European Food Safety Authority

FEED UNIT

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

Minutes of the 90th Plenary Meeting

Held on 16-18 October 2012, Parma

(Agreed on 13 November 2012)

Participants

- **Panel Members**

  Gabriele Aquilina, Alex Bach, Vasileios Bampidis, Maria De Lourdes Bastos, Gerhard Flachowsky, Josep Gasa-Gasó, Mikolaj Gralak, Christer Hogstrand,[1] Lubomir Leng, Secundino López-Puente, Giovanna Martelli, Baltasar Mayo, Derek Renshaw, Guido Rychen,[2] Maria Saarela, Patrick van Beelen, John Wallace and Johannes Westendorf.

- **Hearing Experts**

  Andrew Chesson[3] (for item 5.7)

- **European Commission**

  N/A

- **EFSA**

  - **Feed Unit:** Claudia Roncancio-Peña, Jaume Galobart, Gloria López-Gálvez, Paola Manini, Lucilla Gregoretti, Rosella Brozzi, Montserrat Anguita, Jordi Tarrés-Call and Nicola Jane Reynolds.
  - **Other EFSA Directorates/Units:** Per Bergman[4] and Djien Liem[5]

1. Welcome and apologies for absence

The Vice-Chair welcomed the participants.

Apologies were received from Kristen Sejrsen.

2. Adoption of agenda

The agenda was adopted without changes.

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1 Present only on 17 and 18 October.
2 Present only on 16 and 17 October.
3 Present only on 16 October.
4 Present only on 16 October PM.
5 Present only on 17 October AM.

3. Declarations of interest

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes regarding Declarations of Interests (DoIs)[3] and the Decision of the Executive Director implementing this Policy[4], 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. For further details on the outcome of the screening of the ADoI and SDoI, as well as the Oral Declaration of Interest at the beginning of the meeting, please refer to Annexes I and II.

4. Agreement of the minutes of the 89th Plenary meeting held on 11-13 September 2012, Parma

The minutes of the 89th Plenary meeting were reviewed and agreed.[6]

5. Scientific outputs submitted for discussion and possible adoption

5.1. Roxazyme® G2 G/L (endo-1,4-beta-xylanase, endo-1,4-beta-glucanase and endo-1,(3)4-beta-glucanase) for chickens and turkeys for fattening, laying hens, ducks, poultry and piglets (weaned) (EFSA-Q-2007-185)

The Chair of the working group presented the question and the draft opinion. This question refers to the re-evaluation under Article 10 and the authorisation under Article 4 of Regulation (EC) No 1831/2003 of the additive Roxazyme® G2 G/L, a preparation of endo-1,4-beta-xylanase, endo-1,4-beta-glucanase and endo-1,(3)4-beta-glucanase as a zootechnical additive for poultry and piglets.

The draft opinion was discussed. The Panel concluded that the additive is safe for the target species at the maximum recommended dose, for the consumers of products from animals fed with the additive and for the environment. The enzymes contained in the additive are non-irritant to the eyes or skin and are not dermal sensitizers, however and due to their proteinaceous nature, the additive should be considered as a potential respiratory sensitizer. The Panel concluded that the additive has the potential to be efficacious in the target species, but the minimum efficacious dose, in terms of enzyme activities, could not be established.

The opinion was adopted.[7]

5.2. Prostora Max (*Bifidobacterium animalis* subsp. *animalis* NCIMB 41617) for dogs (EFSA-Q-2009-00817)

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 Prostora Max (*Bifidobacterium animalis* subsp. *animalis* NCIMB 41617) as a zootechnical additive for dogs.

The draft opinion was discussed. The opinion will be submitted to the next Plenary meeting for possible adoption.

6 http://www.efsa.europa.eu/en/events/event/120911-m.pdf
7 http://www.efsa.europa.eu/en/efsajournal/pub/2930.htm

5.3. Chemically defined flavourings from Chemical Group 02 - Branched-chain primary aliphatic alcohols/aldehydes/acids, acetal and esters for all animal species (EFSA-Q-2010-00701)

A member of the working group presented the question and the draft opinion. This question refers to the re-evaluation under Article 10 and the authorisation under Article 4 of Regulation (EC) No 1831/2003 of the chemically defined flavourings from Chemical Group 02 as sensory additives for all animal species.

The draft opinion was discussed. The Panel concluded that four compounds are safe at the proposed use level of 25 mg/kg complete feed for cattle, salmonids and non food-producing animals and at 5 mg/kg complete feed for pigs and poultry. Twenty-three compounds are safe for the target species at a maximum level of 5 mg/kg complete feed. Seven compounds are safe at a maximum of 1.5 mg/kg complete feed for cattle, salmonids and non food-producing animals and of 1.0 mg/kg complete feed for pigs and poultry The compounds are safe for the consumer. The compounds represent potential hazards for skin and eye and respiratory exposure. The compounds do not pose a risk to the environment when used at concentrations considered safe for the target species. They are considered efficacious when used in feed.

The opinion was adopted.[8]

5.4. Chemically defined flavourings from Chemical Group 01 - Straight-chain primary aliphatic alcohols/aldehydes/acids, acetals and esters for all animal species (EFSA-Q-2010-00702)

The rapporteur presented the question and the draft opinion. This question refers to the re-evaluation under Article 10 and the authorisation under Article 4 of Regulation (EC) No 1831/2003 of the chemically defined flavourings from Chemical Group 01 as sensory additives for all animal species.

The draft opinion was discussed. The opinion will be submitted to the next Plenary meeting for possible adoption.

5.5. Chemically defined flavourings from Flavouring Group 06 - Aliphatic, alicyclic and aromatic saturated and unsaturated tertiary alcohols and esters with esters containing tertiary alcohols. Esters may contain any acid component: 13 substances for all animal species and categories (EFSA-Q-2010-00873)

Not discussed due to lack of time.

5.6. Chemically defined flavourings from Flavouring Group 16 - Aliphatic and alicyclic ethers for all animal species and categories (EFSA-Q-2010-00989)

Not discussed due to lack of time.

5.7. Toyocerin® (*Bacillus cereus* NCIMB 40112/CNCM I-1012) for sows, piglets, pigs for fattening, calves for rearing, cattle for fattening, chickens for fattening and rabbits for fattening (EFSA-Q-2010-01095 and EFSA-Q-2011-00832)

The rapporteur presented the question and the draft opinion. These questions refer to the re-evaluation under Article 10 and the authorisation under Article 4 of Regulation

8 http://www.efsa.europa.eu/en/efsajournal/pub/2927.htm

(EC) No 1831/2003 of the product Toyocerin® (*Bacillus cereus* NCIMB 40112/CNCM I-1012) as a zootechnical additive for sows, piglets, pigs for fattening, calves for rearing, cattle for fattening, chickens for fattening and rabbits for fattening.

The draft opinion was discussed. The Panel concluded that the additive is well tolerated by the target species subject of this application. However, the strain shows resistance to two antibiotics, one of which at least can be ascribed to an acquired resistance. For this reason it is inadvisable to introduce into target species a resistance determinant capable of transfer to other bacterial strains. The strain has the capacity to elaborate functional toxins and, thus, to pose a hazard for those exposed to the organism. This would include those handling the additive and consumers inadvertently exposed to contaminated animal products. The additive is non-irritant to eyes, and by extension, to the skin but should be treated as a sensitiser and, in particular, as hazardous to the respiratory tract. *B. cereus* is a ubiquitous soil saprophyte. Consequently, use of the strain in animal nutrition is not expected to measurably increase numbers of the organism in the environment. The addition of Toyocerin® to the feed has the potential to improve at least one aspect of production in chickens for fattening; pigs for fattening; sows, calves; cattle for fattening and rabbits for fattening. Insufficient data was available to conclude on the efficacy of Toyocerin® when used in diets for weaned piglets.

The opinion was adopted.[9]

5.8. Chemically defined flavourings from Flavouring Group 09 - Primary aliphatic saturated or unsaturated alcohols/aldehydes/acids/acetals/esters with a second primary, secondary or tertiary oxygenated functional group including aliphatic lactones for all animal species (EFSA-Q-2010-01177)

This question refers to the re-evaluation under Article 10 and the authorisation under Article 4 of Regulation (EC) No 1831/2003 of the chemically defined flavourings from Chemical Group 09 as sensory additives for all animal species.

The draft opinion was discussed. The FEEDAP Panel was unable to perform an assessment of 2-oxopropanal due to the lack of information on the characterisation of the substance. The Panel concluded that 13 compounds are safe for all animal species at the use levels proposed when used as feed flavourings, four compounds are safe at 20 mg/kg complete feed, eight compounds are safe at 5 mg/kg complete feed, four compounds are safe at 1.5 mg/kg complete feed for cattle, salmonids and non food-producing animals and at 1 mg/kg complete feed for pigs and poultry. The compounds are safe for the consumer. The compounds represent potential hazards for skin and eye and respiratory exposure. The compounds do not pose a risk to the environment when used at concentrations considered safe for the target species. They are considered efficacious when used in feed.

The opinion was adopted.[10]

9 http://www.efsa.europa.eu/en/efsajournal/pub/2924.htm
10 http://www.efsa.europa.eu/en/efsajournal/pub/2928.htm

5.9. Biotin for all animal species (EFSA-Q-2011-00247)

The rapporteur presented the question and the draft opinion. This question refers to the re-evaluation under Article 10 and the authorisation under Article 4 of Regulation (EC) No 1831/2003 of biotin as a nutritional additive for all animal species.

The draft opinion was discussed. The Panel concluded that biotin is safe for the target animals, the consumer and the environment. Biotin is not irritant to skin, eyes and mucous membranes and is unlikely to cause skin sensitisation. Considering the high dusting potential of biotin and the absence of data on inhalation toxicity, the FEEDAP Panel concludes that there is potential for inhalation exposure from handling biotin which could be hazardous. Synthetic biotin is regarded as an effective source of the vitamin in animal nutrition when administered via feed or water for drinking.

The opinion was adopted.[11]

5.10. D-(+)-biotin for all animal species (EFSA-Q-2011-00248)

The rapporteur presented the question and the draft opinion. This question refers to the re-evaluation under Article 10 and the authorisation under Article 4 of Regulation (EC) No 1831/2003 of D-(+)-biotin as a nutritional additive for all animal species.

The draft opinion was discussed. The Panel concluded that D-(+)-biotin (biotin) is safe for the target animals, the consumer and the environment and that it is unlikely that biotin is irritant to skin and eyes or a skin sensitizer. Considering the high dusting potential of biotin and the absence of data on inhalation toxicity, the FEEDAP Panel concludes that there is a potential for inhalation exposure from handling biotin, which could be hazardous. Synthetic biotin is regarded as an effective source of the vitamin in animal nutrition when administered via feed or water for drinking.

The opinion was adopted.[12]

5.11. Cupric sulphate pentahydrate for all animal species (EFSA-Q-2011-00743)

The rapporteur presented the question and the draft opinion. This question refers to the re-evaluation under Article 10 of Regulation (EC) No 1831/2003 of cupric sulphate pentahydrate as a nutritional additive for all animal species.

The draft opinion was discussed. The discussion was not finalised and therefore the opinion will be submitted to the next Plenary meeting for discussion and possible adoption.

5.12. Zinc oxide for all species (EFSA-Q-2011-00844)

Not discussed due to lack of time.

[11] http://www.efsa.europa.eu/en/efsajournal/pub/2926.htm
[12] http://www.efsa.europa.eu/en/efsajournal/pub/2925.htm

6. New Mandates

6.1. 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-2012-00789	Lenziaren (Iron aqua carbonate hydroxy oxo starch sucrose complex) for cats
EFSA-Q-2012-00791	Monimax (monensin sodium and nacarbazin) for chickens for fattening, chickens reared for laying

6.2. Other mandates

EFSA-Q-Number	Subject
EFSA-Q-2012-00847	Standing Working Group on Amino Acids
EFSA-Q-2012-00848	Standing Working Group on Biomasses
EFSA-Q-2012-00853	Standing Working Group on Coccidiostats and Histomonostats
EFSA-Q-2012-00854	Standing Working Group on Colouring Agents
EFSA-Q-2012-00855	Standing Working Group on Enzymes
EFSA-Q-2012-00856	Standing Working Group on Vitamins
EFSA-Q-2012-00857	Standing Working Group on Feed Flavourings
EFSA-Q-2012-00858	Standing Working Group on Micro-organisms
EFSA-Q-2012-00859	Standing Working Group on Mycotoxin Detoxifying Agents
EFSA-Q-2012-00860	Standing Working Group on Organic Acids
EFSA-Q-2012-00861	Standing Working Group on Other Zootechnical Additives
EFSA-Q-2012-00862	Standing Working Group on Silage additives
EFSA-Q-2012-00863	Standing Working Group on Technological Additives
EFSA-Q-2012-00864	Standing Working Group on Trace Elements
EFSA-Q-2012-00865	Standing Working Group on Genetically Modified Microorganisms (FEEDAP)

6.3. 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-2012-00331	Ponceau 4R for dogs, cats and ornamental fish	13/09/2012
EFSA-Q-2012-00333	Brilliant blue FCF for dogs and cats	13/09/2012
EFSA-Q-2012-00438	Manganous oxide and Manganous sulphate monohydrate (MnO Alma®) for all animal species	25/09/2012
EFSA-Q-2012-00581	L-Methionine feed grade for all animal species	07/09/2012
EFSA-Q-2012-00693	Quantum Blue (6-phytase) for chickens for fattening, chickens reared for laying, turkeys for fattening, turkeys reared for breeding, minor poultry species, piglets (weaned), fattening pigs and sows	08/10/2012

7. Feedback from the Scientific Committee/the Scientific Panel, Working Groups, EFSA, the European Commission

- P. Bergman, Director of the Regulated Products Directorate, welcomed the experts of the Panel appointed in July to EFSA.
- D. Liem, Head of Unit of the Scientific Committee of EFSA presented the different working groups set by the Scientific Committee to the Panel.

8. Other scientific topics for information and/or discussion

- A discussion took place concerning the assessment of additives consisting or produced by microorganisms for which there is not a complete identification in terms of genus/species.
- A discussion took place concerning a request from the European Commission regarding the nature of the data that would be required in the technical dossier when there is a change in the production strain of an authorised feed additive produced by fermentation (e.g., amino acid). The Panel discussed the approach that could be followed based on three current applications.

9. Any other business

Not discussed

Annex I

INTERESTS AND ACTIONS RESULTING FROM THE SCREENING OF THE ANNUAL DECLARATION OF INTERESTS (ADoI) OR THE SPECIFIC DECLARATION OF INTEREST (SDoI)

In the ADoI or SDoI filled for the present meeting Dr Alex Bach declared the following interest: Roxazyme® G2 G/L (endo-1,4-beta-glucanase, endo-1,(3)4-beta-glucanase and endo-1,4-beta-xylanase) for chickens and turkeys for fattening, laying hens, ducks, poultry and piglets (weaned) (EFSA-Q-2007-185), Bactocell (*Pediococcus acidilactici*) for fish (EFSA-Q-2012-00441) and Toyocerin® (*Bacillus cereus* NCIMB 40112/CNCM I-1012) for sows, piglets, pigs for fattening, cattle for fattening, calves for rearing, chickens for fattening and rabbits for fattening (EFSA-Q-2010-01095 & EFSA-Q-2011-00832). In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes regarding Declarations of Interests and the Decision of the Executive Director implementing this Policy, and taking into account the specific matters discussed at the meeting in question, the interest above was deemed to represent a conflict of Interest. This results in the impossibility for the expert to be present when those item is discussed, voted on or in anyway processed by that concerned scientific group.

In the ADoI or in the SDoI filled for the present meeting Prof. Josep Gasa-Gasó declared the following interest: research contracts with the producer of Toyocerin® (EFSA-Q-2010-01095 and EFSA-Q-2011-00832). In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes regarding Declarations of Interests and the Decision of the Executive Director implementing this Policy, and taking into account the specific matters discussed at the meeting in question, the interest above was deemed to represent a conflict of Interest. This results in the impossibility for the expert to be present when that item is discussed, voted on or in anyway processed by that concerned scientific group.

Annex II

INTERESTS AND ACTIONS RESULTING FROM THE ORAL DECLARATIONS OF INTERESTS DONE AT THE BEGINNING OF THE MEETING

With regard to this meeting Dr. John Wallace declared the following interest: Roxazyme® G2 G/L (endo-1,4-beta-glucanase, endo-1,(3)4-beta-glucanase and endo-1,4-beta-xylanase) for chickens and turkeys for fattening, laying hens, ducks, poultry and piglets (weaned) (EFSA-Q-2007-185). In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes regarding Declarations of Interests and the Decision of the Executive Director implementing this Policy, and taking into account the specific matters discussed at the meeting in question, the interest above was deemed to represent a conflict of Interest. This results in the impossibility for the expert to be present when that item is discussed, voted on or in anyway processed by that concerned scientific group.