).

The draft proposes the authorisation of certain flavourings for all animal species. A discussion took place.

Vote taken: Unanimity.

B.06 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation concerning the authorisation of 4-allyl-2,6-dimethoxyphenol and eugenyl acetate as feed additives for all animal species except for fish and poultry (CDG 018) .

The draft proposes the authorisation of two flavourings for all animal species. A discussion took place.

Vote taken: Unanimity.

B.07 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation concerning the authorisation of 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-(methyldithio) propanal, 2-methylpropane-1-thiol, methylsulfinyl methane, propane-2-thiol, 3,5-dimethyl-1,2,4-trithiolane and 2-methyl-4-propyl-1,3-oxathiane as feed additives for all animal species (CDG 020).

The draft proposes the authorisation of certain flavourings for all animal species. A discussion took place.

Vote taken: Unanimity.

B.08 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation concerning the authorisation of 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 a species and of veratraldehyde and gallic acid as feed additives for certain animal species (CDF 023).

The draft proposes the authorisation of certain flavourings for all animal species or in case of veratraldehyde and gallic acid for certain species. A discussion took place.

Vote taken: Unanimity.

B.09 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation concerning the authorisation of tannic acid as a feed additive for all animal species.

The draft proposes the authorisation of tannic acid for all animal species. A discussion took place.

Vote taken: Unanimity.

B.10 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation concerning the authorisation of glycyrrhizic acid ammoniated as feed additives for all animal species.

The draft proposes the authorisation of glycyrrhizic acid ammoniated for all animal species. A discussion took place.

Vote taken: Favourable opinion.

C.01 Exchange of views of the Committee on a draft Commission Implementing Regulation concerning the authorisation of the preparations of sodium benzoate, potassium sorbate, formic acid and sodium formate as feed additives for all animal species.

It was requested to modify some conditions of use. A new draft will be presented in a future meeting. A discussion was taken.

C.02 Exchange of views of the Committee on a draft Commission Implementing Regulation concerning the authorisation of a preparation of dolomite-magnesite for dairy cows and other ruminants for dairy production, weaned pigs and pigs for fattening, and a preparation of montmorillonite-illite for all animal species as feed additives.

It was requested to modify some conditions of use. A new draft will be presented in a future meeting. A discussion was taken.

C.03 Exchange of views of the Committee on a draft Commission Implementing Regulation concerning the partial suspension of the authorisation of ethoxyquin (6-ethoxy-1,2-dihydro-2,2,4-trimethylquinoline) when used as antioxidant for all animal species.

Both the context and the preliminary elements for a draft suspension measure of the authorisation of the additive ethoxyquin were presented by representatives of the Commission.
A discussion took place.
The delegations of the Member States were requested to provide their contribution to the Commission in view of the next meeting of the Committee.

M.01 A.O.B.

No item raised.