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Standing Committee on Plants, Animals, Food and Feed

Section *Animal Nutrition*

10 - 12 February 2020

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SUMMARY REPORT

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.02.01. AviPlus® as a feed additive for turkeys for fattening, turkeys reared for breeding and suckling piglets – Annex.

A draft Regulation will be proposed at a future meeting.

A.02.02. Levucell SC® (Saccharomyces cerevisiae CNCM I-1077) as a feed additive for calves and minor ruminant species and camelids at the same developmental stage – Annex.

A draft Regulation will be proposed at a future meeting.

A.02.03. EB15 10 (Bacillus subtilis DSM 25841) as a feed additive for weaned piglets and weaned minor porcine species – Annex.

A new Annex will be proposed at a future meeting.

A.02.04. EB15 10 (Bacillus subtilis DSM 25841) as a feed additive for piglets (suckling and weaned), pigs for fattening, sows in order to have benefits in piglets, sows for reproduction and minor porcine specie – Annex.

A new Annex will be proposed at a future meeting.

A.02.05. ZM16 10 (Bacillus amyloliquefaciens DSM 25840) as a feed additive for sows in order to have benefits in piglets, sows for reproduction, piglets (suckling and weaned), pigs for fattening and minor porcine specie – Annex.

A new Annex will be proposed at a future meeting.

A.02.06. ZM16 10 (Bacillus amyloliquefaciens DSM 25840) as a feed additive for weaned piglets and minor porcine specie – Annex.

A new Annex will be proposed at a future meeting.

A.02.07. Assessment of the application for renewal of authorisation of ECONASE® XT (endo-1,4-b-xylanase) as a feed additive for piglets (weaned),

chickens for fattening, chickens reared for laying, turkeys for fattening and turkeys reared for breeding.

Following the discussion, the applicant will be requested to submit the missing data by a time limit.

A.02.08. Lactic acid and calcium lactate when used as technological additives for all animal species – Annex.

A draft Regulation will be proposed at a future meeting.

A.02.09. Belfeed B MP/ML (endo-1,4-b-xylanase) as a feed additive for sows, in order to have benefits in piglets, and for all porcine species – Annex.

A new Annex will be proposed at a future meeting.

A.02.10. Assessment of the application for renewal of authorisation of Yea-Sacc® (Saccharomyces cerevisiae) for horses.

It was agreed to contact applicant to request new data, if that is the case.

A.02.11. Elancoban® G200 (monensin sodium) for chickens for fattening, chickens reared for laying and turkeys.

The Member States agreed to request supplementary information to the applicant.

A.02.12. APSA PHYTAFEED® 20,000 GR/L (6-phytase) as a feed additive for turkeys for fattening, turkeys reared for breeding and minor poultry species – Annex.

After the discussion with the Member States on the data and motivation provided by the applicant, it has been agreed to proceed following the EFSA conclusions. A draft Regulation will be proposed at a future meeting.

A.02.13. APSA PHYTAFEED® 20,000 GR/L (6-phytase) as a feed additive for piglets (suckling and weaned) and growing minor porcine species – Annex.

After the discussion with the Member States on the data and motivation provided by the applicant, it has been agreed to proceed following the EFSA conclusions. A draft Regulation will be proposed at a future meeting.

A.02.14. Lancer® (lanthanide citrate) as a zootechnical additive for weaned piglets – Annex.

A new Annex will be proposed at a future meeting.

A.02.15. CI-FERTM (ferric citrate chelate) as a zootechnical feed additive for suckling and weaned piglets and minor porcine species.

The Member States agreed to request supplementary information to the applicant.

A.02.16. Astaxanthin dimethyldisuccinate 2 (Carophyll® Stay-Pink 10%-CWS) for salmonids, 3 crustaceans and other fish - Annex entry.

The Annex entry was discussed. A proposal for authorisation will be presented as soon as the administrative procedure will be finished.

A.02.17. Essential oil from *Origanum 1 vulgare ssp*. hirtum (Link) Ietsw. for all animal species - Annex entry.

The Annex entry was discussed but no conclusion was reached.

A.02.18. oct-1-en-3-ol, pent-1-en-3-ol, 1 oct-1-en-3-one, oct-1-en-3-yl acetate, isopulegol and 5-2 methylhept-2-en-4-one, belonging to chemical group 5 and of isopulegone and - damascone belonging to chemical group 8 when used as flavourings for all animal species. EFSA opinion.

The Member States agreed to request complementary information to the applicant.

A.02.19. L-cysteine hydrochloride monohydrate produced by fermentation using Escherichia coli KCCM 80180 and Escherichia coli KCCM 3 80181 as a flavouring additive for all animal species.

The opinion was discussed. A proposal for authorisation will be presented as soon as the administrative procedure will be finished.

A.02.20. Tincture derived from *Artemisia vulgaris L. (*Mugwort tincture) when used as a sensory additive in feed for all animal species - Follow up.

The Member States was informed that complementary information was requested to the applicant.

A.02.21. Essential oil from *Elettaria cardamomum* (L.) Maton when used as a sensory additive in feed for all animal species - Annex entry.

The Annex entry and the aspect related to user safety was discussed and clarified. A proposal for authorisation will be presented as soon as the administrative procedure will be finished.

A.02.22. Tincture derived from *Verbascum thapsus* L. when used as a sensory additive in feed for all animal species (great mullein tincture) - EFSA opinion.

The Member States agreed to request complementary information to the applicant.

A.02.23. Essential oil from *Origanum vulgare* subsp. hirtum (Link) letsw. var. Vulkan (DOS 00001) when used as a sensory additive in feed for all animal species - Annex Entry.

The Member States agreed to request complementary information to the applicant.

A.02.24. Lutein and lutein/zeaxanthin extracts from *Tagetes erecta* for poultry for fattening and laying (except turkeys) - Annex entry.

The Annex entry was discussed. A proposal for authorisation will be presented as soon as the administrative procedure will be finished.

A.02.25. Methylester of conjugated linoleic acid (t10,c12 isomer) for pigs for fattening, sows and cows - Annex entry.

The Annex entry was discussed.

A.02.26. Butylated Hydroxy Anisole for all animal species.

A discussion was held. A draft Regulation will be proposed at a future meeting.

A.02.27. *Lactococcus lactis* NCIMB 30160 as a feed additive for all animal species.

A discussion was held. A draft Regulation will be proposed at a future meeting.

A.02.28. Manganese chelates of lysine and glutamic acid for all animal species (EFSA-Q-2018-00254, FAD-2018-0009).

The opinion was presented. EFSA could not conclude on the safety for all animal species. The Commission services will contact the applicant in order to allow him to deliver supplementary information so that EFSA can update its opinion.

A.02.29. L-Methionine produced by fermentation with Corynebacterium glutamicum KCCM 80184 and Escherichia coli K12 KCCM 80096 for all animal species (EFSA-Q-2018-01017, FAD-2018-00085) - Annex entry.

The Annex was discussed. A draft Regulation will be prepared for vote in one of the next Committees.

A.03 Discussion on amending Regulation (EC) No 429/2008.

The discussion concerned the safety aspect for the consumers, but principally, as requested by Member States, in particular Denmark, on the analytical method for the detection of GMO and its fractions. The discussion will continue in a future Standing Committee.

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.

The Commission's representative referred to the two working documents which have been circulated to the Committee's members. In particular, it was confirmed that two amino-acids previously authorised under Directive 82/471/EEC had to be added to the list of additives to be withdrawn from the market.

A short exchange of views took place.

A.05 Guides to good practice.

The Commission’s representative informed the Member States about the current state of play of the different guides of practice that are underway.

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

A.06.01. Revision of Regulation 68/2013 on the Catalogue of feed materials

The in-depth evaluation of chapters 6 to 13 of Part C of the draft updated Catalogue of feed materials as received from the Feed Chain Task Force (FCTF) took place. Several entries need more clarifications, which will be requested from the FCTF. Some delegation announced written comments in due course. The Commission Services will prepare a revised document for the next Committee based taking into account these comments and the supplementary information from the FCTF.

A.06.02. Discussion of borderline products: biomass from A*shbya gossypii*, Disodium ethylenediaminetetraacetate (EDTA)

- Biomass from A*shbya gossypii*:

The Committee concluded that this fermentation product, which was developed to supply the animals` nutritional needs for the feed additive Vitamin B2, would fall under the scope of the feed additive Regulation (EC) 1831/2003. Some Member States stated that they would accept it as feed material.

- Disodium ethylenediaminetetraacetate (EDTA):

The Committee concluded that EDTA should be rather considered a feed additive than a feed material. According to the information available it could be classified a technological feed additive.

- Feed Material Register Entries from 2010 – 2017 which are considered by the EU FCTF to be illegal:

The Committee appreciated the FCTF`s elaboration of the exhaustive list based on earlier exchanges. The list was discussed and delegations should, if appropriate, send comments to the Commission by end February. The list as revised by the Committee will subsequently be sent to the FCTF to launch the deletion of the illegal entries from the Register of Feed Materials.

A.06.03. Placing of the *Asparagopsis taxiformis* meal as feed material on the market

The Commission's representative recalled from earlier discussions in the Committee that red seaweed meal of the *Asparagopsis s*pp. was considered to be covered by entry 7.1.6 in the feed material Catalogue. However, a specific entry for this algae species might be envisaged in the next revision of Regulation 68/2013. Like other aquatic feed materials, this algae meal has naturally considerable levels of bromine and iodine. When incorporating red seaweed meal into the animals diets, the feed business operators should take into account its evident contribution to the supply with these elements. Considering the concerns about high contents of bromine or iodine, but also other constituents naturally present in aquatic feed materials, the Commission might envisage an assessment to be done by EFSA.

As regards a potential claim "reduction of methane emissions" of ruminants, the Commission's representative referred to Article 13 of Regulation 767/2009. When verifying the scientific substantiation of such claims, the competent authorities should especially consider the inclusion rate of the seaweed linked to the claimed methane reduction and check that the feed intake and milk yield are not significantly impaired.

A.06.04. Legal status of the use of CMIT/MIT in feeding *Artemia nauplii*

The Committee continued its discussion of the legal status of two applications (in cyst production and in enhanced enrichment emulsions) of CMIT/MIT for feeding *Artemia nauplii.* It was concluded that the use of CMIT/MIT in both applications would be considered a feed additive, based on the information available in the functional group hygiene condition enhancer.

A.07 Enforcement of feed additive authorisation acts.

A.07.01. Amino acids produced by fermentation

The Commission's representative reminded the Committee that with the reauthorisation of the lysine forms, all amino acids produced by fermentation can, after the transition periods, only be placed on the EU market, if they have been produced by the microorganisms, which have been set out in the respective authorisation acts. He invited the competent control authorities to verify, e.g. by means of traceability and documentary checks, the compliance of the amino acids produced by fermentation in order to avoid that non-authorised additives are on the EU market.

A.07.02. Trace element chelates of amino acids hydrate

The Commission's representative informed the Committee that various compounds of trace elements, labelled as metal chelates of amino acids hydrate (e.g. zinc chelate with identification number 3b606), are placed on the EU market without complying with the respective product properties, in particular that a maximum of 10 % of the molecules may exceed 1500 Daltons. He invited the competent control authorities to police such fraudulent products.

A.08 RASFF.

A.08.01 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 December 2019.

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

- ragweed seeds (*Ambrosia* spp) in brown linseed from Russia;
- aflatoxins in groundnuts from the United States;
- cyanide in linseed from the United States;
- ergot sclerotia in wheat from France;
- cadmium in complete feed for dogs from Germany.

One delegation raised the issue of the RASFF notification as regards the use of cannabidiol (CBD) in complementary feed for cats and dogs. The company claims that the presence of CBD is related to the use of hemp oil as ingredient in the complementary feed and not as use as unauthorised feed additive. However, given the levels of CBD found (523 mg/kg and 1310 mg/kg), while the product contains only 0.23 % or 0.75 % of hemp oil. It is evident that these high levels of CBD cannot be explained as natural presence in hemp seed oil derived from seeds originating from varieties not containing more than 0.2 % of tetrahydrocannabinol (THC). In order to avoid in future such discussions in cases where lower levels of CBD are found, it might be appropriate to establish a maximum content of CBD in hemp products, which are allowed for use in feed. The Commission’s representative indicated that this point will be discussed in more detail under point A.06.01.

A.09 Undesirable substances.

A.09.01. Exchange of views on issues related to undesirable substances in feed (follow-up on discussions at the WG meeting of 29 January 2020) in particular on:

- T2 and HT-2 toxin
- Deoxynivalenol
- Nickel
- Ergot alkaloids
- Other

The outcome of discussions of the Working Group “undesirable substances” which has taken place on 29 January 2020 was presented and a short exchange of views has taken place.

T2 and HT-2 toxin

Guidance levels for T-2 and HT-2 in cereals and cereal products as feed materials are suggested taking into account the available data in the EFSA database (EFSA report on occurrence data) and in compound feed taking into account the reference point for adverse animal health effects as provided in the EFSA opinion on T-2 and HT-2 toxin from 2011.

The denomination for feed materials have to be brought in line with the denomination in the feed catalogue to avoid confusion.

As the guidance levels for compound feed are directly derived from reference points for adverse animal health effects (and exceedance of these guidance levels might consequently result in adverse animal health effects), it is suggested that it might be appropriate to establish the levels for compound feed as maximum levels to protect the animal health (in the frame of Directive 2002/32/EC) while maintaining the concept of guidance levels for feed materials in Recommendation to ensure flexibility and reasonable use of resources according to seasonal variation.

The Committee welcomed the discussion on the regulatory measures on T-2 and HT-2 toxin but several delegations indicated to need more time for taking a position on the various proposals.

Deoxynivelanol (DON) and modified forms

For enforcement reasons it appears appropriate to maintain for the time being guidance levels for the parent compound only, but these guidance levels for DON only should be protective against the possible adverse animal health effects from the sum of DON, 3-ACDON, 15ACDON and DON-3-glucoside. Therefore guidance levels for DON could be derived taking into account that according to the EFSA opinion from 2017 the average ratio's of 3-Ac-DON to DON, 15-Ac-DON to DON and DON-3-glucoside to DON are 10 %, 15 % and 20 % respectively., meaning the abovementioned guidance values for sum of DON, 15-Ac-DON to DON and DON-3-glucoside to be multiplied by 0.69 to have the comparable level in DON.

However, it is to be noted that this average ratio can vary largely in function of feed materials. The acetylated DON derivatives occur much more in maize than in other cereals. It is proposed to examine in more detail the available data in EFSA to verify this.

Also a guidance level for DON in sugar beet pulp is proposed for discussion.

The denomination for feed materials have to be brought in line with the denomination in the feed catalogue to avoid confusion.

As the guidance levels for compound feed are directly derived from reference points for adverse animal health effects (and exceedance of these guidance levels might consequently result in adverse animal health effects), it is suggested that it might be appropriate to establish the levels for compound feed as maximum levels to protect the animal health (in the frame of Directive 2002/32/EC) while maintaining the concept of guidance levels for feed materials in Recommendation to ensure flexibility and reasonable use of resources according to seasonal variation.

The Committee welcomed the discussion on the review of the regulatory measures on deoxynivalenol but several delegations indicated to need more time for taking a position on the various proposals.

Zearalenone and fumonisins

In relation to the ongoing discussions on regulatory levels for T-2 and HT-2 toxin and DON, it is appropriate to consider also possible changes to zearalenone and fumonisins.

For zearalenone, it is appropriate to set additional guidance levels in sugar beet pulp and soybean and derived products (oilseeds and derived products). Based on the occurrence data available in the EFSA opinion from 2017, it is appropriate to significantly decrease the current guidance level. As regards the discussion of guidance levels versus maximum levels for compound feed, as the current guidance levels for compound feed do not fully reflect the reference points for adverse health effects, they should be reconsidered in case it is opted to establish maximum levels for compound feed (to be consisted with what would be decided for T-2 and HT-2 toxin and DON) and could in certain cases be increased.

For fumonisins, based on the occurrence data available in the EFSA opinion from 2017, it is appropriate to significantly decrease the current guidance level for maize and maize products. Also the guidance levels in compound feed for certain animal species (adult ruminants, pigs, rabbits, ducks and fish) have to be lowered in relation to the reference point for adverse health effects. As these guidance levels for compound feed are directly derived from the reference points for adverse health effects, the discussion of guidance levels versus maximum levels for compound feed, is also relevant for fumonisins (to be consisted with what would be decided for T-2 and HT-2 toxin and DON).

The denomination for feed materials have to be brought in line with the denomination in the feed catalogue to avoid confusion.

The Committee welcomed the discussion on the review of the regulatory measures on zearalenone and fumonisins but several delegations indicated to need more time for taking a position on the various proposals**.**

Nickel

Following the EFSA opinion in 2015 and the EFSA report on occurrence data of nickel in feed and animal exposure assessment in 2019, possible regulatory follow-up is discussed.
While taking into account the available occurrence data, the presence of nickel in feed is not of concern for animal health, the presence of nickel in food is of concern for human health. The food of animal origin is a significant contributor to the human exposure. However it is unclear to which extent the presence of nickel in food of animal origin is related to transfer from feed to food of animal origin or migration from food contact materials. it would be appropriate to have more detailed information on possible carry-over of nickel from feed to food of animal origin.

The feed catalogue provides that fatty acid products (entries 13.6. 2, 3, 4, 6 and 7 in feed catalogue) and (crude) glycerine (entries 13.8.1. and 2 in feed catalogue) may contain up to 50 ppm nickel, but if the nickel content is above 20 ppm, the nickel content has to be compulsory. Available occurrence data indicate that a maximum level of 20 ppm is achievable.

In addition, possible maximum levels were suggested for mineral and products derived thereof (feed materials), feed additives belonging to the functional group of compounds of trace elements and feed additives belonging to the functional groups of binders and anticaking agents (including mycotoxin binders and radionuclide binders).

The Committee welcomed the discussion on maximum levels for nickel in certain feed materials and feed additives, but several delegations indicated to need more time for taking a position**.**

Ergot sclerotia and ergot alkaloids

Following the EFSA opinion on ergot alkaloids in food and feed from 2012 and the EFSA report on human and animal dietary exposure to ergot alkaloids from 2017, the possible setting of guidance levels for ergot alkaloids in compound feed is under consideration (guidance levels for ergot alkaloids – sum of the following 12 ergot alkaloids ergometrine, ergosine, ergocornine, ergotamine, ergocristine, ergocryptine (α- and β-form) and their respective -inine forms, lowerbound levels whereby limit of quantification (LOQ) for individual epimers is 5 µg/kg. The guidance levels for compound feed are based on available information of reference points for adverse animal health effects.

In relation to these guidance values for ergot alkaloids, it seems appropriate to lower the current maximum level of 1000 mg/kg for ergot sclerotia.

The Committee welcomed the discussion on regulatory measures for ergot alkaloids and the review of the maximum level for ergot sclerotia in feed, but several delegations indicated to need more time for taking a position**.**

Other

In relation to the ongoing discussion on maximum levels for pyrrolizidine alkaloids and tropane alkaloids in food, it might be appropriate to consider if regulatory measures in feed would be appropriate to protect animal health, in particular in the case of tropane alkaloids.

The Committee was also informed on the status of the discussions on the maximum level for p-phenetidine (status of the development of a method of analysis), cadmium in Cu(I) oxide (more details on the method of analysis and in particular on the sample preparation to be requested) and lead in game meat used in pet food (more details/background on certain occurrence data to be provided).

A.10 Review of Regulation (EU) 152/2009.

A.10.01. Outcome of the discussions at the meeting of the WG "Methods of Analysis" on 20 January 2020

The Committee was informed of the following main changes as discussed and to a large extend agreed at the latest meeting of the Working Group "Methods of analysis" of 20 January 2020.

- Explicit reference to existing EN standards (established by the European Committee for Standardisation (CEN)):

  - in addition to current provisions in the Annexes to Regulation (EU) 152/2009 (preparation of samples for analysis), or

  - in addition to existing official methods of analysis in the Annexes to Regulation (EU) 152/2009 (moisture content in oilseeds, amino acids (except tryptophan),

tryptophan, total phosphorus, trace elements iron, copper manganese and zinc, halofuginone, robenidine, diclazuril, lasalocid sodium), or

- for the analysis of compounds for which no official method of analysis is included in the Annexes to Regulation (EU) 152/2009 (narasin, nicarbazin, decoquinate, monensin, salinomycin, semduramycin, maduramycin ammonium), or

- for the calculation of the energy value in feed materials and compound feed for cats and dogs.

- New procedure in case of examination by visual inspection or microscopy, including the establishment of an analytical threshold, in order to reduce the workload;

- provisions related to the reporting on correction for recovery;

- determination of moisture content in mineral substances including trace elements and mixtures composed predominantly of mineral substances;

- repeatability and reproducibility criteria for method of analysis for the determination of the nitrogen content and calculation of crude protein content;

- limiting the scope of the method of analysis for determination of urea to determination of urea used as feed additive in ruminant feed;

- changes to the method to determine crude oils and fats, crude fibre, starch;

- deletion of current official methods of analysis: determination of volatile nitrogenous basis (no legal requirement), determination of carbonates (no legal requirement), determination of diclazuril (replaced by method developed by EURL feed additives), determination of free and total gossypol (obsolete), methods of analysis to control illegal presence of no longer authorised additives in feed (because not sensitive enough in comparison with other available methods).

Furthermore, it has still to be discussed and concluded if it is appropriate to include reference to existing EN standards for certain feed additives (other than coccidiostats), inorganic contaminants and nitrogenous compounds, mycotoxins and plant toxins.

The Committee took note of the outcome of the discussion of the working group "Methods of Analysis" but several delegations indicated the need for further internal consultations before being able to take a final position on the proposed changes.

B.01 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation concerning the authorisation of a preparation of 6-phytase, produced by Aspergillus niger (DSM 25770) as feed additive for laying hens and minor poultry and other avian species for laying (holder of the authorisation BASF SE)

Vote Postponed

B.02 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation concerning the authorisation of a preparation of endo-1,4-beta-xylanase (EC 3.2.1.8) produced by Trichoderma reesei (BCCM/MUCL 49755) as a feed additive for all avian species for fattening other than turkeys and chickens for fattening and all weaned porcine species and for fattening other than weaned piglets and pigs for fattening (holder of authorisation Berg und Schmidt GmbH Co. KG)

Vote Postponed

B.03 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation concerning the authorisation of a preparation of endo-1,4-beta-xylanase produced by produced by Aspergillus oryzae (DSM 26372) as a feed additive for lactating sows (holder of authorisation DSM Nutritional Products Sp. z o.o.)

Vote Postponed

B.04 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation concerning the authorisation of the preparation of carvacrol, thymol, D-carvone, methyl salicylate and L-menthol as a feed additive for chickens for fattening, chickens reared for laying, minor poultry species reared for laying (holder of authorisation Biomin GmbH)

Vote Postponed

B.05 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation concerning the authorisation of the preparation of Bacillus subtilis DSM 28343 as a feed additive for calves for rearing and pigs for fattening (holder of authorisation Lactosan GmbH & Co. KG)

Vote Postponed

B.06 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation concerning the authorisation of a preparation of endo-1,4-beta-xylanase produced by Aspergillus oryzae (DSM 26372) as a feed additive for laying hens (holder of authorisation DSM Nutritional Products Sp. z o.o.)

Vote Postponed

B.07 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation (EU) concerning the authorisation of Norbixin (annatto F) as a feed additive for cats and dogs.

The proposal authorises a colorant for cats, dogs.

Vote taken: Favourable opinion.

B.08 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation concerning the authorisation of sodium selenate as feed additive for ruminants

One delegation abstained because the draft Regulation does not take into account the EFSA statement, that safety and efficacy of sodium selenate have been performed only for the use of the additive in the form of boluses. According the text of the draft, sodium

selenate can be used in all types of feed (not only boluses). Furthermore, draft authorizing act does not include the EFSA recommendations for the use of sodium selenate for small-sized ruminants and recommendation to indicate release life time of the additive administered by boluses.

Spain abstained and made the following declaration: "*The draft of Regulation presented for vote and its corresponding Annex do not indicate that the method of administration of the additive shall be restricted to intraruminal bolus. However, the efficacy evaluation carried out by EFSA (published in EFSA Journal 2019;17(7):5788) is base don the administration of the additive exclusively in form of intraruminal bolus, being indicated that "the FEEDAP Panel concludes that sodium selenate delivered by a bolus to ruminants is an efficacious source of selenium in meeting the animals' requirements". Similarly, the safety evaluation has been carried out taking into account exclusively that presentation in form of intraruminal bolus: "The EFSA Panel on Additives and Products or Substances used in Animal Feed (FEEDAP) Panel concludes that based on (i) the estimation of the release of selenium from the bolus, (ii) the similarities in bioavailability with sodium selenite, (iii) the experience with the use of boluses in ruminant nutrition and (iv) the wide margin of safety compared with the maximum tolerable levels of selenium in ruminants, the additive is safe for ruminants*". *Since other presentations different to intraruminal bolus have not been evaluated, and since as EFSA opinion indicates, the intraruminal bolus allows a prolonged release of the additive, it is not possible to extrapolate that method of administration to other different methods, therefore there is no information about the efficacy or the safety of its administration in other presentations. This is indicated in the EFSA opinion: "The safety and efficacy assessment of the additive is based on its use in boluses, with the specific composition reported in the technical dossier". On the other hand, the authorisation shall be approved for the method of administration for which the authorisation has been requested, which is the intraruminal bolus: "The European Commission received a request from Retorte GmbH Selenium Chemicals and Metals for authorisation of the product sodium selenate as feed additive for use in dietetic complementary feeds in the form of a bolus". "The present assessment is based on data submitted by the applicant in the form of a technical dossier in support of the authorisation request for the use of sodium selenate as a feed additive for ruminants in the form of a bolus". Finally, during the discussion the Commission indicated that "the directions about safety when it is used in the form of a bolus have not been taken into account because it is necessary to combine this authorisation with Directive 2008/38/CE, which mentions the ruminal boluses. However, such Directive 2008/38/CE only apply to animal feedingstuffs for particular nutritional purposes, but the authorisation of the additive also covers its use in other feedingstuffs than those for particular nutritional purposes, for which that Directive does not apply".*

For all that, in our opinion in Annex should be indicated that the method of administration authorised is the intraruminal bolus, or, otherwise, studies based on the administration of the additive in the presentations authorised should be carried out".

Vote taken: Favourable opinion.

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

The draft Regulation concerns the authorisation of L-leucine as flavouring and amino acid.

Vote taken: qualified majority.

Spain abstained and made the following declaration: "The draft of annex presented for vote does not indicate that the additive shall be protected of its ruminal degradation. However, in the "whereas" number 5 of the draft of regulation presented for vote is indicated that "For the supplemental L-leucine to be fully efficacious in ruminants, it should be protected against degradation in the rumen". The same consideration has been expressed in the EFSA opinion (EFSA Journal 2019;17(5):5689): "For the supplemental L-leucine to be as efficacious in ruminants as in non-ruminant species, it requires protection against degradation in the rumen"; "Free leucine is degraded by ruminal microorganisms. Accordingly, a great part of free L-leucine provided to ruminants would be expected not to reach the abomasum intact and be absorbed. Measures such as encapsulation are recommended by animal nutritionists to protect the amino acid from microbial degradation and thereby to ensure efficient uptake by the animal". We abstained because we are not sure that this additive can be authorised without forcing operators to protect it from rumen, since in the opinion of EFSA if it is not protected from ruminal degradation it will not be as efficacious as it i son non-ruminant species, because in rumen free leucine is degraded by ruminal microorganisms and, accordingly, a great part of free L-leucine provided to ruminants would be expected not to reach the abomasum intact and be absorbed, since it is transformed into isovaleric acid. This has to be understood as an obligation, not a possibility."

Vote taken: Favourable opinion.

B.10 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation concerning the renewal of the authorisation of L-arginine produced by *Corynebacterium glutamicum* ATCC 13870 and the authorisation of L-arginine produced by *Corynebacterium glutamicum* KCCM 80182 as feed additives for all animal species and repealing Regulation (EC) No 1139/2007

The draft Regulation was discussed and will be revised for a vote in the next Committee.

Vote Postponed

M.01 Update on the new Commission Expert Group on Animal Nutrition.

The Commission's representative informed the Committee about the state-of-play concerning the establishment of the Expert Group on Animal Nutrition. In particular, organisations representing interests in the field of animal nutrition have been selected further to a call for applications. Member States' authorities and other public entities, as members of the Group, are being requested to designate a representative in order to allow the organisation of the Group's meetings.

The Commission's representative replied to several delegations' questions in relation to some practical aspects of the future meetings of the Group.

M.02 Notion of "placing on the market" in relation to intra-EU circulation of non-authorised feed additives intended for export to third-countries.

Several delegations referred to the conclusions mentioned in the summary report of the Committee's meeting of September 2019 concerning this issue.

The Commission's representative invited the delegations to submit in written to the Commission any possible further question concerning the interpretation of the notion of "placing on the market" in relation with the application of the EU Feed legislation.