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 NOVEMBER 2015 - 13 NOVEMBER 2015

(Section Animal Nutrition)

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

A.01 Feed Additives - Applications under Regulation (EC) N° 1831/2003 Art. 4 or 13.

Documents were distributed.

A.02 Feed Additives - Applications under Regulation (EC) N° 1831/2003 Art. 9.

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

A.2.1. Friedland clay (montmorillonite–illite mixed layer clay) when used as a technological additive for all animal species – Annex

Following the discussion, an Annex will be proposed at a future meeting.

A.2.2. Bacillus subtilis KCCM 10673P and Aspergillus oryzae KCTC 10258BP as feed additives for all animal species

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

A.2.3. Calsporin® (Bacillus subtilis DSM 15544) as a feed additive for laying hens and avian species for laying – Annex

Following the discussion, a draft Implementing Regulation will be proposed for possible vote at a future meeting.

A.2.4. Sorbic acid and potassium sorbate when used as technological additives for all animal species based on two dossiers from Nutrinova Nutrition Specialties & Food Ingredients GmbH.

No discussion took place.

A.2.5. complexation products of Sodium tartrates with iron(III) chloride for all animal species and categories – Annex

Following the discussion, an Annex will be proposed at a future meeting.

A.2.6. VevoVitall® (benzoic acid) as a feed additive for pigs for reproduction (gestating and lactating sows, boars and gilts) – Annex

Following the discussion, a draft Implementing Regulation will be proposed for possible vote at a future meeting.

A.2.7. Cibenza® EP150 (a preparation of Bacillus licheniformis (ATCC 53757) and its protease (EC 3.4.21.19)) as a feed additive for chickens for fattening, chickens reared for laying and minor avian species for fattening and to point of lay and ornamental birds – Annex

Following the discussion, a draft Implementing Regulation will be proposed for possible vote at a future meeting.

A.2.8. Zinc compounds as feed additives for all species : zinc acetate, dihydrate; zinc chloride, anhydrous; zinc oxide; zinc sulphate, heptahydrate; zinc sulphate, monohydrate; zinc chelate of amino acids, hydrate; zinc chelate of glycine, hydrate - Annex

Annex entries for the 9 zinc compounds were presented and discussed. The main issues were the maximum contents in the complete feed for the different target species and the description of the chelates. The annex entries will be revised in the light of the discussion for the next meeting.

A.2.9. L-tryptophan, technically pure, produced by Escherichia coli strains DSM 25084, KCCM 11132P or SARI12091203 for all animal species based on a dossier submitted by AMAC EEIG

The EFSA opinion was presented. As it is conclusive for L-tryptophan produced by Escherichia coli strains DSM 25084 and KCCM 11132P, these applications will be further processed together with the other positive opinions for L-tryptophan. For L-tryptophan produced by Escherichia coli strain SARI12091203, EFSA could not conclude on the safety of the genetic modification. Thus, the applicant will be contacted in order to clarify the follow-up.

A.2.10. L-threonine produced by Escherichia coli strains NRRL B-30843, DSM 26131, KCCM11133P or DSM 25085 for all animal species based on a dossier submitted by AMAC EEIG

The EFSA opinion was presented. As it is conclusive for L-threonine produced by Escherichia coli strains NRRL B-30843, KCCM11133P and DSM 25085, these applications will be further processed together with the other positive opinions for L-threonine. For L-threonine produced by Escherichia coli strains DSM 26131, EFSA could not conclude on the safety of the genetic modification. Thus, the applicant will be contacted in order to clarify the follow-up.

A.2.11. Erythrosine in feed for cats, dogs, reptiles and ornamental fish

Following the discussion the Commission will contact the applicant to request additional information in order to discuss the follow-up.

A.2.12. Flavourings - Chemically Defined Group 01 SANTE-2015-12049

Following the discussion a new annex will be proposed for the next meeting.

A.03 Discussion on possible modifications and updating of Annexes of Regulation (EC) No 429/2008.

No discussion took place.

A.04 Discussion on proposal for new functional groups.

No discussion took place.

A.05 Follow up of OECD TF Novel Food-Feed Safety - Innovative novel feed ingredients and FAO/WHO Expert Meeting on Hazards Associated with Animal Feed.

A representative of the Commission informed about the report and future initiatives at international level.

A.06 Feed marketing Regulation (EC) N° 767/2009 :

A.6.1. Revision of Directive 2008/38/EC establishing the list of intended uses as particular nutritional purposes - Annex

Annex entries for 4 revised intended uses and the 3 remaining applications for intended uses with high additive concentrations were presented and discussed. The draft will be revised in the light of the discussion and presented in the next Committee.

A.6.2. Third amendment of the EU Catalogue of feed materials (Regulation (EU) N° 68/2013)

The draft revised by the Feed Chain Task Force based on the comments from the delegations was discussed. The comments from the Member States will be forwarded to the Task force. The Committee will come back on the issue once the Feed Chain Task Force submitted the necessary supplementary information.

A.6.3. Code of Good labelling practices for compound feed for food producing animals as presented by COPA-COGECA/FEFAC

A Commission representative stated that the assessment of the delegations of the draft Code of Good labelling practices for compound feed for food producing animals as elaborated by COPA-COGECA/FEFAC is finalised. The comments received will be forwarded to COPA-COGECA/FEFAC in order to fine tune their draft.

A.6.4. Revision of Annex VI and VII (labelling provisions)

Based on a working document distributed in the Committee the issues to be addressed on the occasion of the modernisation of the labelling provisions were discussed. The main issues were the indication of the active substance instead of the additive amount, the quantitative labelling of additives with a reduced recovery rate and the simplification for the indication of the functional groups. The draft will be further improved to consider the comments received.

A.07 RASFF.

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

The Committee was informed on recent RASFF notifications related to the presence of :

- aflatoxin B1 in maize from Italy and groundnuts for birdfeed from Brazil;
- lead in sunflower cake from China;
- dioxins in fish oil from Denmark;
- mercury in sugar beet pellets from Russia;
- pesticide residues imidacloprid in linseed from Kazakhstan and tolfenpyrad in citrus pulp pellets from the United States.

Following a request from Belgium, the Commission representative confirmed of having been informed by FEDIOL a few days earlier of the possible adulteration in Ukraine of sunflower oil with refined poultry oil. This adulteration is controlled by measuring the cholesterol levels in crude sunflower seed oil and which should not exceed 0,7 % related to total sterols. Based on controls performed by FEDIOL members there is no evidence that possibly adulterated sunflower oil has been placed on the EU market. The Commission representative committed to distribute all available information on this possible adulteration in Ukraine of sunflower oil by refined poultry oil via the RASFF.

A.08 Nitrites and nitrates.

A.08.1. Final discussion on the provisions as regards nitrites in Directive 2002/32/EC on undesirable substances in feed

A.08.2. Discussion on possible provisions as regards nitrites and nitrates in feed as Commission Recommendation.

Given the divergent views on the way forward expressed at previous meetings, the Commission representative distributed a questionnaire in order to identify the majority view of the committee on the way forward as regards the current provisions on nitrites in feed legislation and the possible future provisions on nitrates. The questionnaire lists the different options as regards
- the current maximum levels on nitrite in Directive 2002/32/EC;
- possible maximum levels on nitrate in Directive 2002/32/EC;
- a possible Commission Recommendation on the presence of nitrites and nitrates in feed.

Based on the answers received, the Commission has the intention to present the way forward at the next meeting of the Standing Committee.

A.09 Code of practice for the Manufacture of feed flavourings.

The presentation of the Code of Practice for the Manufacture of Feed Flavourings - FEFANA / FEFAC of September 2015 (version 1.0.) was circulated via Circa Bc to all EU Member States prior to this meeting, in view to be evaluated and commented by Member States.
This guide describes best practices regarding the design, manufacturing and labelling of flavourings and flavouring premixtures used for sensory purposes in animal feed. Considering the specificity of the creation of mixtures of flavourings and their use in feed, the manufacturers of these additives are acknowledged for having the full knowledge on the most appropriate practices in the production and use of feed flavourings.

Some Member States' comments were already sent to the Commission and other Member States informed that they will submit them soon. However some Member States questioned the legal basis of the guide and the fact that such guide should not be evaluated only according to Hygiene Regulation (EC) No 183/2005 but also according to Regulation (EC) No 767/2009.

A.10 Discussion on approval and registration of certain feed business operators (Regulation (EC) N° 183/2005).

The Commission replied to these queries during the meeting but some Member States would prefer receiving a written copy of these responses, due to the complexity of some questions.

A.11 Undesirable substances.

A.11.1. Gossypol in cotton seed. Discussion on possible amendments to current regulatory provisions

The Spanish delegation requested to review the maximum level for free gossypol in whole cottonseed and in complete feed for dairy cattle. The Spanish delegation

proposes to increase the maximum level of gossypol in cottonseed from 5000 mg/kg to 7000 mg/kg and for complete feed for dairy cows from 500 mg/kg to 700 mg/kg.
Data were provided to justify the request to increase the current maximum level for free gossypol in cottons seed and an scientific assessment demonstrating that the proposed increase of the maximum level for free gossypol in complete feed for dairy cattle would not result in adverse health effects.
The Commission representative indicated to have no objections to the proposed changes and no objections were raised at this stage from other delegations. Nevertheless several delegations indicated to wish to be able to examine the proposal in more detail before taking a final position.
The Commission representative indicated to put the issue back on the agenda for the next meeting of the Committee.

A.11.2. Other issues - tetrahydrocannabinol (THC) in feed

The EFSA panel on Contaminants in the Food Chain adopted on 5 June 2015 a Scientific Opinion on the risks for human health related to the presence of tetrahydrocannabinol (THC) in milk and other food of animal origin [1] .
The possible regulatory follow-up as regards the presence of THC in food of animal origin was discussed at the Expert Committee "Agricultural contaminants" on 18 September 2015. Based upon the available information, it was concluded that the presence of THC in food of animal origin, as a consequence of carry-over from feed, is unlikely to pose a health concern. It was found appropriate to monitor the presence of THC in food of animal origin in order to confirm that the assumptions on which the EFSA conclusion is based (i.e. only low levels of THC in food of animal origin as the consequence of carry-over from feed) are confirmed. On the other hand it was however noted that much higher levels of THC are found in hemp derived foods and foods containing hemp and hemp derived ingredients and that it would be appropriate to consider regulatory measures at EU level to limit the presence of THC in these foods.
Based on this outcome and currently available information, the Commission representative indicated that additional restrictions on the use of hemp and hemp derived feed materials in feed seems not to be necessary (taking into account the already existing restriction that only hemp and hemp derived feed materials may be used from varieties with a THC content not exceeding 0.2 %).
No comments were raised by the Committee on this conclusion.

[1] EFSA CONTAM Panel (EFSA Panel on Contaminants in the Food Chain), 2015. Scientific Opinion on the risks for human health related to the presence of tetrahydrocannabinol (THC) in milk and other food of animal origin. EFSA Journal 2015;13(6):4141, 125 pp. doi:10.2903/j.efsa.2015.4141 Available online: www.efsa.europa.eu/efsajournal

B.01 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation concerning the authorisation of the preparation of alpha-galactosidase (EC 3.2.1.22) produced by Saccharomyces cerevisiae (CBS 615.94) and endo-1,4-beta-glucanase (EC 3.2.1.4) produced by Aspergillus niger (CBS 120604) as a feed additive for laying hens and minor

poultry species for laying (holder of the authorisation Kerry Ingredients and Flavours).

The draft Regulation is related to new authorisation as zootechnical additive of an enzyme preparation.

Vote taken: unanimous in favour.

B.02 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation concerning the authorisation of the preparation of endo-1,4-beta-xylanase and endo-1,3(4)-beta-glucanase produced by Talaromyces versatilis sp. nov. IMI CC 378536 and Talaromyces versatilis sp. nov DSM 26702 as a feed additive for turkeys for fattening and reared for laying and for breeding (holder of the authorisation Adisseo France S.A.S.).

The draft Regulation is related to new authorisation as zootechnical additive of an enzyme preparation.

Vote taken: unanimous in favour.

B.03 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation concerning the authorisation of the preparation of endo-1,4-beta-glucanase (EC 3.2.1.4) produced by Trichoderma citrinoviride Bisset (IM SD142) as a feed additive for chickens for fattening, minor poultry species for fattening and weaned piglets, and amending Regulations (EC) No 2148/2004, (EC) No 1520/2007 (holder of authorisation Huvepharma NV).

The draft Regulation is related to new authorisation as zootechnical additive of an enzyme preparation.

Vote taken: unanimous in favour.

B.04 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation concerning the authorisation of L-cysteine hydrochloride monohydrate as a feed additive for cats and dogs.

The draft proposes to authorise L-cysteine hydrochloride monohydrate as a feed flavouring for cats and dogs. A discussion took place.

Vote taken: favourable opinion.

B.05 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation concerning the authorisation of menadione sodium bisulphite and menadione nicotinamide bisulphite as feed additives for all animal species.

The draft proposes to authorise two forms of vitamin K_3 as nutritional additives for all animal species.

Vote taken: unanimous in favour.

C.01 Exchange of views 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 and pigs for fattening.

A representative of the Commission presented the draft Commission Implementing Regulation as a preliminary working document. As a result of the discussion held in the Committee at its meeting of 7 and 8 September 2015, the document proposes a measure based on Article 15 of Regulation (EC) No 1831/2003, consisting of a provisional authorisation.
An exchange of views took place. A draft measure will be submitted possibly for an opinion of the Committee at its next meeting.

M.01 A.O.B.

a) The delegation of Denmark referred to the recent Commission Regulation (EU) 2015/1940 of 28 October 2015 amending Regulation (EC) No 1881/2006 as regards maximum levels of ergot sclerotia in certain unprocessed cereals intended for human consumption and requested if there were consequences as regards the provisions of ergot sclerotia in cereals for animal feed. The Commission representative indicated that Directive 2002/32/EC already provides for a maximum level of ergot sclerotia in unground cereals intended for animal feed. Commission Recommendation 2012/154/EU of 15 March 2012 on the monitoring of ergot alkaloids in feed and food, recommends that Member States should perform with the active involvement of the feed and food business operators monitoring on the presence of ergot alkaloids in cereals and cereal products intended for human consumption or intended for animal feeding, in pasture/forage grasses for animal feeding and in compound feed and food. It is foreseen to establish maximum levels for ergot alkaloids in food before 1 July 2017 and it was indicated that simultaneously to the discussions in food expected to take place end of 2016 early 2017, the need to set possible maximum levels for ergot alkaloids in feed will be discussed in this Committee.
b) the delegation of Finland made reference to the provisions of Commission Regulation (EU) 2015/786 of 19 may 2015 defining the acceptability criteria for the detoxification processes applied to products intended for animal feed and requested if guidelines are under elaboration or will be elaborated by EFSA and/or the Commission for the information to be provided to the Commission to enable EFSA to perform a scientific risk assessment on the detoxification process. The Commission representative indicated that such guidelines are not under elaboration and it is not the intention to elaborate such guidelines. The Annex to the Regulation provides in detail the information that has to be provided to enable EFSA to assess the detoxification process and to conclude if the detoxification process complies or not with the acceptability criteria. In case there are specific question on one or another aspect, these can be addressed to the Commission services for reply.
c) The delegation of Germany reported the finding of significant levels of the unauthorised ethylenediamine in imported feed for birds. Ethylenediamine is used in

large quantities for production of many industrial chemicals. Furthermore according to Wikipedia, ethylenediamine dihydroiodide (EDDI) is added to animal feeds as a source of iodine.