



EUROPEAN COMMISSION

Health and Food Safety Directorate General

sante.ddg2.g.5(2018)6479752

**SUMMARY REPORT OF THE
STANDING COMMITTEE ON PLANTS, ANIMALS, FOOD AND FEED
HELD IN BRUSSELS ON 07 NOVEMBER 2018 - 09 NOVEMBER 2018
(Section *Animal Nutrition*)**

CIRCABC Link: <https://circabc.europa.eu/w/browse/80074c87-07cf-4939-a16a-2cd8451d1a3e>

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. alpha-amylases from *Bacillus amyloliquefaciens* DSM 9553, *Bacillus amyloliquefaciens* NCIMB 30251 and *Aspergillus oryzae* ATTC SD-5374 and endo-1,4-beta-glucanase from *Trichoderma reesei* ATCC PTA-10001 as silage additives for all animal species – Annex

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

A.02.2. renewal of authorisation of Levucell® SC (*Saccharomyces cerevisiae* CNCM I-1077) as a feed additive for dairy ewes and dairy goats – Annex

A draft Regulation will be proposed to a future meeting.

A.02.3. renewal of authorisation of Calsporin® (*Bacillus subtilis* DSM 15544) for chickens for fattening – Annex

A draft Regulation will be proposed to a future meeting.

A.02.4. renewal of authorisation of Actisaf® Sc47 (*Saccharomyces cerevisiae* CNCM I-4407) for lambs for fattening, minor dairy ruminants, horses and pigs for fattening – Annex

A draft Regulation will be proposed to a future meeting.

A.02.5. Aviax 5% (semduramicin sodium) for chickens for fattening

This item was not discussed.

A.02.6. COXAM® (amprolium hydrochloride) for chickens for fattening and chickens reared for laying

An updated of the conclusion on consumer safety was presented.

A.02.7. updated on Avatec for re-evaluation

This item was not discussed.

A.02.8. sodium saccharin when used as a feed flavour for piglets, pigs for fattening, calves for rearing and calves for fattening (EFSA Opinion)

Member States were informed that the Commission sent to the applicant a request of complementary information to clarify the concerns expressed in the EFSA Opinion. Notably, certain effects on the environment.

A.02.9. a super critical carbon dioxide 1 extract of *Humulus lupulus* L. flos when used as a feed flavouring for all animal species

The annex entry was discussed. Member states were invited to submit comments with a view to adopt the Regulation. For those species for which the EFSA Opinion did not conclude, the applicant will receive a letter asking complementary information although he has already indicated its willingness to submit that information.

A.02.10. Zinc chelate of methionine hydrate for all animal species

The Opinion was presented and a draft Annex will be prepared for the next Committee meeting.

A.02.11. L-Threonine for all animal species

The Opinion was presented and a draft Annex will be prepared for the next Committee meeting.

A.02.12. renewal of authorisation of selenomethionine produced by *Saccharomyces cerevisiae* CNCM I-3060 (selenised yeast inactivated) for all animal species - Annex entry

The Annex was discussed and a draft authorisation Act will be prepared for a future Committee meeting.

A.02.13. benzoic acid for pigs and poultry as flavouring compound under the conditions of Regulation (EC) 1831/2003

After discussion, it was agreed to prepare a letter to the applicant to respond to the arguments indicated in his letter dated on 20 September 2018.

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

A.03.1. Dietetic feed (Directive 2008/38/EC) - state of play of pending evaluations and discussion of the draft Regulation for repealing the Directive

A revised draft for a Regulation was presented considering the Member States' comments received. The draft will be further revised in the light of the discussions and presented in the next Committee.

A.03.2. Feed material classification - arbitrary entries in the Register of feed materials

The Committee discussed several lists of arbitrary entries in the Register of feed materials elaborated by several Member States. It became evident that the number of incorrect entries is enormous. An updated screening of the Feed Chain Task Force will be distributed to the Member States for their comments. For the future, the Committee suggested a better filtering of incorrect entries in the moment of their notification.

A.03.3. Legal status of borderline substances - C(M)IT/MIT, Sodium hydroxide ("caustic soda")

The legal status of C(M)IT/MIT used in feed for aquatic animals was discussed. Before a conclusion, supplementary information is needed.

With respect to the use of sodium hydroxide (NaOH), the Committee confirmed its assessment of its meeting in March 2011. NaOH used to rumen protect feed materials or to digest the external fibres of straw or other fibre rich feed materials is to be considered a processing aid and not a feed additive. However, if the NaOH is used to produce a silage of cereal grains with a high moisture content (instead of drying them), it would be considered a feed additive for which an authorisation is required.

A.04 List of products considered out of the scope of Regulation (EC) No 1831/2003 and list of feed additives to be withdrawn from the market.

A discussion took place on the basis of two preliminary working documents which were circulated to the Committee's members.

Those documents will be reviewed taking into account the comments and position expressed during the meeting and communicated to the Commission in due time before the next Committee's meeting.

A.05 Issues related to Regulation (EC) No 183/2005 laying down requirements for feed hygiene.

A.05.1. Outcome of the final consultation about the Commission working document - Guidance document on the implementation of certain provisions of Regulation (EC) No 183/2005 on the hygiene of feedstuffs

The final version of the document was not discussed. However a brief discussion was held on some particular questions raised by some delegations. The final version of the document will be presented during a future Committee meeting.

A.05.2. European Guide to Good Practice for the Processing of Former Foodstuffs for Use as Feed for Food-Producing Animals (EFFPA)

The Commission's representative presented to the Member States the "European Guide to Good Practice for the Processing of Former Foodstuffs for Use as Feed for Food-Producing Animals" drawn up by the European Formerfoodstuffs Processors Association. It was agreed on sending written comments before 15 January 2019.

A.05.3. Possible establishment of EU harmonised criteria in order to verify the manufacturing and mixing accuracy in feed business (Document from DE)

The Commission's services have been contemplating to propose an Unionguide on matters relating to homogeneity and carryover in the feed production. The need of a guidance with harmonized criteria to evaluate the measures put in place by the FeBOs in this regard seems also opportune, based on the outcome of recent feed audits carried out by Directorate F of DG SANTE in several Member States.

Later some delegations have also raised this issue on how harmonized criteria could be established in the EU in order to verify the manufacturing and mixing accuracy in feed businesses. Germany has issued a guidance document to be used by control authorities in order to promote a harmonised approach among different competent authorities which has been distributed to all Member States.

A discussion was held and a majority of Member States supported the initiative of developing a guide as the one mentioned, taking into account the already existing measures in place in the Member States.

The Commission's representative invited the Member States which already have developed national guides and would wish to share them in view of developing an Union guide, to provide them to the Commission before drafting could be started.

A.06 Discussion on a possible amendment of Annex I to Regulation (EC) No 1831/2003.

After short discussion, it was agreed to consider some changes in the text. Member States were invited to submit proposals.

A.07 Status of gelling agents in water to limit the drowning of larvae.

Question

The use of gelling agents in water for farmed insects was discussed.

The product is comprised of gelling agents already authorised for use in feed and/or food. The technical aim of adding gelling agents to the water is to keep the insects (mealworms farmed at larvae stage) hydrated, and limit their risk of drowning.

The gelling substances would be ingested together with the water, but there is no actual nutritional effect aimed or expected to come from the gelling agents themselves.

If this product does not fall within the definition of a technological feed additive, would you consider such an additive to fall under the zootechnical category under the welfare functional group, whereby the claim would be to reduce mortality from drowning? We could perform studies in insects (the target animal) to show a significant reduction in mortality as an endpoint. Do you think that this would be a viable approach?

Response

After discussion, it was agreed that those gelling agents fall under the category "technological additives" and under functional group "gelling agents" as they perform a technological function on the water and they ingested by the larvae. To be used they need to be authorised under Regulation (EC) No 1831/2003 for the use in water.

A.08 Discussion on the amending Regulation (EC) No 429/2008.

A new part on the analytical method for the detection of some impurities has been presented. A discussion has been held. Some Member States requested to organise a Working Group. A new version will be presented in a future meeting.

A.09 Discussion on the possible use of Sacox for rabbit (Article 15).

This item was not discussed.

A.10 RASFF.

A.10.1. 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 September 2018.

The notifications related to a too high level/content of :

- aflatoxins in groundnuts from India (2) and Tanzania;
- dioxins in coated calciumchloride from Belgium;
- dioxins, dioxin-like PCBs and non-dioxin-like PCBs in sunflower fatty acids from Ukraine;
- lolitrem B in hay from France;
- ragweed (*Ambrosia* spp) in sunflower seeds from Slovakia;
- salinomycin in poultry feed ingredient from the Netherlands and diclazuril in frozen chick liver from Brazil for pet food;
- dichlorvos in corn for feed from Argentina.

Lolitrem B is an indole diterpene alkaloid produced by the fungus *Neotyphodium lolii*, an endophyte of perennial rye grass (*Lolium perenne*), the primary causative agent of ryegrass staggers.

Following the recurrent findings of dioxins and PCBs in feed materials originating from Ukraine, it is necessary to remain very vigilant as regards the presence of dioxins and PCBs in feed materials from Ukraine and to perform the necessary controls.

A.11 Undesirable substances.

A.11.1. Exchange of views on issues related to undesirable substances in feed (details to follow)

Endosulfan in feed

The Committee was informed of the data provided by Member States and professional stakeholder organisations on the presence of endosulfan in fish feed. Taking into account these data, the current maximum level of endosulfan in feed for *Salmonids* of 0.05 mg/kg can be lowered. Also the maximum level of endosulfan in compound feed for other animal species can be lowered. However as it is important that the lower maximum level can be reliably enforced by routine methods of analysis, the EURL shall be requested to provide for next meeting advice on what levels can be reliably analysed by routine methods of analysis.

Ambrosia seeds

The delegation of France informed the Committee of [opinions from ANSES](#) on *Ambrosia* sp., highlighting that the risks linked to [Ambrosia trifida](#) are much higher than from [Ambrosia psilostachya](#). Introduction from the area of origin is difficult to control and therefore a very strict application and enforcement of the provisions in Directive 2002/32/EC is necessary.

It was again highlighted by several delegations that there are currently no provisions as regards the presence of seeds from *Ambrosia* sp. in food and that it is necessary to have similar provisions for food as for feed in order to prevent further dissemination of *Ambrosia* on the European territory.

The Commission's representative mentioned to be aware thereof and acknowledged the need to establish similar provisions as regards the presence of *Ambrosia* seeds in food as in feed. However, the scope of the undesirable substances in feed legislation is larger than the scope of the contaminants in food legislation. The commitment was

made to consider again the possibility to include a provision to restrict the presence of *Ambrosia* seeds in food to prevent further dissemination of *Ambrosia* in the environment and thereby protecting public health.

The Committee was also informed that the Commission services would address a request to EFSA to assess the efficacy of different processing and detoxification methods to make the *Ambrosia* seeds unviable/ to destroy the germination power.

Detoxification

The Committee was informed that the assessment by EFSA on the application for the detoxification of groundnut meal by ammonia for the presence of aflatoxins is still ongoing, awaiting additional data from the applicant.

In the detoxification process, formaldehyde is used to enhance the efficacy of the detoxification process. Given the denial of authorisation of formaldehyde as feed additive by [Commission Implementing Regulation \(EU\) 2018/183](#), the feasibility and efficacy of the detoxification process without the use of formaldehyde is currently examined by the applicant. Based on the outcome the applicant shall inform the Commission before the end of this year to pursue or withdraw the application.

Hydroxymethylfurfural (HMF) in feed for honeybees

The Committee was informed that the Commission services have the intention to request EFSA to perform an assessment of the animal health risks for bees due the presence of HMF in feed for honeybees, in view of possible regulatory measures.

Information on opinions from EFSA relevant for feed

The Committee was informed of the publication within short notice of the opinion on [Risk for animal and human health related to the presence of dioxins and dioxin-like PCBs in feed and food](#). Discussions on the follow up of this opinion as regards possible risk management measures, e.g. review of current maximum levels, to prevent and reduce the presence of dioxins and dioxin-like PCBs in feed will take place in the next meetings of the Committee.

The Committee was informed that one of the recommendations in the opinion is that more occurrence data on dioxins and dioxin-like PCBs in feed are needed. The Commission representative indicated that that there are many controls performed on the presence of dioxins and dioxin-like PCBs in feed by authorities and feed business operators. However, most of the occurrence data from controls are not useful for the purpose of the risk assessment. This is because the controls are performed in many cases by a screening technique such as CALUX (while congener specific data were requested) and controls are performed risk-based (targeted or based on suspicion), while for the purpose of the risk assessment occurrence data on background presence (random sampling) were requested.

Furthermore, the Committee was informed of the future publication of the EFSA opinion on Perfluorooctane Sulfonate (PFOS) and Perfluorooctanoic Acid (PFOA). Once the opinion is published a discussion will need to take place to which extent a regulatory follow up as regards feed is needed.

A.12 Review of Commission Regulation (EC) No 152/2009 of 27 January 2009 laying down the methods of sampling and analysis for the official control of feed.

A.12.1. Update and exchange of views

The Committee was informed of the additional comments as regards topics to be reviewed as regards the provisions provided for by Regulation (EC) 152:2009. The Commission's representative requested delegations who have not yet submitted comments to do so as soon as possible (in case they have comments). A specific dedicated meeting to discuss the review of the Regulation 152/2009 will take place later on this year or early next year.

A.13 A.O.B.

- The issue of vitamin B2 as a feed additive was raised, in relation to RASFF notification 2018.2755 and to Commission Implementing Regulation (EU) 2018/1254 concerning the denial of authorisation of riboflavin (80 %) produced by *Bacillus subtilis* KCCM-10445 as a feed additive.

An exchange of views took place. In particular, a Commission representative made clear that Commission Implementing Regulation (EU) 2018/1254 applies without prejudice to the application of other relevant EU legislation, such as Regulation (EC) No 1829/2003 on genetically modified food and feed.

This issue will be further discussed on the occasion of the next Committee's meeting, taking account of the last information received as a follow-up to the RASFF notification.

- Concerning the discussion on muramidase from *Trichoderma reesei* DSM 32338 as a feed additive for chickens for fattening and minor poultry species, a draft Regulation will be proposed to a future meeting.

- Use of flavourings in oysters

Question raised by France

A French operator has designed a process to change the taste of oysters by immersing them in water containing natural flavourings for a few hours, right before packaging them and sending them away. The French delegation seeks clarification on how to regulate this practice, as :

- the oysters are still alive and ingest the flavouring (thus giving flavour their flesh) as they filtrate the water => it qualifies as a use of feed additives;
- but live oysters (ready to eat, since the process takes place at the very end of production) are also foodstuffs according to the definition of Regulation 178/2002 => it could be considered a use of a flavouring compound on food.

The matter is further complicated by the fact that, according to Annex I of Regulation 1831/2003, flavourings in feed can only be used to change the smell or palatability of the feed. It is not allowed to use flavourings in feed in order to change the taste of the food produced by the animal.

Response

Article 5(3) to Regulation 1831/2003 allows feed additives to favourably affect the characteristics for the feed. It is the case for example of a colorant that provides colour to meat of eggs. For flavourings there is not a functional group established to perform this action, therefore, they cannot be used as feed additives.

The use as food flavourings was also indicated by some delegations provided that the flavourings are authorised under the food legislation and they are labelled in

accordance with the relevant labelling provisions applicable to food. It was agreed to further explore this possibility.

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

The draft Regulation authorises a nutritional additive “betaine anhydrous” as a feed additive for food-producing animals except rabbits.

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 sodium selenite, coated granulated sodium selenite and zinc-L-selenomethionine as feed additives for all animal species.

The draft Regulation concerns the authorisation of three compounds of selenium as feed additives.

The UK delegation made the following declaration :

"In July 2014, the UK abstained on the feed additive authorisation of selenomethionine following the statutory reduction of a maximum content for the organic form to 0.2 mg/kg selenium in complete feed. Prior to this reduction, organic forms of selenium authorised as feed additives had a maximum content of 0.5 mg/kg. Work undertaken on behalf of the United Kingdom Government has suggested that a significant proportion of our population is under-exposed to dietary selenium, a trace element that is essential for human health. In view of the possibility that the low maximum limit for this organic form of selenium could result in lower levels of this essential trace element in the diet of consumers, the United Kingdom maintains its principle in not supporting the European Commission's proposal for point B.02 and therefore abstained in the decision taken for this item."

Vote taken: Favourable opinion.

B.03 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation concerning the authorisation of L-arginine as a feed additive for all animal species.

The draft Regulation concerns the authorisation of L-arginine as a feed additive.

Vote taken: Favourable opinion.

B.04 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation concerning the authorisation of hydroxy analogue of methionine and its calcium salt as a feed additive for all animal species.

The draft Regulation concerns the authorisation of hydroxy analogue of methionine and its calcium salt as a feed additive.

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 a preparation of a natural mixture of illite, montmorillonite and kaolinite as a feed additive for all animal species.**

The draft Regulation refers to an authorisation as technological additive. A discussion took place.

Vote taken: Favourable opinion.

- B.06 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation concerning the authorisation of diclazuril as a feed additive for chickens reared for laying and pheasants for fattening or reared breeding (holder of authorisation Huvepharma NV).**

Vote Postponed

- B.07 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation concerning the authorisation of the preparation of *Enterococcus faecium* NCIMB 10415 as a feed additive for sows, suckling piglets, weaned piglets, pigs for fattening, and amending Regulations (EC) No 252/2006, (EC) No 943/2005 and (EC) No 1200/2005 (holder of authorisation DSM Nutritional products Ltd., represented by DSM Nutritional Products Sp. Z o.o).**

The draft Regulation refers to an authorisation of a microorganism as zootechnical additive. Following the discussion, the draft Implementing Regulation received a favorable opinion.

Vote taken: Favourable opinion.

- B.08 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation amending Regulation (EC) No 371/2011 concerning the authorisation of dimethylglycine sodium salt as feed additive for chickens for fattening (holder of the authorisation Taminco N.V.) as regards the maximum limit of dimethylaminoethanol (DMAE).**

The draft Regulation refers to a modification of the authorisation of a zootechnical additive. A discussion took place.

Vote taken: Favourable opinion.

- B.09 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation amending Regulation (EC) No 2017/2325 concerning the authorisation of preparations of lecithins liquid, lecithins hydrolysed and lecithins de-oiled as feed additives for all animal species and amending Implementing Regulation (EU) 2017/1007 as regards of the modification of characteristics of the additives.**

The draft Regulation refers to a modification of the authorisation of a technological additive. A discussion took place.

Vote taken: Favourable opinion.

B.10 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation amending Regulation (EC) No 885/2010 concerning the authorisation of the preparation of narasin and nicarbazin as a feed additive for chickens for fattening (holder of authorisation Eli Lilly and Company Ltd) and amending Regulation (EC) No 2430/1999.

The draft Regulation refers to a modification of the authorisation of a coccidiostat. A discussion took place.

Vote taken: Favourable opinion.