MINUTES OF THE 81ST PLENARY MEETING

OF THE SCIENTIFIC PANEL ON ADDITIVES AND PRODUCTS OR SUBSTANCES USED IN ANIMAL FEED (FEEDAP)

(PARMA, 15-17 NOVEMBER 2011)

(AGREED ON 13 DECEMBER 2011)

PARTICIPANTS

Panel Members
Gabriele Aquilina, Georges Bories, Andrew Chesson, Pier Sandro Cocconcelli, Joop de Knecht, Noël Dierick, Mikolaj Antoni Gralak, Jürgen Gropp, Ingrid Halle (2nd and 3rd days), Christer Hogstrand, Reinhard Kroker, Lubomir Leng, Secundino López Puente, Alberto Mantovani, Giovanna Martelli, Miklós Mézes, Derek Renshaw, Maria Saarela, Kristen Sejrsen and Johannes Westendorf (1st and 2nd days).

Apologies
Ingrid Halle (1st day), Anne-Katrine Lundebye Haldorsen and Johannes Westendorf (3rd day).

EFSA
Claudia Roncancio-Peña, Jaume Galobart, Matteo Lorenzo Innocenti, Rosella Brozzi, Irene Bustos Sepúlveda, Maria Vittoria Vettori, Paola Manini, Jordi Tarrés-Call and Nicola Jane Reynolds.

European Commission
Marta Ponghellini and Marina Marini (DG SANCO).

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1. WELCOME AND APOLOGIES FOR ABSENCE

The Chair opened the meeting and welcomed the participants to the 81st Plenary meeting of the FEEDAP Panel.

Members not able to attend the meeting sent their apologies (see under participants).

2. ADOPTION OF THE AGENDA

The agenda was adopted.

3. DECLARATIONS OF INTEREST

In accordance with EFSA's Policy on Declarations of Interests, EFSA screened the Annual Declaration of interest (ADoI) and the Specific Declaration of interest (SDoI) filled in by the experts invited for the present meeting. No conflicts of interests related to the issues discussed in this meeting have been identified during the screening process or at the beginning of this meeting.

4. ADOPTION OF THE DRAFT MINUTES OF THE 80TH PLENARY MEETING

The minutes of the 80th Plenary meeting of the Panel held on 11-13 October 2011 were

reviewed and agreed.[1]

5. WORK PROGRAM

5.1. Discussion and possible adoption of the following scientific opinions

- **Biogalactosidase BL (alpha-galactosidase and 1,4-beta-glucanase) for chickens for fattening (EFSA-Q-2009-00534)**

  The Rapporteur presented the question and the draft opinion. This question refers to the authorisation under Article 4(1) of Regulation (EC) No 1831/2003 of the product Biogalactosidase BL as a zootechnical additive for chickens for fattening. This product is a preparation of an α-galactosidase produced by the genetically modified strain *Saccharomyces cerevisiae* and an endo-1,4-beta-glucanase produced by *Aspergillus niger*. The safety of the genetic modification was assessed by the GMO Panel.

  The draft opinion was discussed. The FEEDAP Panel concluded that the additive is safe for the target species, the consumer and the environment. It is irritant to eyes and skin and should be considered a dermal and respiratory sensitizer. The additive has the potential to improve performance of chickens for fattening.

  The opinion was adopted.[2]

- **Biosprint® (*Saccharomyces cerevisiae*) for cattle for fattening (EFSA-Q-2009-00818)**

  The Chair of the Working Group (WG) presented the question and the draft opinion. This question refers to the re-evaluation under Article 10(2) of Regulation (EC) No 1831/2003 of the product Biosprint® (*Saccharomyces cerevisiae*) as a zootechnical additive for cattle for fattening. As the last assessment of the safety of Biosprint® was made in 2010, the FEEDAP Panel did not consider a re-assessment necessary.

  The draft opinion was discussed. The FEEDAP Panel concluded that the there is insufficient evidence to conclude on the efficacy of Biosprint® when used in feed for cattle for fattening.

  The opinion was adopted.[3]

- **Technical Guidance on the assessment of the toxigenic potential of *Bacillus* and related genera used in animal nutrition (EFSA-Q-2009-00973)**

  The Rapporteur presented the question and the draft guidance. This question is a self-task of the Panel intended to produce a Technical Guidance on the safety of use of *Bacillus* species in animal nutrition taking into account the opinion from the Scientific Committee for Animal Nutrition (SCAN) on the safety of use of *Bacillus* species in animal nutrition[4] and any new scientific data available. The draft guidance was the subject of a public consultation from May to September 2011.

  The comments received during the public consultation were presented to the Panel and the changes introduced in the guidance were reviewed.

  The guidance was adopted.[5]

  In addition, the Technical Report on the Outcome of the public consultation on the draft Technical Guidance on the assessment of the toxigenic potential of *Bacillus* species used in

[1] http://www.efsa.europa.eu/en/events/event/111011-m.pdf
[2] http://www.efsa.europa.eu/en/efsajournal/pub/2451.htm
[3] http://www.efsa.europa.eu/en/efsajournal/pub/2439.htm
[4] http://ec.europa.eu/food/fs/sc/scan/out41_en.pdf
[5] http://www.efsa.europa.eu/en/efsajournal/pub/2445.htm

animal nutrition was endorsed by the Panel.

- **Update of the "Guidance for the preparation of dossiers for technological additives to include the new functional group 'substances for reduction of the contamination of feed by mycotoxins'" (EFSA-Q-2010-00017) and Update of the "Guidance for the preparation of dossiers by categories of feed additives – Technological additives" (EFSA-Q-2010-00902)**

  The update of the guidance was discussed during the October Plenary. The final adoption will take place together with the revisions of the other guidance documents currently underway.

- **Chemically defined flavourings from Chemical Group 18 – Allylhydroxybenzenes for all animal species and categories (EFSA-Q-2010-00815)**

  The Rapporteur presented the question and the draft opinion. This question refers to the re-evaluation under Article 10(2) and authorisation of new use under Article 4 of Regulation (EC) No 1831/2003 of the flavourings from the Chemical Group 18 as sensory additives for all species.

  The draft opinion was discussed. An initial discussion took place in the October Plenary. The use of these additives in fish was found contra-indicated. The FEEDAP Panel concluded that the applicant's proposed range of use levels of 5 to 25 mg/kg feed for eugenol and *trans*-anethole and of 1 to 5 mg/kg feed for 4-allyl-2,6-dimethoxyphenol and eugenyl acetate are safe for all animal species (other than fish) with a margins of safety of 2 to 6 and 10 to 30, respectively. The use of the additives as flavours in mammals is considered safe for the consumers, although the lack of data on metabolism and residues in poultry precludes an assessment of consumer exposure from this source. Eugenol is regarded as an irritant to the respiratory system, the eyes and the skin and as a skin sensitiser. 4-Allyl-2,6-dimethoxyphenol is regarded as an irritant to eyes and skin, eugenyl acetate as a skin irritant and *trans*-anethole as a skin sensitiser. The impact on the environment from the use of the additives in animal feed is expected to be low. Since the function of these additives in feed is essentially the same as that in food, they are considered efficacious when used in feed.

  The opinion was adopted.[6]

- **Chemically defined flavourings from Flavouring Group 27 - Anthranilate derivatives for all animal species and categories (EFSA-Q-2010-00990)**

  The Rapporteur presented the question and the draft opinion. This question refers to the re-evaluation under Article 10(2) and authorisation of new use under Article 4 of Regulation (EC) No 1831/2003 of the flavourings from the Chemical Group 27 as sensory additives for all species.

  The draft opinion was discussed. The use of methyl anthranilate and methyl-N-methylanthranilate in avian species was found contra-indicated. The FEEDAP Panel concluded that the applicant's proposed use levels of 5 to 25 mg methylanthranilate/kg complete feed are safe in the other species with a margin of safety up to three. For methyl-N-methylanthranilate, the highest feed concentration safe for all animals species other than avian species is 4 mg/kg complete feed. Considering the absent or very low margin of safety, the simultaneous administration of either substance in feed and water for drinking, and the simultaneous use of both compounds are not considered safe without a proportional reduction in their concentration. The additives are considered safe for the consumers and

[6] http://www.efsa.europa.eu/en/efsajournal/pub/2440.htm

their use in animal nutrition is not expected to have a significant impact on the environment. Both substances are regarded as irritants to the respiratory system, the eyes and the skin. Since the function of both compounds in feed is essentially the same as that in food, no further demonstration of efficacy is considered necessary.

The opinion was adopted.[7]

- **Update of the "Guidance for the preparation of dossiers by categories of feed additives – Sensory additives" (EFSA-Q-2010-01157)**

  The Rapporteur presented the question. This question is a self-task of the Panel intended to update the guidance for the preparation of dossiers for sensory additives to take into account the experience of the Panel in the assessment of these additives.

  The proposed modifications were reviewed and discussed. The Panel agreed to adopt this opinion together with the revisions of the other guidance documents currently underway.

- **Update of the "Guidance for the preparation of dossiers by categories of feed additives – Nutritional additives" (EFSA-Q-2010-01158)**

  The Rapporteur presented the question. This question is a self-task of the Panel intended to update the guidance for the preparation of dossiers for nutritional additives to take into account the experience of the Panel in the assessment of these additives.

  The proposed modifications were reviewed and discussed. The Panel agreed to adopt this opinion together with the revisions of the other guidance documents currently underway.

- **Update of the "Guidance for the preparation of dossiers by categories of feed additives – Zootechnical additives" (EFSA-Q-2010-01159)**

  Not discussed due to lack of time.

- **Update of the "Technical guidance on User safety" (EFSA-Q-2010-01162)**

  Not discussed due to lack of time.

- **Neohesperidine dihydrochalcone for piglets, pigs for fattening, calves for rearing and fattening, lambs for rearing and fattening, dairy sheep, ewes for reproduction, salmonids and dogs (EFSA-Q-2010-01229)**

  The Rapporteur presented the question and the draft opinion. This question refers to the re-evaluation under Article 10(2) and authorisation of new use under Article 4 of Regulation (EC) No 1831/2003 of neohesperidine dihydrochalcone (NHDC) as a sensory additive for piglets, pigs for fattening, calves for rearing and fattening, lambs for rearing and fattening, dairy sheep, ewes for reproduction, salmonids and dogs.

  The draft opinion was discussed. The FEEDAP Panel concluded that the applicant's proposed use levels of up to 35 mg NHDC/kg feed and 5 mg NHDC/L water for drinking are safe for the target species with a margin of safety ranging from three to eight. The use of NHDC in mammals and poultry is considered safe for the consumers, although the lack of data on metabolism and residues in fish precludes an assessment of consumer exposure from this source. No impact from the use of NHDC in animal feed on the environment is foreseen. In solid form, the additive should be considered as a possible eye and respiratory irritant. Since its function in feed is essentially the same as that in food, NHDC is considered efficacious when used in feed.

[7] http://www.efsa.europa.eu/en/efsajournal/pub/2441.htm

The opinion was adopted.[8]

- **Propionic acid, sodium propionate, calcium propionate, ammonium propionate for all animal species (EFSA-Q-2010-01302)**

  The Rapporteur presented the question and the draft opinion. This question refers to the authorisation under Article 4 and re-evaluation under Article 10(2) of Regulation (EC) No 1831/2003 of the products propionic acid, sodium propionate, calcium propionate, ammonium propionate as technological additives for all animal species.

  The draft opinion was discussed. The FEEDAP Panel concluded that the maximum safe level of propionic acid for poultry is 10 g/kg complete feed and for pigs 30 g/kg complete feed. The corresponding maximum concentrations in water for drinking would be 4 g/L for poultry and 10 g/L for pigs, while the additive at the proposed use level is safe for ruminants, horses and rabbit. Propionic acid is safe for all animal species when used as a silage additive. Differences in the safety for target animals between the salts and propionic acid are not expected. Propionic acid and its calcium, sodium or ammonium salts are safe for the consumers and the environment. Propionic acid and sodium propionate are corrosive to skin and mucous membranes and strongly corrosive to the eyes. No data on sensitizing effects are available for the acid, but sodium propionate is not a skin sensitizer. Exposure by inhalation should be minimised. In the absence of data, ammonium propionate should be treated as propionic acid. The FEEDAP Panel also concluded that propionic acid and its salts have the potential to act as preservatives in feedingstuffs but not in water. The efficacy of propionic acid and its sodium and ammonium salts as silage additive was not demonstrated.

  The opinion was adopted.[9]

- **Erythrosine for cats and dogs, ornamental fish and reptiles (EFSA-Q-2010-01527)**

  The vice-chair of the WG presented the question and the draft opinion. This question refers to the authorisation under Article 4 and re-evaluation under Article 10(2) of Regulation (EC) No 1831/2003 of the product erythrosine as colouring additive for cats and dogs, ornamental fish and reptiles.

  The draft opinion was discussed. Since the additive is only applied for non food-producing animals, the assessment of safety was limited to the target species and the user. The FEEDAP Panel concluded that the maximum use level indicated by the applicant (500 mg/kg complete feed) is not safe for the cats and ornamental fish. A level of 1000 mg/kg complete feed could be derived as the maximum safe concentration for dogs. No conclusion can be drawn on the safety of erythrosine for reptiles. Although erythrosine has not shown any irritant effect in the toxicological tests provided, dermatological reactions, including photosensitivity, erythroderma and desquamation have been attributed to erythrosine. Since 90 % of the particles have a diameter < 10 μm an exposure of the lower respiratory tract is considered a hazard. No inhalation toxicity studies were available. An assessment of efficacy was not possible due to absence of data.

  The opinion was adopted.[10]

- **Quantum™ (6-phytase) for turkeys for fattening (EFSA-Q-2011-00148)**

  Not discussed due to lack of time.

[8] http://www.efsa.europa.eu/en/efsajournal/pub/2444.htm
[9] http://www.efsa.europa.eu/en/efsajournal/pub/2446.htm
[10] http://www.efsa.europa.eu/en/efsajournal/pub/2447.htm

- ***Lactococcus lactis* (NCIMB 30117) for all species (EFSA-Q-2011-00373)**

  The Rapporteur presented the question and the draft opinion. This question refers to the re-evaluation under Article 10(2)/(7) of Regulation (EC) No 1831/2003 of the product *Lactococcus lactis* (NCIMB 30117) as silage additive for all species.

  The draft opinion was discussed. The FEEDAP Panel concluded that the active agent fulfils the requirements of the qualified presumption of safety approach to safety assessment and therefore the use of the strain in the production of silage is considered safe for the target species, the consumer and the environment. Given the proteinaceous nature of the active agent and in the absence of evidence to the contrary, the additive should be considered to have the potential to be a skin/respiratory sensitiser. The Panel also concluded that the additive has the potential to improve the production of silage from all forages by reducing the pH and increasing the preservation of dry matter.

  The opinion was adopted.[11]

- ***Lactobacillus pentosus* (DSM 14025) for all species (EFSA-Q-2011-00388)**

  The Rapporteur presented the question and the draft opinion. This question refers to the re-evaluation under Article 10(2)/(7) of Regulation (EC) No 1831/2003 of the product *Lactobacillus pentosus* (DSM 14025) as silage additive for all species.

  The draft opinion was discussed. The FEEDAP Panel concluded that the bacterial strain *L. pentosus* is resistant to tetracycline, ampicillin and clindamycin, all antibiotics of human and veterinary importance. In the absence of information on the genetic basis of these resistances, the extent of the risk of horizontal gene transfer to other bacteria in the food chain and in the environment cannot be established.

  The opinion was adopted.[12]

- **Coxidin® (monensin sodium) for chickens reared for laying (EFSA-Q-2011-00425)**

  The Rapporteur presented the question and the draft opinion. This question refers to the authorisation under Article 4 of Regulation (EC) No 1831/2003 of the product Coxidin® (monensin sodium) as a coccidiostat for chickens reared for laying.

  The draft opinion was discussed. Coxidin® is intended to be used in the control of coccidiosis in chickens reared for laying up to a maximum age of 16 weeks at the same doses as presently authorised for chickens for fattening (100-125 mg/kg complete feed). Concerning exposure and susceptibility to *Eimeria* infections, the FEEDAP Panel extended its conclusions on the safety and efficacy of monensin from Coxidin® in chickens for fattening to chickens reared for laying. The FEEDAP Panel considers Coxidin® at a maximum dose of 125 mg monensin sodium/kg feed as safe for chickens reared for laying and the environment.

  The opinion was adopted.[13]

- **Protural (sodium benzoate) for weaned piglets (EFSA-Q-2011-00964)**

  The Chair of the WG presented the question and the draft opinion. This question refers to a modification of the terms of authorisation under Article 13 of Regulation (EC) No

[11] http://www.efsa.europa.eu/en/efsajournal/pub/2448.htm
[12] http://www.efsa.europa.eu/en/efsajournal/pub/2449.htm
[13] http://www.efsa.europa.eu/en/efsajournal/pub/2442.htm

1831/2003 of the additive Protural (sodium benzoate) for weaned piglets. The applicant is requesting to reduce the minimum concentration of sodium benzoate from ≥ 99.9 % to ≥ 99.0 %.

The draft opinion was discussed. The FEEDAP Panel concluded that the additive Protural (sodium benzoate) with a minimum content of ≥ 99.0 % is as safe for the target species, the consumer, the user and the environment and efficacious as the previous formulation, under the same conditions of use.

The opinion was adopted.[14]

6. PROGRESS REPORT ON ONGOING WORK

Not discussed

7. FEEDBACK FROM THE SCIENTIFIC COMMITTEE

Not discussed

8. NEW REQUESTS TO EFSA

8.1. New applications under Regulation (EC) No 1831/2003

The Commission has forwarded to EFSA the following new applications of feed additives seeking authorisation under Regulation (EC) No 1831/2003 since the last Plenary meeting. These applications were presented to the Panel, who accepted them:

EFSA-Q-Number	Subject
EFSA-Q-2011-01109	L-selenomethionine for all animal species
EFSA-Q-2011-01147	Sodium metabisulphite for dogs and cats
EFSA-Q-2011-01148	Sodium metabisulphite for dogs and cats
EFSA-Q-2011-01149	Butylated hydroxytoluene (BHT) for all animal species
EFSA-Q-2011-01150	Butylated hydroxytoluene (BHT) for all animal species
EFSA-Q-2011-01151	*Bacillus subtilis* PB6 (*Bacillus subtilis* ATCC PTA-6737) for turkeys for fattening, turkeys reared for breeding
EFSA-Q-2011-01152	Biostrong® 510 (Preparation of essential oil of thyme and star anise) for chickens and minor avian species for fattening and rearing to point of lay
EFSA-Q-2011-01153	AviPlus® (Preparation of sorbic acid, citric acid, thymol and vanillin) for Chickens and minor avian species for fattening and laying, minor porcine species (weaned)

8.2. Valid applications under Regulation (EC) No 1831/2003 since the previous meeting

Applications considered valid for the start of the assessment:

EFSA-Q-Number	Subject	Valid on
EFSA-Q-2011-00881	Rovabio® Excel (endo-1,3(4)-beta-glucanase and endo-1,4-beta-xylanase) for lactating sows	04/11/2011

[14] http://www.efsa.europa.eu/en/efsajournal/pub/2443.htm

EFSA-Q-2011-00060	Diarr-Stop S Plus (Na_2EDTA, castanea sativa mill, thyme oil, oregano oil) for pigs for fattening	14/11/2011
EFSA-Q-2010-01222	Polyoxyethylene (20) sorbitan monooleate for all animal species	20/10/2011

8.3. Selftasks

EFSA-Q-Number	Subject
EFSA-Q-2011-01108	Update of the Technical guidance: Update of the criteria used in the assessment of bacterial resistance to antibiotics of human or veterinary importance
EFSA-Q-2011-01095	Update of the Technical guidance: Additives already authorised for use in food

9. GENERAL INFORMATION FROM EFSA

- The Panel were informed about the 3rd session of the Systematic Review training that will take place on 25-27 March 2012.

- The experts were informed that the EFSA's "Draft Science Strategy 2012-2016" is open for public consultation until the 21st November 2011.[15]

10. EMERGING RISKS

Not discussed.

11. MISCELLANEOUS

- The working group on colouring agents asked the views of the Panel on the approach to be taken for the assessment of the safety for the consumer of an additive based on astaxantin. After discussion, the Panel endorsed the approach proposed by the WG based on the Benchmark dose modelling.

- The Chair of the WG on Microorganisms made an introduction about the current knowledge of *Enterococcus faecium* virulence. It was agreed that Technical Guidance can be produced to establish criteria to allow the differentiation between safe and virulent strains of *E. faecium.*

[15] http://www.efsa.europa.eu/en/consultations/call/111104.htm