



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 15 SEPTEMBER 2014 - 16 SEPTEMBER 2014
(Section Animal Nutrition)**

CIRCABC Link: <https://circabc.europa.eu/w/browse/ccf0d60a-208f-4eac-be78-160e1cbe6caf>

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. Coxiril® (diclazuril) as a feed additive for turkeys for fattening - Annex

Following the discussion, a new Annex will be submitted to a future meeting.

A.2.2. Coxiril® (diclazuril) as a feed additive for guinea fowl - Annex

Following the discussion, a new Annex will be submitted to a future meeting.

A.2.3. Coxiril® (diclazuril) as a feed additive for chickens for fattening – Annex

Following the discussion, a new Annex will be submitted to a future meeting.

A.2.4. Sodium bisulphate (SBS) for all species as preservative and silage additive - Annex.

No discussion took place.

A.2.5. Lactobacillus acidophilus D2/CSL for laying hens - Annex

Following the discussion, a new Annex will be submitted to a future meeting.

A.2.6. Formaldehyde for pigs and poultry.

A first discussion was held on the EFSA opinions. Member States pointed out in particular their concerns on workers safety. A new discussion will be in a future meeting.

A.2.7. Lenziaren (iron, aqua carbonate hydroxy oxo starch sucrose complex) for cats
- Annex.

No discussion took place.

A.2.8. Sorbic acid and potassium sorbate for all animal species – Annex.

Following the discussion, it should be checked if EFSA provided all opinions on this substances.

A.2.9. Toyocerin® (Bacillus toyonensis NCIMB 14858T) for chickens for fattening, weaned piglets, pigs for fattening, sows for reproduction, cattle for fattening, calves for rearing and rabbits for fattening.

A first discussion was held on the EFSA opinion. Following the request of the Member States a new discussion will be held with EFSA representative to clarify several points of the document.

A.2.10. Bentonite-and sepiolite (Toxfin® Dry) as feed additive for all species - Annex.

Following the discussion, a new Annex will be submitted to a future meeting.

A.2.11. Ronozyme® Rumistar (alpha-amylase) as a feed additive for dairy cows - Annex.

Following the discussion, a draft Regulation will be submitted to a future meeting.

A.2.12. Selenium in the form of organic compounds produced by the selenium enriched yeast *Saccharomyces cerevisiae* (NCYC R645) for all species.

As the recent EFSA opinion is not complete a revision will be necessary in order to take into account the updated report of the EURL. The Committee will come back on the application once the updated EFSA opinion is available.

A.2.13. Copper chelate of L-lysinate-HCl as feed additive for all animal species – Annex

The Annex entry was discussed. A draft Regulation will be elaborated for vote in one of the next meetings.

A.2.14. L-threonine produced by *Escherichia coli* (DSM 25086) for all animal species and categories based on a dossier submitted by Evonik Industries A.G. - Annex

As the EFSA opinion was not yet fully published, the point was postponed.

A.2.15. L-valine (ValAMINO®) produced by *Corynebacterium glutamicum* (DSM 25202) for all animal species.

The Annex entry was discussed. A draft Regulation will be elaborated for vote in one of the next meetings.

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

A.3.1. State of play on applications for amending Directive 2008/38/EC by modifying the list of intended uses as particular nutritional purposes.

A Commission representative informed the Committee about the situation of the different pending applications.

A.3.2. Revision 1 of the FEDIAF Code of Good Labelling Practice for Pet Food.

A Commission representative introduced the document received from FEDIAF. He invited the representatives in the Committee to have an in-depth scrutiny of the changes and to report their comments to the Commission. The comments will be collected in order to draft a response to FEDIAF.

A.04 Revision of the dioxin testing requirements as laid down in Regulation (EU) No 225/2012.

A Commission representative informed the Committee about the results of the dioxin monitoring received from the competent authorities and asked the Member States that still intend to deliver their results to do so within the next month. Furthermore the Commission received information from IFFO, EBB and COCERAL which will be uploaded in CIRCABC. It is the intention - based on the information received from the Authorities, stakeholders and the FVO - to elaborate a working document with the elements of the revision for one of the next meetings of the Committee.

A.05 Feed additives placed on the market as preparations - working document.

A majority of delegations agreed on a working document clarifying the characteristics of preparations and the differences between premixtures and preparations. The main matters dealt with in the aforesaid document are indicated below:

"Characterisation of preparations:

The definition of feed additive implies the possibility to authorise preparations "Feed additives: substances, micro-organisms or preparations, other than feed material and premixtures, which are intentionally added to feed or water in..."

An additive as a preparation may contain one or more active substances (e.g. microorganisms, enzymes, flavourings, preservatives or zootechnical additives) having a specific function and may also contain other products or substances or technological additives helping to stabilise, or standardise the active substance or facilitate its handling or incorporation into feedingstuffs (feed materials, premixtures or compound feed). The technological additive in the preparation is not intended to have any continuing technological function in the feedingstuff to which the preparation is added. To conclude, the preparations may only contain technological additives, products or substances that are added exclusively to modify the physicochemical characteristics of the active substance.

Differences between premixtures and preparations:

1. Premixtures may contain all categories of additives. Preparations can only contain technological additives to help the active substance.

2. The technological additives in the preparation can only help the active substance.

The technological additives in the premixtures may play two different roles

a. Have a specific function in the feed to which the premixture is incorporated,

b. Facilitate the handling of the premixture or its incorporation to the feed.

3. Labelling

a. Premixtures:

- the feed materials used as carriers need to be declared. If water is used as carrier the moisture content need to be declared.

- the feed additives incorporated in the premixture need to be declared (except for flavouring compounds that are declared by a generic reference) and the specifications laid down in Annex III to Regulation (EC) No 1831/2003 such as the level of the active substance, colony forming units etc shall apply.

b. Preparations: only the active substance is declared and the specifications laid down in Annex III to Regulation (EC) No 1831/2003 such as the level of the active substance, colony forming units etc shall apply. Unless specified in the corresponding authorisation, the technological additives, products or substances used to help the active substance are not declared.

4. Feed hygiene requirements

The requirements for both additives and premixtures in the feed hygiene regulation are basically the same except for the approval of establishments."

On the basis of the discussion the Commission has started a procedure for the adoption of a Regulation amending Annexes III and IV to Regulation (EC) 1831/2003. This proposal will precise the role of the different substances or additives included in the preparations and will laid down certain labelling requirements.

A.06 Vitamins in water - working document.

A discussion took place on a working document to clarify the use of vitamins in water. Many delegations agreed on the documents although further discussion is necessary to precise certain aspects and to refine the document. The Commission, depending on the outcome of the final discussion, may draft a legal act to minimise the possibility of exceeding the maximum limits authorised for certain additives, when they are used via complementary feed in water for drinking.

A.07 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 cotton seeds from Ghana (1 notification), in maize from Serbia (1 notification), in maize from India (1 notification);
- dioxin-like PCBs and non dioxin-like PCBs in dicalciumphosphate from France (1 notification). The delegation from France indicated that the source of contamination is under investigation and that the Committee will be informed on the outcome at a next meeting;
- dioxins and dioxin-like PCBs in palm kernel fatty acid distillate from Malaysia (1 notification), dioxins in hydrogenated palm oil from Spain (2 notifications);
- hexachlorobenzene in fish meal from peru (1 notification);

- meadow saffron (*Colchicum autumnale*) in hay from Germany (1 notification);
- hydroxymethylfurfural (HMF) in complementary feed for honeybees from Germany (1 notification);
- fluorine in complementary feed for pigs and cattle from Belgium (1 notification);
- cadmium in celery stalks from Poland (1 notification).

Extensive information was provided by the Dutch delegation on the finding of the prohibited substance furalozidone (nitrofurane) in compound feed from the Netherlands.

In spring of 2014 the Dutch authorities have identified at a farm the presence of the prohibited substance furazolidone in veal. The presence could be traced back to the feed. The feed was originating from a compound feed manufacturer, which mainly used by-products from the food industry for the production of animal feed. At the same premises there is also a production facility for raw materials, used in biogas production. There are several hypotheses as regards the possible source of contamination. Criminal investigations are ongoing to elucidate the source of contamination. Given the many shortcomings identified at the feed manufacturer in question e.g. as regards traceability, the registration of the feed manufacturer has been suspended.

The Dutch authorities have taken all necessary measures to ensure a high level of consumer protection. The risk period has been identified from 1 March 2014 to 5 June 2014 (day of suspension of the registration of the feed company). All contaminated feed have been blocked and withdrawn from the market and could no longer be used for feed. The farms which have received possibly contaminated feed directly or indirectly from the feed manufacturer in question have been initially blocked as a precautionary measure. Also all contaminated meat (with a level of furazolidone > 1µg/kg) has been withdrawn from the market.

The possibly contaminated feed materials were also traded to plants in Germany and Poland but further investigations showed that these were mainly biogas plants and only to a limited extent farms.

In the Netherlands most affected farms received feed from 3 compound feed manufacturers which had received feed materials from the feed manufacturer where the contamination was found. Controls on these farms did not show the presence of furazolidone and therefore no restrictions apply anymore to these 3 feed manufacturers and related farms.

In some of the veal farms which received directly feed from the feed manufacturer in question the animals had to be culled, regarding the Dir. 96/23/EC, because of the presence of too high levels of furazolidone. There is also still a dairy farm blocked which received also directly feed from the feed manufacturer in question.

A.08 Undesirable substances in feed.

Clarification of the term “trace amounts not quantitatively determinable”

To clarify the term “trace amounts not quantitatively determinable” there are two conditions which need to be considered: the recognisability and manageability of the seeds or fragments, and level of experience and skill of the technician.

“Recognisability” refers to the characteristics of the seeds and fragments for recognition and for distinction of other seeds or fragments (mimics or look-alikes).

“Manageability” refers to the ability to select, handle, and collect the targeted fruits, seeds or fragments thereof.

Following preliminary bilateral discussions/exchange of views with experts experienced in microscopic analysis of feed, it appears to be necessary to convene a meeting with selected experts, experienced in microscopic analysis of feed, to discuss this issue in detail.

Once this expert meeting has taken place, the conclusions of the meeting will be presented and discussed at a meeting of the Committee.

A.09 Application of Article 10 (b) of Regulation (EC) N° 183/2005 - approval for premixtures productions.

As requested by the French delegation, on the interpretation of Article 10(b) of Regulation (EC) No 183/2005, the Commission provided the response to this query.

Article 10(b) of Regulation (EC) No 183/2005 reads as follows:

"Feed business operators shall ensure that establishments under their control and covered by this Regulation are approved by the competent authority, where manufacturing and/or placing on the market of premixtures prepared using feed additives referred to in Chapter 2 of Annex IV to this Regulation."

Therefore, there are three type of situations :

- * a feed business operator manufactures and places on the market premixtures;
- * a feed business operator places on the market premixtures;
- * a feed business operator manufactures premixtures.

The last case is only relevant if the producer of premixtures works by order of another feed business operator or he works only for the use of premixtures in his own establishment. The production of premixtures for internal use is in particular relevant for such additives which can be used for the production of compound feed only in form of a premixture (such as mentioned in Annex IV Chapter 2 – coccidiostats, histomonostats, vitamin A and D, Cu and Se).

In conclusion, all producers of premixtures containing additives mentioned in Annex IV Chapter 2 for their own use as well as for placing on the market need an approval for this operation.

A.10 Presentation of the update Guide for the Safe Manufacture of Feed Materials version 3.0 with accompanying sector reference documents by FEDIOL, AAF and EBB and the update Guide EFMC version 12 by FEFAC.

The Commission presented the background, the latest developments and the rationale behind these 2 updated EU feed guides, by illustrating the main updates in a power-point presentation. The main aim is to endorse the revised 2 EU guides prepared by FEFAC and FEDIOL in a next meeting with Member States, either in October or at the latest in November 2014. Member States are invited to submit substantial comments till 26/09/2014 on these set of guides and excel sheets listing all the comments made by Member States and a state of play of all comments taken on board by the Industry. In addition, Member States were invited to inform the Commission if they want to be part of the next restricted working group (to date 12 Member States are involved) before the deadline of 26/09/2014 as the Commission has received new updates of other EU feed guides (in particular from FEDIAF and CEFIC) in view to discuss them.

B.01 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation concerning the authorisation of a new use of *Enterococcus faecium* DSM 7134 (Bonvital) as a feed additive and repealing Commission Regulation (EC) No 1521/2007.

Following discussion, the draft Implementing Regulation received a favourable opinion.

Vote taken: unanimous in favour.

B.02 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation concerning a new use of a preparation of *Clostridium butyricum* (FERM BP-2789) as a feed additive for turkeys for fattening and reared for breeding (holder of authorisation Miyarisan Pharmaceutical Co.Ltd. represented by Miyarisan Pharmaceutical Europe S.L.U.).

Following discussion, the draft Implementing Regulation received a favourable opinion.

Vote taken: unanimous in favour.

B.03 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation amending Commission Regulation (EC) No 271/2009 as regards the minimum content of a preparation of endo-1,4-beta-xylanase and endo-1,4-beta-glucanase as a feed additive for laying hens (holder of the authorisation BASF SE).

Following discussion, the draft Implementing Regulation received a favourable opinion.

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 a preparation of *Saccharomyces cerevisiae* (CBS 493.94) as a feed additive for dairy cows and minor dairy ruminant species and cattle for fattening and minor ruminant species for fattening and amending Regulations (EC) No 1811/2005 and (EC) No 1288/2004 (holder of the authorisation ALLTECH France).**

Following discussion, the draft Implementing Regulation received a favourable opinion.

Vote taken: unanimous in favour.

- B.05 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation concerning a new use of a preparation of endo-1,4-beta-xylanase and endo-1,3(4)-beta-glucanase produced by *Talaromyces versatilis* sp. nov. (IMI CC 378536) as a feed additive for lactating sows (holder of the authorisation Adisseo France S.A.S.).**

Following discussion, the draft Implementing Regulation received a favourable opinion.

Vote taken: unanimous in favour.

- B.06 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation concerning the authorisation of a preparation of fumonisin esterase produced by *Komagataella pastoris* (DSM 26643) as a feed additive for pigs.**

Following discussion, the draft Implementing Regulation received a favourable opinion.

Vote taken: unanimous in favour.

- B.07 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation (EU) concerning the authorisation of preparations containing a smoke flavouring extract (2b0001) as feed additives for dogs and cats.**

The draft proposes to authorise a new additive consisting of a smoke flavouring for cats and dogs. A discussion took place.

Vote taken: unanimous in favour.

B.08 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 of 7 May 2002 on undesirable substances in animal feed as regards arsenic, fluorine, lead, mercury, endosulfan and Ambrosia seeds.

The proposed amendments relate to:

- an increase of the maximum level of arsenic, fluorine and lead in calcareous marine shells given that new data have been provided demonstrating that the current maximum levels are not achievable and the proposed maximum levels keep a high level of animal and public health protection;
- an adaptation 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 to ensure the supply of these feed materials whilst keeping a high level of animal health protection;
- a decrease of the maximum level for endosulfan in oilseeds, maize and derived products thereof following an assessment of recent occurrence data;
- re-introduction of the footnote on the presence of Ambrosia seeds in feed materials, which was erroneously deleted through an earlier amendment.

Experience has shown that certain provisions of the footnote have to be strengthened to avoid dissemination of Ambrosia seeds into the environment.

Comments were received from FEDIAF as regards the proposed changes on mercury and from the Dutch Oils and Fat Industry as regards the proposed changes on endosulfan. The comments were considered in detail.

Vote taken: unanimous in favour.

B.09 Exchange of views and possible opinion of the Committee on a draft Commission Regulation defining acceptability criteria for detoxification processes in application of Article 8 of Directive 2002/32/EC of the European Parliament and of the Council of 7 May 2002 on undesirable substances in animal feed.

Following the consultation within the Commission, the approach has been changed. The detoxification process shall be assessed by EFSA to verify if the acceptability criteria are met. In case of a favourable outcome, Member States can approve establishments to vary out this detoxification process.

The following issues were discussed: the scope of the Regulation (in particular as regards decontamination of fish oil with active carbon as part of an integrated process), the need to provide a solution for emergency situations, to replace metabolites by transformation/reaction or breakdown products and the need to characterise the chemical substance used in case of a chemical detoxification process.

Given that the modified text including the new approach was only presented shortly before the meeting, the vote has not been taken.

Vote postponed

M.01 AOB

Production and intra-EU transfers of unauthorised feed additives intended to be exported to third countries.

This issue, which has been previously discussed on the occasion of several meetings of the Standing Committee (in June 2014 lastly), was raised by a delegation in order to highlight that Member States' actions in respect of the operators and products concerned are very different and sometimes even based on completely contradictory criteria, which jeopardise the principles of the single market and equal opportunities. That delegation therefore calls for the adoption of an official common position at E.U. level in order to regulate the sector of activity concerned.

A discussion took place. A representative of the Commission indicated that the nature of the Member States' actions concerned should be well identified and clarified before examining the legal framework that could be envisaged for tackling the issue, considering that the operations concerned are not included within the scope of Regulation (EC) No 1831/2003.

M.02 Placing on the EU market of maxammon.

On request of a Member State the Committee discussed the placing on the market of maxammon as complementary feed. Considering its composition it would qualify as compound feed. However, the product is not meant to be given directly to the animals but to be added - in combination with urea - to cereals in order to support their preservation. In the discussion it became evident that more information is necessary, particularly about the functionality of the product. The Committee will come back on the topic once this information is available.