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 17 JULY 2017 - 19 JULY 2017

(Section Animal Nutrition)

CIRCABC Link: https://circabc.europa.eu/w/browse/05639f41-cc19-4f70-8a00-c69a572f5065

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

A.01.1. Discussion on Sacox for rabbits.

Following the discussion, the application submitted under Article 15 can be forwarded to EFSA for the assessment.

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

A.02.1. Bacillus subtilis PB6 (Bacillus subtilis ATCC PTA-6737) as a feed additive for sows – Annex

A draft Regulation will be submitted for the vote in a future meeting.

A.02.2. lecithins for all animal species – Annex

A draft Regulation will be submitted for the vote in a future meeting.

A.02.3. OPTIPHOS® (6-phytase) as a feed additive for finfish – Annex

A draft Regulation will be submitted for the vote in a future meeting.

A.02.4. Calsporin® (Bacillus subtilis DSM15544) for sows and suckling piglets – Annex

An Annex will be presented in a future meeting.

A.02.5. Lactobacillus acidophilus D2/CSL (Lactobacillus acidophilus CECT 4529) as a feed additive for chickens for fattening – Annex

An Annex will be presented in a future meeting.

A.02.6. Lactobacillus hilgardii CNCM I-4785 as a silage additive for all animal species – Annex

An annex will be presented in a future meeting.

A.02.7. Amylofeed (endo-1,3(4)-b-glucanase and end o-1,4-b- xylanase and a-amylase) as a feed additive for piglets and minor porcine species

Supplementary information will be requested to the applicant.

A.02.8. BioPlus 2B® (Bacillus subtilis DSM 5750 and Bacillus licheniformis DSM 5749) as a feed additive for sows, piglets, pigs for fattening, turkeys for fattening and calves

An annex will be presented in a future meeting for the authorization on suckling piglets.

A.2.9. zinc chelate of methionine sulfate for all animal species

The opinion was presented. As EFSA could not conclude on the safety for the target species, the applicant will be contacted.

A.2.10. L-arginine produced by Corynebacterium glutamicum KCCM 80099 for all animal species

The conclusive opinion was presented. An Annex entry will be prepared for the next meeting.

A.02.11. indigo carmine (E 132)

The Commission's representative explained that the applicant submitted new information on the purity of the additive with a view to demonstrate that for that purity the additive was safe. The information has been submitted to EFSA for its assessment.

A.02.12. flavourings belonging to CDG 024 for all animal species

After the discussion of the Annex entry a draft will be proposed for vote.

A.02.13. flavourings belonging to CDG 014 for all animal species

After the discussion of the Annex entry a draft will be proposed for vote.

A.03 Feed marketing Regulation (EC) No 767/2009

A.3.1. Dietetic feed (Directive 2008/38/EC): state of play of pending evaluations, new applications and draft Regulation for repealing the Directive

The Commission's representative gave an update on the ongoing evaluation of applications and informed the committee about a new application concerning the "Reduction of risk of milk fever", replacing an earlier one from the same applicant. Furthermore, part A of the Annex to the revised draft dietetic feed Regulation was discussed. In the light of the comments received, the draft Regulation will be further revised.

A.3.2. Guidelines for the use of former foodstuffs as feed

The discussion was postponed.

A.3.3. Feed material classification: brewery by-product, Morus Alba

The Committee concluded that "Alcohol water" produced as by-product from alcohol-free beer production can be considered a feed material. In line with the Catalogue entry "Feed beer" (13.1.15), the alcohol should be declared and considered when formulating the animals diet.

The entry "Morus Alba" in the Register of feed materials was discussed. Whereas there is no concern about the description (Morus Alba twig dried and powdered), the denomination of the feed material with the botanical name of the plant should be changed.

The presence of superoxide dismutase in feed materials was discussed. The Committee will come back on the issue.

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

As an outcome of the work of the reduced working group, the Commission's representative presented for discussion a new version of the document. Some of the Chapters still need further discussions. It was agreed on sending written comments.

A.04.2. Exchange of views on measures for non-authorised additives intended for export. The Commission's representative presented for discussion a new version of the document. It was agreed on sending written comments

A.04.3. National guidelines and database related to Regulation (EC) No 183/2005

The Commission's representative informed that the new database for national guidelines in the feed sector is already available in the webpage of DG SANTE. It was requested to provide information on the national contact points for the managing of the database.

A.05 RASFF.

A.05.1 Update and exchange of views on recent RASFF notifications.

The Commission representative informed the Committee on the RASFF notifications related to undesirable substances in animal feed, issued since the meeting of the Committee in May 2017.

The notifications related to a too high level/content of

- ragweed seeds (Ambrosia spp.) in birdfeed from Poland and in seeds mixtures for birds from the Netherlands;
- aflatoxins in groundnut kernels for birdfeed from China, in peanuts from US, in peanuts from Egypt and in rice bran from UK;
- dioxins in cobalt carbonate from China and zinc oxide from Spain;
- mercury in fodder yeast from Russia;
- free gossypol in cotton seeds from Greece.

A delegation raised the issue that certain notifications are rejected by the RASFF while these were in the past accepted by RASFF. The delegation highlighted the importance of the notification in order to inform other competent authorities of the finding of non-compliance, to ensure an appropriate follow-up in the Member States and to inform the competent authority of the country of origin of the non-compliance to enable them to take the necessary measures to avoid such non-compliance in the future.

The Commission's representative indicated that this issue was already extensively discussed at a previous meeting of the Committee (point A.06.2 of the meeting of the Committee on 18-19 February 2016).

He shortly re-iterated that only notifications related to a finding indicating a "serious risk" are accepted for notification through the RASFF system. This means that not every non-compliance with EU legislation has to be notified through the RASFF system but that there should be a serious risk to human or animal health or to the environment. Where the outcome of official controls on feed and food indicates a non-compliance but not involving a serious risk and the finding requires action in more than one Member State, competent authorities shall provide each other with administrative assistance. Commission Implementing Decision (EU) 2015/1918 of 22 October 2015 establishing the Administrative Assistance and Cooperation system ('AAC system') lays down the rules concerning the establishment and use of the Administrative Assistance and Cooperation system (the 'AAC system') to support the exchange of information between the competent authorities of the Member States, and between those competent authorities and the Commission. It was concluded that it would be appropriate that a representative from the RASFF team provides at a next meeting of the Committee an update on the progress on the interaction/integration between the two systems and this also in view of the Information management system for official controls (IMSOC) to be set up in application of Regulation (EU) 2017/625 (Official Controls Regulation).

A.06 Undesirable substances.

A.06.1 Exchange of views on a draft Recommendation on nitrites and nitrates in feed

Divergent views were expressed on the necessity to have guidance values for nitrates and nitrites in certain feed. The relevance of the presence of high levels of nitrates and nitrites in silage was highlighted, noting that no maximum levels were set for nitrites in silage. In addition some Member States in favour of setting guidance levels indicated that such levels should be set on the basis of a risk assessment and therefore it would be appropriate to request EFSA to perform a comprehensive risk assessment on the presence of nitrates and nitrites in feed (including an update of the opinion on nitrites in feed).

As regards the other recommendations on good practices, including good feeding practices, in relation to the presence of nitrate and nitrites in feed, it was found appropriate to compile information on sources and factors resulting in the presence of high levels of nitrates and nitrites in feed.

Also the difficulties as regards the analysis of nitrates and nitrites in certain feed materials and the lack of screening methods providing a quick result was highlighted. The Commission representative informed the Committee that the report on the state of art on the methods of analysis for analysing the presence of nitrites in (wet) feed was not yet available. Information on a method of analysis was made available (determination of nitrite and other anions in molasses using ion chromatography).

Following the discussions, the Commission's representative suggested the following way forward:

- to request EFSA for an opinion on the risks for animal health related to the presence of nitrates and nitrites in feed.
- to provide a compilation of sources and factors resulting in the presence of high levels of nitrates and nitrites in feed.
- to ensure that further work is undertaken on the analysis of nitrites (and nitrates) in feed, in particular wet feed materials. This would be one of the tasks of the EURL on metals and nitrogenous compounds in feed and food.
- to discuss at a next meeting the need to maintain in the meantime the current maximum levels for nitrites in feed established by Directive 2002/32/EC on undesirable substances in feed.

A.06.2. Exchange of views on the different topics for possible future amendment of the annexes of Commission Directive 2002/32/EC (arsenic in peat and leonardite, nitrites, gossypol, definition of trace amounts, dioxins and p-phenetidine)

The Committee was informed of the updated information on the presence of arsenic in leonardite (data on the presence organic and inorganic arsenic in leonardite), gossypol (EFSA statement), dioxins in binders and anti-caking agents (data on the presence of dioxins in binders and anti-caking agents and p-phenetidine (information provided by the authorisation holder of ethoxyquin).

As regards the different points the following way forward was suggested for further discussion:

- to consider the setting of a higher level for total arsenic in peat and leonardite with the requirement that upon request of the competent authorities, the feed business operator must perform an analysis to demonstrate that the content of inorganic arsenic is lower than 2 ppm (the current maximum level for total arsenic).
- as regards nitrites in feed, reference is made to the discussions under point A.06.1.
- the Scientific Panel on Contaminants in the Food Chain (CONTAM) adopted at its 84th plenary meeting in May 2017 a scientific statement on the presence of free gossypol in whole cottonseed. It was concluded that an update to the Scientific Opinion on gossypol as an undesirable substance in animal feed was not required. Taking into account the conclusions of the scientific statement, a higher maximum level than the current maximum level of 5000 mg/kg of free gossypol in cottonseed could be considered.- The Committee was informed that as regards the proposed clarification of the term "trace amounts not quantitatively determinable", the Commission has the intention to consult experienced microscopic analysts before finalising it.
- to consider the extension of the maximum level of dioxins, sum of dioxins and dioxin-like PCBs and non-dioxin like PCBs established for certain binders and anticaking agents to all additives of the functional group of binders and anti-caking agents.
- information was provided on the progress of the development of a sufficiently sensitive method of analysis to analyse p-phenetidine in feed (additives, feed materials and compound feed).

These issues shall be discussed in more detail at the next meeting of the Committee.

A.06.3 Update on assessment by EFSA on detoxification processes

The Committee was informed that EFSA's CONTAM Panel has adopted at its 85th meeting in July 2017 an opinion as regards an application of the decontamination of fish oil for dioxins and PCBs by physical filtration with activated carbon. For the other 5 applications additional information was requested to the applicant to enable completion of the assessment.

A.06.4. Other issues, including the points raised under any other business at the last meeting as regards the presence of tetrahydrocannabinol in hemp derived products and presence of opium alkaloid containing plants in hay for race horses.

- tetrahydrocannabinol in hemp derived products: the Commission's representative informed the Committee to expect to be able to provide the requested information at the next meeting of the Committee
- opium alkaloid containing plants in hay for race horses: The Commission's representative informed the Committee to have consulted experts on the question whether the consumption of hay, contaminated with Papaver sp. by race horses could result in positive blood tests for opium alkaloids. Papaver somniferum (white flower) does not grow in the wild and the probability that this plant grows in a grass field and contaminates hay is very unlikely. The Papaver rhoeas (red flower) grows very frequently in the wild, however the alkaloid content is very low and the consumption by horses of this plant as botanical impurity in hay would not give rise to positive blood test results.

- a delegation requested to have an overview of undesirable substances for which it is expected that possible regulatory measures might be discussed in the near future. This information would be useful for the laboratories to develop the methods of analysis therefore if needed and for competent authorities to take this into account in future surveys to collect the necessary monitoring results in support of risk assessment and/or the discussion on possible risk management measures. The Commission's representative indicated to provide that information at the next meeting of the Committee.

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

A discussion took place on proposed modifications of Annex I, Annex II, Section II: 2.1, 2.2, 2.3, 2.4, 2.5. Section III: 9, 10 and 11. Annex IV. Several comments were done to clarify some aspects. A new proposal on Annex III and a possible a new version of the documents already discussed will be proposed in a future meeting.

A.08 Products intended to disinfect equipments in feed producing factories (France's request).

France's representative explained the issue due to the use of some products to disinfect equipment contaminated by Salmonella. It was concluded that they would be considered as biocide and not as feed additives.

B.01 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation concerning the authorisation of cholecalciferol as a feed additive for all animal species.

The draft proposes the authorisation of cholecalciferol (vitamin D3) for all animal species.

A discussion took place.

The Commission's representative informed that increasing the levels for fish will require additional studies for the impact on the environment. The Commission will contact the representative of Norway to verify if those studies will be available and then request to EFSA a new assessment for the environment.

Vote taken: Unanimity.

B.02 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation concerning the authorisation of disodium 5'-ribonucleotides, disodium 5'-guanylate, disodium 5'-inosinate as feed additives for all animal species.

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

Vote taken: Favourable opinion.

B.03 Exchange of views and possible opinion of the Committee on a draft Commission Regulation amending Annexes II, IV, VI, VII and VIII to Regulation (EC) No 767/2009 on the placing on the market and use of feed.

The draft Regulation concerns the revision of the Annexes II, IV, VI, VII and VIII to Regulation (EC) No 767/2009 concerning feed labelling.

Vote taken: Unanimity.

B.04 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation concerning the authorisation of Manganous chloride tetrahydrate, Manganese (II) oxide, Manganous sulphate monohydrate, Manganese chelate of amino acids hydrate, Manganese chelate of protein hydrolysates, Manganese chelate of glycine hydrate and Dimanganese chloride trihydroxide as feed additives for all animal species.

The draft Regulation concerns the authorisation of seven compounds of manganese as trace elements for all animal species.

Vote taken: Unanimity.

B.05 Exchange of views and possible opinion of the Committee on a draft Commission Regulation amending Annex I to Directive 2002/32/EC of the European Parliament and of the Council as regards maximum levels for certain undesirable substances.

The draft Regulation envisaged following changes to the Annex I to Directive 2002/32/EC:

- establishment of a specific maximum level of 200 mg/kg of lead in dicopper oxide;
- increase of the maximum level for mercury for fish, other aquatic animals and products derived thereof intended for the production of compound feed for dogs, cats, ornamental fish and fur animals;
- establishment of a maximum level of melamine in the feed additive guanidinoacetic acid ('GAA');
- deletion of the maximum level for unavoidable carry-over of decoquinate in withdrawal feed for chickens for fattening following changes in the authorisation conditions.

Following discussions, the Committee agreed to limit the increase of the maximum level for mercury in tuna and products derived thereof intended for the production of compound feed for dogs, cats, ornamental fish and fur animals.

The Committee was furthermore informed that following previous discussions it was concluded that fish on the hook as fish bait is not to be considered as feed.

Vote taken: Unanimity.

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

A discussion took place. Member States requested a lot of clarifications on the legal and technical aspects on the denial and on the provisional authorisation. Not all Member States took part to the discussion and not all of them expressed a clear position on the proposal, so the document will be submitted for the discussion to a future meeting of the Standing Committee, pending also some legal aspects.

C.02 Exchange of views of the Committee on a draft Commission Implementing Regulation amending Implementing Regulation (EU) No 1068/2011 as regard the modification of the concerning the authorisation of Salinomycin sodium 120 g/kg (Sacox 120 microGranulate) and Salinomycin sodium 200 g/kg(Sacox 200 microGranulate) as a coccidiostat for chickens for fattening and chickens reared for laying, and amending Regulations (EC) No 1852/2003, (EC) No 1463/2004 and 500/2007 (holder of authorisation Huvepharma NV).

Following the discussion, the draft Regulation will be submitted for the vote in a future meeting, pending some legal aspects.

M.01 A.O.B.

- The Commission's representative informed that FEFANA (European Association for Specialty Feed Ingredients and their Mixtures) had indicated some difficulties in the implementation of the new flavouring regulations.

Some recommended levels were insufficient for certain additives to cover all the species and uses.

The transitional measures do not allow sufficient time to implement all the changes in due time although the sector is doing a huge effort to comply with the deadlines.

- A delegation indicated that it would be appropriate to establish at EU level sampling procedures for the control of the presence of microbiological contamination in feed. The Commission's representative indicated that the establishment of sampling procedures for microbiological contamination is linked to the establishment of microbiological criteria, which are to be defined in accordance of Article 5 of Regulation (EC) No 183/2005 of the European Parliament and of the Council of 12 January 2005 laying down requirements for feed hygiene.
- At the occasion of Better Training For Safer Food trainings and the inspections performed by the Directorate F - Health and food audits and analysis of the DG Health and Food Safety of the European Commission, the appropriateness of a guidance document for official controls to detect carry-over of coccidiostats and to evaluate homogeneity of feed in view of a harmonised approach was highlighted. The Committee expressed a favourable attitude to this but highlighted the need to make use of existing guidance documents and to clearly identify in advance the scope and the purpose of such a guidance document. The Commission's representative indicated that it would be appropriate to make an inventory existing

national/international/industry guidance documents as a starting point for further discussions.

- Short information was circulated on the update of the ongoing studies to complete the assessment of ethoxyquin.